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# Montana Board of Pharmacy

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## Compliance Corner

Hi all,

I do not know where the confusion is coming from as it relates to proper licensure and certification of pharmacists, interns, and technicians, but with all the action the Montana Board of Pharmacy is having to take, it is an appropriate time for a reminder.

Montana Pharmacy Code (MCA) 37-7-302(2) states: "Each person licensed and registered under this chapter must receive from the department an appropriate license. The license must be conspicuously displayed at all time in the place of business."

In addition, Montana administrative rules for technicians under 24.174.701 and the succeeding rules state the requirements and qualifications to be a technician in training or a certified pharmacy technician, and the role they may play in pharmaceutical distribution. I point specifically to 24.174.701(1c) and 24.174.702(1d), which refer to the proof of certification by the Pharmacy Technician Certification Board or other Board-approved certification to become or practice as a certified pharmacy technician in Montana, and your record-keeping requirements.

Also, interns under 24.174.303(5) receive an "Intern Certificate of Registration" from the Board, by statute (37-7-302(2)), and must display this registration at any place of business that they happen to work.

All licensees should also be familiar with renewal requirements, especially those pointed out in rule ARM 24.174.2102 and the succeeding rules for pharmacists and technicians.

The last area that is apparently causing confusion is "who is responsible for ensuring licensure and certification?" While it is the responsibility of each registrant to ensure they are properly licensed or certified, it still falls upon the pharmacist-in-charge (PIC) to verify that each individual working within their facility or department is in fact current or not working until they are. In other words, they cannot work unless they can display proper licensure, registration, and certification. Why the PIC? ARM 24.174.301(27) de-

fines the PIC as "a pharmacist licensed in Montana who accepts the responsibility for the operation of a pharmacy in conformance with all laws and rules pertinent to the practice of pharmacy and who is personally in full and actual charge of such pharmacy." I hope that this information is of help to you all.

Sincerely,

Your compliance officer, Bill

## Handling Fraudulent Prescriptions

Sooner or later every pharmacist will have to deal with a fraudulent prescription. When the validity of a prescription is an issue, after the practitioner has been contacted and it has been determined you have a forged document, here are some steps a pharmacist can take:

1. Contact local law enforcement immediately using "911."
2. Advise the patient that the prescription will take a little time to fill. Do not mention your suspicions of fraud or diversion. Hopefully this will allow time for a police officer/deputy to come to the pharmacy while the customer or suspect is still present.
3. Obtain a clear description of the suspect and any other persons with them. If possible, record or make a copy of any personally identifying information such as a driver's license with a photo on it. Record name and address if possible.
4. If your pharmacy has video surveillance, secure the tape for police to review.
5. Document any facts concerning the transaction, ie, the usual who, what, where, when, and how. Document, document, document!
6. Maintain custody of the prescription, if possible. Do not, however, put your staff or yourself at risk. If you are or feel threatened, give the prescription back to the suspect. Do not put others or yourself in harms way.

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## Study Fuels Concerns over Foreign Drugs Bought Online

According to study results published in the May 2008 issue of *Annals of Pharmacotherapy*, many prescription medications purchased from foreign pharmacies through Internet drug outlets differ significantly from the versions approved by the Food and Drug Administration (FDA). "These findings have implications for safety and effectiveness that should be considered by clinicians to potentially safeguard patients who choose to purchase foreign-manufactured drugs via the Internet," the study authors say.

The study evaluated 20 simvastatin tablets and capsules, including the US innovator product and 19 generic samples obtained from international Internet drug outlets. Tablet samples were tested according to United States Pharmacopeia (USP) guidelines where applicable, using high-performance liquid chromatography, disintegration, dissolution, weight variation, hardness, and assessment of physical characteristics.

Several international samples analyzed were not comparable to the US product in one or more aspects of quality assurance testing, and significant variability was found among foreign-made tablets themselves. Five samples failed to meet USP standards for dissolution, and two for content uniformity. Among all samples, variability was observed in hardness, weight, and physical characterization.

## Testing Medication Names Prior to Marketing



*This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with 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!**<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 Medi-*

*cation Errors Reporting Program. ISMP address: 200 Lakeside Dr, Horsham, PA 19044. Phone: 215/947-7797. E-mail: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

Medication names that look-alike and sound-alike, confusing or absent drug labeling, and non-distinct or ambiguous drug packaging significantly contributes to medication errors. This is not a new problem. These conditions have led to serious drug mix-ups and deaths. Research has identified that one of the most frequent causes of pharmacy drug dispensing errors (29%) is failure to accurately identify drugs, most prominently due to look-and sound-alike drug names (Leape et al. *JAMA*, July 5, 1995).

In addition, many medications are packaged in bottles with similar shapes and similar labels, making it easy to confuse one drug with another.

