



Montana Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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New Executive Director

The Montana Board of Pharmacy is pleased to announce the appointment of Ronald J. Klein, RPh, as executive director. Mr Klein comes to Helena from Nebraska where he was inspector and chief inspector for the Nebraska Board of Pharmacy.

Mr Klein is a graduate of the Creighton University School of Pharmacy in Omaha, NE. He completed a general residency in hospital pharmacy at Mercy Hospital and Medical Center in Rockville Centre, NY, and also earned a master of science in pharmacy institution administration from St John's University in New York, NY.

Mr Klein has managed both hospital and community pharmacies in Nebraska.

The Board extends a warm welcome to Mr Klein and his family to Montana.

Changing Information on Schedule II Prescriptions

The United States Drug Enforcement Administration (DEA) provides information on what can be changed or added to a Schedule II controlled substance prescription by a pharmacist.

The majority of changes can be made only after the pharmacist contacts the prescribing practitioner. After consultation with the prescribing practitioner, the pharmacist is permitted to change the patient's address, drug strength, drug quantity, and directions for use. The pharmacist is permitted to make information additions that may be provided by the patient or bearer such as the patient's address, and such additions should be verified by the pharmacist. The pharmacist may also add the dosage form to the prescription order after verification with the prescribing practitioner. The pharmacist is never permitted to make changes to the patient's name, controlled substance prescribed (except for generic substitution to the extent permitted by state law), or the prescriber's signature. These types of changes challenge the integrity of the original prescription and would require a new prescription from the prescribing practitioner.

Fifty Years of Service

Congratulations to the following pharmacists for completing 50 years of continuous licensed service to the citizens of Montana and the profession of pharmacy. The Montana Board of Pharmacy is grateful for their years of contribution to the profession.

- Jon R. Severson..... Billings
- Dale C. Staffanson..... Deer Lodge
- Donald G. Peterson..... Dillon
- Vernon W. Ott..... Hesperia, CA

Montana Medicaid Notice

Physicians, Mid-level Providers, Dentists, Pharmacies, and Inpatient and Outpatient Hospitals Tamper-Resistant Prescription Pads – Postponed

The federal law requiring written Medicaid prescriptions to be on tamper-resistant pads has been delayed until March 31, 2008, by HR 3668, the TMA, Abstinence Education, and QI Programs Extension Act of 2007.

The Montana Department of Public Health and Human Services advises prescribers to take this time to obtain supplies of tamper-resistant prescription pads for their Medicaid prescriptions. The department will continue to update the list of tamper-resistant prescription pad vendors on its Web site at <http://medicaidprovider.hhs.mt.gov/providerpages/prescriptions.shtml>. For providers who elect to seek out their own vendors, the department is available to evaluate these tamper-resistant prescription pads upon request to ensure compliance with published guidelines.

Please direct any questions regarding this notice to the following personnel.

- ◆ Physician and mid-level providers: Denise Brunett at 406/444-5778
- ◆ Dentists: Jan Paulsen at 406/444-3182
- ◆ Pharmacy providers: Wendy Blackwood at 406/444-2738
- ◆ Hospitals: Debra Stipcich at 406/444-4834

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Public Hearing Garners Recommendations on Use of Medication Guides

Participants in a public hearing held in June 2007 by the Food and Drug Administration (FDA) Center for Drug Evaluation and Research suggested ways to improve the FDA Medication Guide program. The program provides for the distribution of FDA-approved written patient information for certain medications that pose serious and significant public health concerns.

FDA officials heard testimony from a member of Congress and 40 individuals representing academia, consumers and consumer groups, the pharmaceutical industry, health care professional groups, practicing physicians, pharmacists, and pharmacy organizations.

Participants acknowledged the importance of patients receiving appropriate risk information in the form of Medication Guides to make informed decisions about certain prescribed medications. Some said the current program is too cumbersome and lacks a standard distribution system. Participants urged FDA to increase awareness of Medication Guides, make them easier to read and understand, move toward facilitating electronic distribution, and consider combining the information contained in Medication Guides with other information such as in Consumer Medication Information.

The public hearing is summarized on the FDA Web site at www.fda.gov/cder/meeting/medication_guides_200706.htm.

