

August 2008



# Montana Board of Pharmacy

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Helena, MT 59620-0513

## ***Dispensing of Outpatient Medications in Emergency Department by Licensed Nurses***

### **July 2008 Joint Position Statement of the Montana Boards of Pharmacy, Medical Examiners, and Nursing**

This joint position statement addresses the role of licensed nurses functioning in the Emergency Department (ED) setting in the issuance of take-home medications to patients upon the order of a licensed health professional with prescribing authority. This agreement pertains to such practices when there is no open pharmacy within a 10-mile radius and when there is no staff pharmacist on duty at the time such services are necessary.

All three boards agree that no violation of rule or statute occurs when a licensed prescriber gives a licensed nurse an order for medications to be taken home by a registered ED patient. Pharmacists and practitioners holding prescribing authority may package and label medications for home use in this setting.

Because patients are best served by receiving these outpatient prescriptions at the point of care, the boards support the following procedures that are designed to safeguard public health and provide necessary services under these conditions.

Pharmacists who are responsible for medication provision in such facilities are required to establish procedures that support this practice in collaboration with their Pharmacy and Therapeutics Committee, hospital administration, staff physicians, [advanced practice registered nurses], [physician assistants], and nurses. Procedures should include the identification of common medications typically prescribed for such purposes, and define appropriate quantities, packaging, and labeling requirements.

The pharmacist and/or the licensed prescriber are responsible for the following procedures:

- ◆ proper packaging, such as placing the medication in moisture and light resistant, childproof containers
- ◆ expiration date is noted on the packaging
- ◆ appropriate quantities of the medications are included based on typical utilization practices (medications, such as some antibiotics, that require reconstitution may be packaged together with a labeled bottle containing the correct amount of water and specific instructions for reconstitution)
- ◆ enclose/attach complete patient instructions (standard drug information/counseling sheet) with the package

- ◆ provide name of the medication, strength/dose, and quantity of the medication on the package label
- ◆ place auxiliary labels on the package as applicable
- ◆ provide a place to write the date, prescriber, and patient's name on the label

Upon receiving an order for one of the prepared, packaged outpatient prescriptions, the licensed nurse must write the prescriber's full name, the date, and the patient's full name on the package label and document the action in the patient's medical record. The nurse must also extend an offer for medication counseling from either the pharmacist or the prescriber and explain how that may occur based on the organization's established policies and procedures.

We believe that this statement clarifies a formerly gray area without sacrificing patient safety. Please direct any questions you may have to your respective board.

#### **Ronald Klein, RPh**

Executive Director  
Board of Pharmacy

#### **Barbara Swehla, MN, RN**

Executive Director  
Board of Nursing

#### **Jeanne Worsech**

Executive Director  
Board of Medical Examiners

## ***Board Disciplinary Actions – Pharmacy***

The Montana Board of Pharmacy took the following disciplinary actions on April 22, 2008.

**Heather Watson, CPhT, Livingston, MT.** Failure to submit Pharmacy Technician Certification Board (PTCB) certification in a timely manner. Letter of reprimand. For licensure renewal in 2008, 2009, and 2010 licensee shall submit proof of current certification.

**Miriam Walters, RPh, Vaughn, MT.** Noncompliance with continuing pharmacy education requirements. Complete continuing pharmacy education requirements for 2007. For licensure renewal in 2008, 2009, and 2010 licensee shall submit proof of continuing pharmacy education. No carryover of hours in 2008. \$750 fine.

*Continued on page 4*



## A Community Pharmacy Technician's Role in Medication Reduction Strategies



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 Food and Drug Administration (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!**<sup>®</sup> **Community/Ambulatory Edition** by visiting [www.ismp.org](http://www.ismp.org). If you would like to report a problem confidentially to these organizations, go to the ISMP Web site ([www.ismp.org](http://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: 200 Lakeside Dr, Horsham, PA 19044. Phone: 215/947-7797. E-mail: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).