MedMARX data reports there are 1,470 different drugs implicated in medication errors due to brand and/or generic names that looked or sounded alike. From this data, USP has compiled a list of 3,170 pairs of names that look and/or sound alike.

FDA is also concerned about drug naming confusion and its subsequent potential error effects. On June 5-6, 2008, FDA hosted a public workshop to discuss a concept paper ([www.fda.gov/cder/drug/MedErrors/meeting\\_names.pdf](http://www.fda.gov/cder/drug/MedErrors/meeting_names.pdf)) about a pilot program to address look- and sound-alike brand names. The pilot, called for in the FDA Amendments Act of 2007, would allow drug companies (or outside contractors) to voluntarily evaluate proposed brand names and submit the data for review to FDA. Currently, FDA's Division of Medication Error Prevention screens drug names using its own safety testing methods, in consultation with other divisions responsible for product approval.

The concept paper outlines the types of studies that should be conducted, including simulations of real-world conditions with practicing clinicians who evaluate handwritten, electronic, and oral prescribing scenarios to detect name similarities and other potential confusion with laboratory and medical terms or abbreviations. Dosage form, strength, and frequency also should be considered, as well as the clinical environment where it will be used. Based on discussions during the June meeting and submitted comments, FDA will revise the concept paper and present testing methods to the pharmaceutical industry.

It is hoped that testing drug names prior to marketing will decrease the number of look-and sound-alike medication names. ISMP receives numerous reports of



errors and potential errors caused by look-and-sound-alike medications every year. ISMP, through its wholly owned for-profit subsidiary Med-E.R.R.S., Inc<sup>®</sup>, has been reviewing drug names and packaging for pharmaceutical manufacturers for more than 10 years.

If you are a pharmacist or other health care practitioner who is interested in medication safety and error prevention, you can make a difference! Med-E.R.R.S. is looking for pharmacists from all practice settings to help test labeling, packaging, and nomenclature in the pre-marketing phase for pharmaceutical companies. The process is fun, simple, and easy and a small honorarium is paid for your participation.

For more information or to sign up, go to [www.med-errs.com](http://www.med-errs.com) and click on "Become a Reviewer."

## **Coalition Looks to Pharmacies, Regulators to Reduce Diversion**

A recent report by the Coalition Against Insurance Fraud looks to pharmacies and pharmacy regulators, among others, to cut down on the prevalence of prescription drug diversion, particularly of controlled substance analgesics.

The report, "Prescription for Peril: How Insurance Fraud Finances Theft and Abuse of Addictive Prescription Drugs," calls on the pharmacy profession to provide additional training on prescription drug abuse and diversion in pharmacy education curricula and continuing professional education, and to exert closer point-of-sale scrutiny of certain prescriptions and patients. For instance, the report suggests diversion could be reduced significantly if pharmacies asked for photo identification in connection with controlled substance prescriptions, similar to regulations in place for pseudoephedrine-containing products.

The coalition also recommends wider adoption of prescription monitoring programs to maintain state-wide records of narcotic prescriptions, allowing closer monitoring by prescribers and dispensers. In addition, the coalition calls on lawmakers and licensing boards to "swiftly and decisively penalize the small fraction of prescribers and dispensers who facilitate drug diversion and abuse."

## **FDA Encourages Pharmacists to Use Patient Safety News**

*FDA Patient Safety News* is a monthly video news program produced by FDA targeted to pharmacists and other health care professionals. The program provides the

latest information on recalled and counterfeit products, important safety alerts, preventing medical errors and mitigating risks from the use of medical products, including drugs, devices, vaccines, and diagnostic products.

The videos can be watched online or downloaded free of charge. Pharmacists can view the entire program or individual segments, and FDA encourages further use and distribution of the video or text of the program, as there are no copyright restrictions. The video and demonstrations can also be used in staff-development programs or in other teaching environments.

Pharmacists can search for video segments on topics of interest, get additional information about topics, e-mail segments to others, report problems with medical products to FDA, and sign up to be notified about each month's program. The show is also broadcast on several medical satellite networks: VHA, GE TiP-TV, HSTN, LTCN, and HNN. These networks presently reach over 4,000 hospitals and long-term care facilities across the US.

More information about the program and how to join the program mailing list is available on the FDA Web site at [www.fda.gov/psn](http://www.fda.gov/psn) or by sending an e-mail to [PSNews@cdrh.fda.gov](mailto:PSNews@cdrh.fda.gov).