Reporting Makes a Difference



*This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing 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 recommendations for prevention of reported errors that you can put into practice today, subscribe to **ISMP Medication Safety Alert!**[®] **Community/Ambulatory Edition** by visiting www.ismp.org. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

In both Institute of Medicine (IOM) reports, *To Err is Human: Building a Safer Health System*, and *Identifying and Preventing Medication Errors*, the importance of error reporting is highlighted. The reports suggest that greater effort is needed to identify medication errors in most care settings, both to measure the extent and scope of errors and to assess the impact of prevention strategies. Although no single recommendation or activity offers a full solution to medical error, error prevention experts agree that successful error reduction strategies depend heavily on responsible detection and open reporting of errors.

According to the IOM report, reporting programs, whether voluntary or mandatory, must satisfy two primary purposes:

1. to hold providers accountable for performance and patient safety; and
2. to provide information that leads to new knowledge and improved patient safety.

Reports to voluntary systems typically come from front-line practitioners or others similarly close to the error, who can best describe the specific conditions that led to that error. Better error descriptions make possible more effective analysis of the system-based causes of errors. This first-hand reporting and the improved analysis it affords has been used by error prevention experts to create a "road map" for improvement that easily and realistically can be extrapolated and implemented at the broadest variety of health care organizations. These practical recommendations for safe practice have been established, published, and widely disseminated throughout the health care community.

Further, voluntary reporting programs have learned that many errors are caused by factors outside the health care practice site and beyond the direct control of a health care practitioner. Thus, safe practice recommendations have been communicated to medical device manufacturers, pharmaceutical companies, automation technology companies, health care reimbursement systems, and others less directly involved in patient care, but nonetheless influential in the safe provision of care.

The success of current voluntary reporting systems also stems from the trust and respect that has typically developed between reporters and recipients who use the information to improve patient safety across the nation. Reporting is perceived to have immense value when those who report an error or potentially hazardous situation can readily see that the information is swiftly acted upon and used confidentially and proactively to develop and publish safe practice recommendations that can prevent errors.

The USP-ISMP Medication Errors Reporting Program (MERP) operated by the United States Pharmacopeia (USP) in cooperation with ISMP is a confidential national voluntary reporting program that provides expert analysis of the system causes of medication errors and disseminates recommendations for prevention. Regulatory agencies and manufacturers are notified of needed changes in products when safety is of concern.

Without reporting, such events may go unrecognized and thus important epidemiological and preventive information would be unavailable. Errors, near-errors, or hazardous conditions may be reported to the program. These include, but are not limited to, administering the wrong drug, strength, or dose of medications; confusion over look-alike/sound-alike drugs; incorrect route of administration; calculation or preparation errors; misuse of medical equipment; and errors in prescribing, transcribing, dispensing, and monitoring of medications.

Providing causative information on actual or potential errors, or near misses to USP and ISMP, which is automatically shared with FDA and the involved manufacturers, has resulted in drug name changes. For example:

- ◆ Losec[®] (error reports indicating mistaken as Lasix[®]) to Prilosec[®],
- ◆ Levoxine (error reports indicating mistaken as Lanoxin[®]) to Levoxyl[®],
- ◆ Reminyl[®] (error reports indicating mistaken as Amaryl[®]) to Razadyne[™] (and unfortunately new error reports show Razadyne being mistaken as Rozerem[™])



◆ and the most recent, Omacor[®] (error reports indicating mistaken as Amicar[®]) to Lovaza.

To those who report medication errors, keep up the great work. The actions resulting in the name changes listed above, alone, demonstrate the tremendous impact you make when you report your experiences to USP-ISMP MERP. Many other error reports have resulted in manufacture label and stock bottle changes. For more information on reporting incidents, visit www.ismp.org and click on "Report Errors."

FDA Finds Consumers Still Buying Potentially Risky Medications via Internet

FDA continues to warn the American public about the dangers of buying medications over the Internet.

New data collected by FDA show that consumers who are trying to save money on prescription drugs need not take chances by buying prescription drugs from foreign Internet sites because low-cost generic versions are available in the United States. These findings also indicate that some consumers are likely buying foreign drugs online to avoid having to obtain a prescription from their doctors or health care professionals, as many Web sites do not require a prescription.