Pharmacy technicians play a major role in community pharmacy practice. The pharmacist relies on the technician to provide an extra layer of safety. It is important for technicians to follow system-based processes and inform the pharmacist when these processes do not work or are unmanageable.

### Prescription Drop Off

The date of birth should be written on every hard copy prescription so the pharmacist has a second identifier readily available during verification. Allergy information should be questioned and updated at every patient encounter. Medical condition information, such as pregnancy, communicated to the technician at drop off should be updated in the computerized profile system to help the verification pharmacist determine counseling opportunities. Knowing a person's medical conditions also helps the pharmacist determine if prescriptions are written incorrectly or for the wrong drug.

### Data Entry

Medication safety is enhanced when technicians know the particular language of pharmacy when entering a prescription.

New drugs are at a particular risk because it is more likely that the technician is not aware of the new drug and a more familiar drug is selected. Pharmacists and technicians should work together to determine the best method of distributing information regarding availability of new drugs on the market.

It is important that the technician understands the safety features of the computer system and does not create work-arounds to improve efficiency at the risk of decreasing accuracy and safety. Drug alerts can be numerous, and the technician may be inclined to override the alert and not "bother" the pharmacist. A better way to resolve too many alerts would be to establish protocol between the technician and the pharmacist to determine which level and type of alert needs pharmacist intervention.

### Production

Mix-ups occur primarily due to incorrectly reading the label. The problem is aggravated by what is referred to as *confirmation bias*. Often a technician chooses a medication container based on a mental picture of the item, whether it be a characteristic of the drug label, the shape and size or color of the container, or the location of the item on a shelf. Consequently the wrong product is picked. Physically separating drugs

with look-alike labels and packaging helps to reduce this contributing factor.

### Point of Sale

Correctly filled prescriptions sold to a patient for whom it was not intended is an error that can be avoided by consistent use of a second identifier at the point of sale. Ask the person picking up the prescription to verify the address or in the case of similar names, the date of birth, and compare the answer to the information on the prescription receipt.

Internal errors should be discussed among all staff for training purposes. In addition, it is important to read about and discuss errors and methods of prevention occurring and being employed at other pharmacies within a chain and in other pharmacies, nationwide. ISMP Medication Safety Alert! Community/Ambulatory Edition offers this information to both pharmacists and technicians.

## FDA's Effort to Remove Unapproved Drugs From the Market

Pharmacists are often not aware of the unapproved status of some drugs and have continued to unknowingly dispense unapproved drugs because the labeling does not disclose that they lack FDA approval. FDA estimates that there are several thousand unapproved drugs illegally marketed in the United States. FDA is stepping up its efforts to remove unapproved drugs from the market.

### Background

There are three categories of unapproved drugs that are on the market. The first category consists of those that have been approved for safety, or that are identical, related, or similar to those drugs, and either have been found not to be effective, or for which FDA has not yet determined that they are effective. Between 1938 (passage of the Federal Food, Drug, and Cosmetic Act) and 1962, manufacturers were only required to demonstrate that drugs were safe; the requirement that they also demonstrate that drugs were effective was added in 1962. Drugs that fall in this category have been part of the DESI (Drug Efficacy Study Implementation) review, which was implemented to determine whether drugs approved between 1938 and 1962, or drugs that are identical, related, or similar to such drugs, met the new effectiveness requirements. While the DESI review is mostly completed, some parts of it are still continuing. The second category of unapproved drugs consists of those drugs that were on the market prior to 1938 (passage of the Federal Food, Drug, and Cosmetic Act). The third category, new unapproved drugs, comprises unapproved drugs that were first marketed (or changed) after 1962. Some also may have already been the subject of a formal agency finding that they are new drugs.

### FDA's Concerns About Unapproved Drugs

FDA has serious concerns that drugs marketed without FDA approval may not meet modern standards for safety, effectiveness, manufacturing quality, labeling, and post-market surveillance. For example, FDA-approved drugs must demonstrate that their manufacturing processes can reliably produce drug products of expected identity, strength, quality, and purity. In addition, FDA's review of the applicant's labeling ensures that health care professionals and patients have the information necessary to understand a drug product's risks and its safety and efficacy.