## **Switch to HFA-Propelled Albuterol Inhalers Advised in Anticipation of CFC Ban**

FDA recently issued a public health advisory alerting patients, caregivers, and health care professionals to switch to hydrofluoroalkane (HFA)-propelled albuterol inhalers because chlorofluorocarbon (CFC)-propelled inhalers will not be available in the United States after 2008. CFC-propelled albuterol inhalers are being phased out to comply with the Clean Air Act and an international environmental treaty, the Montreal Protocol on Substances that Deplete the Ozone Layer. Under this treaty, the US has agreed to phase out production and importation of ozone-depleting substances including CFCs. No CFC-propelled albuterol inhalers may be produced, marketed, or sold in the US after December 31. Three HFA-propelled albuterol inhalers have been approved by FDA: Proair<sup>®</sup> HFA Inhalation Aerosol, Proventil<sup>®</sup> HFA Inhalation Aerosol, and Ventolin<sup>®</sup> HFA Inhalation Aerosol. In addition, an HFA-propelled inhaler containing levalbuterol is available as Xopenex<sup>®</sup> HFA Inhalation Aerosol. More information is available on the FDA Web site at [www.fda.gov/cder/mdi/albuterol.htm](http://www.fda.gov/cder/mdi/albuterol.htm).

7. Suspects often realize that the prescription in question is evidence of a crime and can be the evidence needed for a successful criminal prosecution. Try to preserve such evidence.
8. Limit handling of the suspect prescription to the extent possible. Ways to accomplish this include placing the document in a plastic or paper bag, or in an envelope.
9. Notify the Board of Pharmacy of the incident. The suspect(s) may be working the area, and the Board can thus provide useful information to law enforcement jurisdictions.

### **Medicaid Tamper-Resistant Prescription Information**

The following information was supplied by the Centers for Medicare and Medicaid Services (CMS) via its Web site on August 17, 2007. Beginning on October 1, 2007, in order for Medicaid outpatient drugs to be reimbursable by the federal government, all written, non-electronic prescriptions were required to be executed on tamper-resistant pads. This requirement was included in section 7002(b) of the US Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act 2007. In August 2007, CMS issued a letter to state Medicaid directors with guidance on implementing the new requirement.

CMS has outlined three baseline characteristics of tamper-resistant prescription pads, but each state will define which features it will require to meet those characteristics in order to be considered tamper resistant. The baseline characteristics must: (1) prevent unauthorized copying of a completed or blank prescription form; (2) prevent the erasure or modification of information written on the prescription by the prescriber; or (3) prevent the use of counterfeit prescription forms.

By April 1, 2008, states needed to require at least one of these baseline requirements. By October 1, 2008, states must require all three characteristics on prescription pads in order to be considered tamper resistant. The letter to state Medicaid directors outlines situations where the new requirement does and does not apply. The requirement does not apply when the prescription is communicated by the prescriber to the pharmacy electronically, verbally, or by fax; a managed care entity pays for the prescription; or in most situations when drugs are provided in certain institutional and clinical facilities. The letter also allows emergency fills as long as a prescriber provides a verbal, faxed, electronic, or compliant written prescription within 72 hours. For detailed information on the requirements, please refer to the state Medicaid director letter.

For the full article, please visit the CMS Web site at [www.cms.hhs.gov/DeficitReductionAct/Downloads/Tamper.pdf](http://www.cms.hhs.gov/DeficitReductionAct/Downloads/Tamper.pdf).

### **New Board of Pharmacy Members**

The Montana Board of Pharmacy is pleased to announce the appointment of three new Board members by Governor Brian Schweitzer. Susan Hagen replaces Ann Pasha of Great Falls; Rebekah Matovich, CPhT, replaces James Cloud, CPhT, of Stevensville; and Frances Carlson replaces Colette Bernica of Great Falls.

Susan Hagen of Glasgow is a public member of the Board of Pharmacy. Her term expires July 1, 2012.

Susan is married to Ellis Hagen from Westby. She has been employed at Eastern Montana Community Mental Health Center in Glasgow since 2001 as a therapist. She and Ellis continue to farm and operate Hilltop House Bed and Breakfast in Westby. They have two adult children, Chet and Allyson.

Rebekah Matovich, CPhT, is the pharmacy technician member of the Board of Pharmacy. Her term expires on July 1, 2013.

Rebekah began her career in pharmacy at the age of 18 at Hi-School Pharmacy, a local Oregon chain. She was promoted to the corporate office for the 45-store chain, where she helped manage and bill Medicaid and Medicare durable medical equipment. She also worked for Costco Pharmacy. Rebekah and her husband Mike moved to Billings, MT, where Mike took over the operation of his father's pharmacy in Columbus. Rebekah went to work for Billings Clinic where she worked in the inpatient pharmacy. Today Rebekah and Mike manage and operate Columbus Health Mart Pharmacy. They have one child, Mason, born in 2007.

Frances Carlson of Great Falls is a public member of the Board of Pharmacy. Her term expires on July 1, 2013.

Frances attended Tufts University and received a bachelor of science degree. Along with her husband, she lived for five years in Alberta, Canada. They also lived in Maine, but liked the west and eventually moved to Great Falls. For 25 years Frances worked as a pediatric occupational therapist in Alberta, ME, Columbus, MT, and Great Falls. She now pursues her first love, and second career, creating art. She is presently self-employed and works out of her home. They have one adult child.