FDA urges consumers to obtain prescriptions from their doctors or other health care professionals before using prescription drugs, stating that the use of prescription medications without a prescription is an "inherently unsafe practice." FDA also encourages consumers to review www.fda.gov for information on buying medications online before making such purchases.

FDA cites the following potential risk factors associated with buying medications from unregulated Internet sellers:

- ◆ inadequate labeling for safe use;
- ◆ inappropriate packaging and, therefore, uncertain product integrity;
- ◆ possible previous withdrawal from the US market for safety or efficacy reasons;
- ◆ drug-specific risks requiring initial screening and/or periodic patient monitoring;
- ◆ potential harm or abuse, such as with the use of controlled substances; and
- ◆ potential drug-drug interactions.

Recent examinations of a sample of drugs shipped to US consumers found several drugs are associated with higher risks if used without the supervision of a doctor or health care professional. For example: the use of warfarin requires close monitoring to prevent stroke or death; amoxicillin and other antibiotics should not be used for self-treatment because of the risk of antibiotic-resistant infections; levothyroxine use requires close monitoring to ensure effective treatment; and clopidogrel may pose increased risk of cardiac events, such as heart attack, if used in suboptimal doses, which might be found in imported tablets.

Improper labeling also presents a risk to consumers. For example, alendronate sodium labeling should warn patients of significant side effects with improper use. In addition, imported eye drop preparations may have been manufactured under unsterile conditions, presenting a risk of contamination that may result in serious infections.

In light of these and other risks associated with medications purchased over the Internet, FDA stresses the importance of obtaining only FDA-approved drugs along with health care provider monitoring.

Death in Canada Tied to Counterfeit Drugs Bought via Internet

Canada's first confirmed death from counterfeit drugs purchased over the Internet reinforces long-stated concerns of the Canadian Pharmacists Association (CPhA), the association states in a recent press release.

A British Columbia coroner's report concludes that pills bought from a fake online pharmacy are to blame for the March death of a Vancouver Island woman. These drugs were later determined to be contaminated with extremely high quantities of metal.

CPhA is calling on Canadian pharmacists to be especially vigilant and discuss these issues with patients when necessary.

Since 1999, NABP, through its Verified Internet Pharmacy Practice Sites[™] program, has warned of the dangers of purchasing potentially counterfeit drugs from illegitimate online pharmacies.

FDA Sets Standards for Dietary Supplements

FDA recently issued a final rule requiring current good manufacturing practices (CGMP) for dietary supplements. The rule is intended to ensure that dietary supplements are produced in a quality manner, free of contaminants and impurities, and accurately labeled.

The regulations establish the CGMP needed to ensure quality throughout the manufacturing, packaging, labeling, and storing of dietary supplements. The final rule includes requirements for establishing quality control procedures, designing and constructing manufacturing plants, and testing ingredients and finished products, as well as requirements for record keeping and handling consumer product complaints.

Manufacturers also are required to evaluate the identity, purity, strength, and composition of their dietary supplements. If dietary supplements contain contaminants or lack the dietary ingredient they are represented to contain, FDA would consider those products to be adulterated or misbranded.

FDA also issued an interim final rule that would allow manufacturers to request an exemption to the CGMP requirement for 100% identity testing of specific dietary ingredients used in the processing of dietary supplements. To be eligible for an exemption, the manufacturer must provide sufficient documentation that less frequent testing would still ensure the identity of the dietary ingredients. FDA is soliciting comments from the public on the interim final rule until September 24, 2007. Comments may be addressed to the Division of Dockets Management Branch at www.fda.gov/dockets/ecomments.

The final CGMP and the interim final rule became effective on August 24, 2007. The rule has a three-year phase-in for small businesses. Companies with more than 500 employees have until June 2008, companies with fewer than 500 employees have until June 2009, and companies with fewer than 20 employees have until June 2010 to comply with the regulations.

The FDA Web site provides background information at www.cfsan.fda.gov/~dms/dscgmps7.html and a fact sheet at www.cfsan.fda.gov/~dms/dscgmps6.html.

More information is available on the FDA Unapproved Drugs Web site at www.fda.gov/cder/drug/unapproved_drugs/default.htm.