Sponsors that market approved products are subject to more extensive reporting requirements for adverse drug events than sponsors of unapproved drugs. Reporting of adverse events by health care professionals and patients is voluntary, and under-reporting is well documented. FDA, therefore, cannot assume that an unapproved drug is safe or effective simply because it has been marketed for some period of time without reports of serious safety or effectiveness concerns.



## Enforcement Priorities

Manufacturers of unapproved drugs are usually fully aware that their drugs are marketed illegally, yet they continue to circumvent the law and put consumers' health at risk.

Most recently, in June 2006, FDA issued a guidance entitled "Marketed Unapproved Drugs – Compliance Policy Guide" (CPG) outlining its enforcement policies aimed at bringing all such drugs into the approval process. (The CPG is available at [www.fda.gov/cder/guidance/6911fnl.pdf](http://www.fda.gov/cder/guidance/6911fnl.pdf)) The agency provided industry with specific notice that anyone who markets an unapproved drug is subject to enforcement action. This CPG outlines the agency's risk-based enforcement policies aimed at bringing all such drugs into the approval process without imposing undue burdens on consumers or unnecessarily disrupting the market. For all unapproved drugs, the CPG gives highest enforcement priority to the following:

- ◆ Drugs with potential safety concerns
- ◆ Drugs that lack evidence of effectiveness
- ◆ Fraudulent drugs
- ◆ Drugs with formulation changes made as a pretext to avoid enforcement
- ◆ Unapproved drugs that directly compete with an approved drug

Table 1 lists examples of drugs or classes of drugs that, consistent with the CPG, FDA has identified as a higher priority because of safety or other concerns. For six of them, FDA has specifically announced its intention to take enforcement action against companies marketing unapproved versions of those drug products. FDA has withdrawn the approval of the seventh product.

Extended release combination drug products containing guaifenesin (competed with approved products)
Trimethobenzamide hydrochloride suppositories (lacked evidence of effectiveness)
Ergotamine-containing drug products (labeling did not include critical warnings regarding the potential for serious, possibly fatal interactions with other drugs)
Quinine sulfate drug products (665 reports of adverse events, including 93 deaths, and the labeling lacked necessary warnings and safe dosing information)
Carbinoxamine drug products (associated with 21 infant deaths)
Colchicine injectables (50 reports of adverse events, including 23 deaths)

## Importance to Pharmacists

FDA is taking steps to ensure that all marketed US drugs have met approval requirements. FDA recognizes that some unapproved drugs may provide benefits; however, since these products have not undergone FDA review for safety and efficacy, the agency recommends that pharmacists, prescribers, and patients carefully consider the medical condition being treated, the patient's previous response to a drug, and the availability of approved alternatives for treatment. FDA will proceed on a case-by-case basis and make every effort to avoid adversely affecting public health, imposing undue burdens on health care professionals and patients, and unnecessarily disrupting the drug supply. More information regarding the FDA's Unapproved Drug Initiative can be found on its Web site: [www.fda.gov/cder/drug/unapproved\\_drugs/](http://www.fda.gov/cder/drug/unapproved_drugs/).

## NABP Educates Public on Buying from Internet Pharmacies with New Section on its Web site

On May 16, 2008, the National Association of Boards of Pharmacy® (NABP®) launched the Internet Pharmacies section of its Web site, educating patients on the potential dangers of buying medicine online and empowering them to make informed choices. As of mid-June, the site listed 250 Internet drug outlets that appear to be out of compliance with state and federal laws or NABP patient safety and pharmacy practice standards, thereby putting those who purchase from these sites in danger of purchasing drugs that could cause patients serious harm or even death.

NABP developed these standards for its new Internet Drug Outlet Identification program with input from its member boards of pharmacy, interested stakeholders, and regulatory agencies, including the FDA and the US Drug Enforcement Administration. Internet drug outlets operating in conflict with these criteria are listed on the NABP Web site as "not recommended." NABP has identified another 300 suspiciously operating Internet drug outlets and is in the process of verifying its findings before posting these sites to the "not recommended" list. Of the hundreds of sites reviewed under this program so far, only nine have been found to be potentially legitimate, pending verification of licensure and other criteria. At this time, NABP recommends that patients buying medicine online use only Internet pharmacies accredited through the VIPPS® (Verified Internet Pharmacy Practice Sites™) program. NABP has verified that these pharmacies are appropriately licensed and have successfully completed the well-recognized and rigorous VIPPS criteria evaluation and on-site inspection. These pharmacies, representing more than 12,000 pharmacies, are listed on the NABP Web site as "recommended."

These lists, along with program criteria and related patient information, are accessible in the Internet Pharmacies section of the NABP Web site.

The new program is an outgrowth of a 2007 NABP resolution, "Internet Pharmacy Public Safety Awareness," in which the Association pledges to continue collaborating with federal agencies and other interested stakeholders to educate the public and health care professionals of the dangers of acquiring drugs illegally through the Internet and from foreign sources. As part of this initiative, NABP will provide information to assist state and federal regulators in their efforts to shut down rogue Internet drug outlets.

## RxPatrol Video Helps Pharmacists Address and Prevent Pharmacy Theft

Pharmacy theft is a serious crime that is on the rise, costing pharmacies billions annually in stolen medication according to the Federal Bureau of Investigation (FBI). RxPatrol® has teamed up with Crime Stoppers and other law enforcement officials to disseminate information regarding pharmacy crime. One resource that pharmacists can use to educate themselves and their coworkers is a training video that provides tips for pharmacists to address the rising issue of pharmacy robberies. The video includes interviews with law enforcement officials from the FBI and police department about what can be done to prevent such activity. The video can be found on the RxPatrol Web site at [www.rxpatrol.com/videos.asp](http://www.rxpatrol.com/videos.asp) and by clicking on "Pharmacy Safety – Robbery."

RxPatrol is a collaborative effort between industry and law enforcement designed to collect, collate, analyze and disseminate pharmacy theft information. RxPatrol helps protect the pharmacy environment and ensure legitimate patients' access to life-sustaining medicines.

Continued from page 1

**Diane Moothart, RPh, Missoula, MT.** Allowing unlicensed practice by a pharmacy technician. \$200 fine.

**Joseph Harris, RPh, Cheney, WA.** Noncompliance with continuing pharmacy education requirements. Complete continuing pharmacy education requirements for 2007. For licensure renewal in 2008, 2009, and 2010 licensee shall submit proof of continuing pharmacy education. No carryover of hours in 2008. \$250 fine.

**Jack Armstrong, RPh, Mica, WA.** Noncompliance with continuing pharmacy education requirements. Complete continuing pharmacy education requirements for 2007. For licensure renewal in 2008, 2009, and 2010 licensee shall submit proof of continuing pharmacy education. No carryover of hours in 2008. \$250 fine.

**Randal Adair, RPh, Elk, WA.** Noncompliance with continuing pharmacy education requirements. Letter of reprimand. For licensure renewal in 2008, 2009, and 2010 licensee shall submit proof of continuing pharmacy education. No carryover of hours in 2008.

**Heather Elliot, CPhT, Caldwell, ID.** Failure to submit proof of current PTCB certification. For licensure renewal in 2008, 2009, and 2010 licensee shall submit proof of current certification. \$300 fine.

**Debra Rice, RPh, Florence, MT.** Practice of pharmacy while license is suspended. Default order of Board. Licensee shall continue to abide by previous final order of Board. Failure to abide by order shall be grounds for revocation of license. Licensee must continue to renew suspended license and abide by all continuing pharmacy education requirements.