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Contact Information

For claims questions or additional information, contact Provider Relations:

Toll-free in- and out-of-state: 1-800/624-3958

Helena: 406/442-1837

Visit the Montana Medicaid Provider Information Web site at www.mtmedicaid.org

Methadone and Suboxone

The Board receives many calls about the administration and dispensing of methadone and Suboxone® (buprenorphine and naloxone). Methadone may be used for the treatment of pain, and any pharmacy may dispense methadone for such an indication. This would include using methadone as part of a formal pain management program in which a patient is switched from other licit drugs to methadone to control or gradually reduce dosage.

Methadone may only be used to maintain treatment of addiction or to detoxify a patient when the prescriber is working for a narcotic treatment facility (NTF) registered by DEA, Department of Public Health and Human Services, and the Board. In such cases, the drug may only be administered at the NTF. If an addicted patient is admitted to a hospital for a condition other than addiction, methadone can be administered in the same amount as provided by the patient's NTF or an amount sufficient to keep the patient from going into withdrawal. You cannot continue therapy when the patient is discharged from the hospital.

You also cannot provide the patient with a discharge prescription of this drug. Outside of the NTF, methadone cannot be prescribed or administered to addicted patients. However, DEA regulations allow a physician to personally administer, not prescribe, daily methadone doses for a period of up to three days.

The Drug Addiction Treatment Act of 2000 expanded the clinical context of medication-assisted opioid treatment by allowing qualified physicians to dispense or prescribe specifically approved Schedule III, IV, and V medications in settings other than an NTF. At the present time Suboxone and Subutex® (buprenorphine) are the only two Schedule III, IV, or V medications that have been approved by Food and Drug Administration for this medication for treatment of opioid addiction. In order to prescribe this medication for maintenance therapy, a qualified physician must receive training and a registration number. Any pharmacy can fill a Suboxone or Subutex prescription. You can verify participation in this program by consulting <http://buprenorphine.samhsa.gov> and clicking on Buprenorphine Locator. There is also a frequently asked questions link on the site, which is extremely useful. Please contact the Board office for additional information.

Montana Pharmacy Association Meeting

The Montana Pharmacy Association will be holding a wintertime continuing education meeting at the Fairmont Hot Springs Resort in Fairmont, MT, January 25-27, 2008. In conjunction with the meeting, the Board of Pharmacy will

be holding its January meeting January 24 from 1 - 5 PM, and January 25 from 9 AM - 3 PM.

This is an excellent opportunity for pharmacists to meet the members of the Board and the new executive director of the Board, Ronald Klein.

Brochures were mailed in mid-October.

New DEA Number Assignment

Due to the large Type "A" (practitioner) registrant population, the initial alpha letter "B" has been exhausted. The letter "F" will be used as the initial character for all new practitioner registrations.

The Role of the Montana Board of Pharmacy

The Montana Board of Pharmacy is a government body responsible for the protection of public health and safety as it relates to pharmaceuticals and pharmaceutical distribution. It is the responsibility of the Board of Pharmacy to regulate the practice of pharmacy in this state.

Among other things, it is the responsibility of the Board to set minimum standards for the practice of pharmacy including equipment necessary in and for a pharmacy, the purity of drugs and devices by use of official compendia, specifications for the facilities, environment, supplies, technical equipment, personnel and procedures for the storage, compounding, or dispensing of drugs and devices, monitoring drug therapy, and the integrity and confidentiality of prescription information and other patient records.

The Montana Board of Pharmacy is **not** a membership organization of pharmacists and pharmacy technicians responsible for protecting and/or promoting the profession of pharmacy.

The Board of Pharmacy is responsible for enforcing the statutes and regulations that govern the practice of pharmacy. These statutes and regulations may be accessed at www.pharmacy.mt.gov.

The Montana Board of Pharmacy cannot change statutes adopted by the Montana State Legislature; however, the Board is empowered to adopt regulations to implement and clarify statutes. The Board is also empowered to adopt legal standards of practice. Rules promulgation, regulatory adoption, and changes are a public process.

The Board of Pharmacy does regulate the scope of pharmacy practice; however, it does **not** regulate conditions of employment such as hiring, firing, and discipline imposed by an employer.

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