**Debra Rice, RPh, Florence, MT.** Failure to comply with a term, condition, or limitation of a license by final order of Board. Unprofessional conduct. License to practice pharmacy in the state of Montana is suspended for an indefinite period of time. Licensee may not reapply or petition the Board for reinstatement of her license to practice pharmacy until she has entered into a contract with the Montana Impaired Pharmacist Program (MIPP) and remained compliant with the terms of the contract and the requirements of the program for a period of at least one (1) year from the date of the final order. If licensee petitions Board for reinstatement, she shall be required to present sufficient proofs and to comply with certain conditions as the Board may require in its discretion. This final order supersedes final order of default entered July 19, 2007.

**Sing Kai Vang, CPhT, Missoula, MT.** Practice while license is expired. \$200 fine.

**Tammy Schweigert, CPhT, Havre, MT.** Unlicensed practice without current state registration. \$200 fine.

**Alvin Fitzgerald, RPh, Chehalis, WA.** Unlawful practice. Conduct that does not meet the generally accepted standards of practice. Default order of Board. Probation for one (1) year from date of the final order. Enroll and successfully complete two (2) hours of continuing pharmacy education in pharmacy law. Enroll and complete a course regarding the transfer of prescriptions within one (1) year of the date of the final order.

**Larry Fangsrud, RPh, Havre, MT.** Aiding and abetting unlicensed practice. \$500 fine.

**Shiree Dupuis-Ryan, CPhT, Ronan, MT.** Assisting in the unlicensed practice of a profession. Conduct that does not meet the generally accepted standards of practice. Private censure in the form of a letter of reprimand. Not available to public.

**Norman Anderson, RPh, Plains, MT.** Failure to notify Board of termination of employment as pharmacist-in-charge. \$350 fine.

The Montana Board of Pharmacy took the following disciplinary actions on July 14, 2008.

**Broadwater Health Center Pharmacy, Townsend, MT.** Institutional pharmacy practice while license is expired. \$200 fine.

**Larry Chapman, RPh, White Salmon, WA.** Noncompliance with continuing pharmacy education requirements. Letter of reprimand. For licensure renewal in 2008, 2009, and 2010 licensee shall submit proof of continuing pharmacy education. No carryover of hours in 2008.

**Alvin Fitzgerald, RPh, Chehalis, WA.** Failure to comply. Default order of Board. License suspended until such time as licensee complies with final default order of Board entered April 22, 2008. \$300 fine.

**Scott James, RPh, Seeley Lake, MT.** Addiction to or dependency on a habit-forming drug or controlled substance; misappropriating property or funds from a client or workplace or failing to comply with a Board rule regarding the accounting and distribution of a client's property or funds; conduct that does not meet the generally accepted standards of practice; unprofessional conduct consisting of engaging in any activity that violates state and federal statutes and rules governing the practice of pharmacy; dispensing medication without proper authorization; unprofessional conduct consisting of any act performed in the practice of pharmacy that is hostile to the public health and that is knowingly committed by the holder of the license. Summary suspension of license for an indefinite period of time beginning March 19, 2008. Default order of Board. License to practice pharmacy suspended for an indefinite period of time. Licensee may not reapply for a new license or petition the Board for reinstatement until he has entered into a contract with MIPP and remained compliant with the terms of the contract and the requirements of the program for a period of at least one (1) year. If licensee applies for a new license, or petitions Board for reinstatement, he shall be required to present sufficient proofs and to comply with certain conditions as the Board may require in its discretion.

**Dava Pharmaceuticals, Inc, Fort Lee, NJ.** Wholesale drug distributor license expired. Unlicensed operation of wholesale drug distributor. \$500 fine.

**Village Health Care Center, Missoula, MT.** Institutional pharmacy practice while license is expired. \$200 fine.

**Brendan House, Kalispell, MT.** Institutional pharmacy practice while license is expired. \$200 fine.

**Michelle Tade, CPhT, Glasgow, MT.** Practice while license is expired. Default order of Board. \$200 fine.

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Page 4 – August 2008

The *Montana Board of Pharmacy News* is published by the Montana Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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