

November 2007



# Ohio State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

77 S High St, Room 1702, Columbus, OH 43215-6126  
Tel: 614/466-4143 Fax: 614/752-4836  
[www.pharmacy.ohio.gov](http://www.pharmacy.ohio.gov)

## What is a Valid Signature on a Prescription?

Please remember that rule 4729-5-30 (Manner of Issuance of a Prescription) of the Ohio Administrative Code requires that all hard-copy (written) prescriptions must be manually signed by the prescriber. If a patient arrives with a prescription that has a computer-generated signature, a rubber-stamped signature, or a signature that has the format of prescriber's name/office nurse's signature, the prescription is not valid and must be verified prior to dispensing. Of course, if it is a prescription for a Schedule II controlled substance, it may not be filled without the manual signature.

## Tamper-Resistant Prescription Pads and Federal Law

By now, everyone should be aware that President Bush signed HR 3668 on September 29, 2007, thereby delaying for six months the implementation of the requirement that all written Medicaid prescriptions be on tamper-resistant paper. The new effective date will be April 1, 2008. While that is a date that may strike some people as being appropriate for this type of a proposal, it should be assumed by everyone that this will probably be the only extension, although there will certainly be some continuing efforts made to amend or remove this requirement on the federal level. For right now, however, please assume that on April 1, 2008, doctors will be required to issue all written prescriptions for Medicaid patients on tamper-resistant forms. While the law requires the doctor to issue every prescription on the right form, the penalties for violations of this law will probably fall on the pharmacists who knowingly fill prescriptions that are written on incorrect forms and then bill Medicaid for the drugs. Please be aware that this is still coming and help your doctors prepare so we do not experience all the last-minute panic like we did in late August and September.

One additional aspect of this change in format is that the prescriptions that are written and then sent to the pharmacy via fax will now be coming through with "COPY" or "VOID" or another similar designation appearing on the fax when it arrives in the pharmacy. Please treat these as you would any other fax. If you are sure that the source of the fax is the prescriber's office and it is a prescription issued legitimately, then please fill the prescription. As far as is known, it is impossible to fax one of these tamper-resistant forms without that warning appearing at the pharmacy end. Please use good judgment and take care of the patient as you have always tried to do.

## Health Care Professionals Needed for Disaster Response – Ohio Medical Reserve Corps

*This article was primarily written by Timothy R. Lanese, RPh, MBA, FASHP, FACHE.*

We do not know when the next disaster will occur, but when it does, Ohio Medical Reserve Corps (OMRC) volunteers *are ready to respond*. The landscape of emergency management has changed since the terrorist attacks of September 11, 2001, and Hurricane Katrina. In these large-scale emergencies, first responders and the health care system quickly became overwhelmed. As a result, it was realized that the only way to answer the needs of the community is to have an organized group of health care professional volunteers that can be quickly mobilized.

OMRC provides the structure for organized health care volunteers in the Buckeye State. Dr Forrest Smith, state epidemiologist and OMRC co-coordinator says "Ohio Medical Reserve Corps will help to ensure that if a medical crisis hits, our communities will be ready to respond and protect our citizens." Since OMRC's inception in 2003, the program has rapidly grown with more than 7,000 volunteers throughout the state. Volunteers are coordinated through local health jurisdictions or county emergency management agencies. OMRC operates in most of the state's counties including all major metropolitan areas. OMRC volunteers are willing to donate their time and expertise to prepare for and respond to emergencies and promote healthy living throughout the year. Pharmacists are specifically needed to assist in mass prophylaxis and vaccination programs should the need arise. Several communities have already developed point-of-dispensing (POD) programs with critical need for pharmacist input. Timothy Lanese is a member of several Cleveland-area teams and has been involved in the planning and activation of several POD drills. He feels this "has been a very valuable and rewarding experience. The other members of the team have varying degrees of medical experience and really value my contribution. It is amazing how many questions come up during these events that only a pharmacist can answer."

Liability protection is provided (Ohio Revised Code 121.404) for OMRC volunteers during local, state, or federally declared emergencies, disasters, drills, and trainings. The statute also protects a registered volunteer's personal information on the OMRC database from public disclosure.

Pharmacists are often reluctant to become involved due to a fear of liability for the dispensing process. The Ohio State Board of Pharmacy explains that, as in all cases, it is the pharmacist's duty to act in the best interests of patients being served. In a declared emergency, the pharmacist's knowledge and expertise can be critical to the proper

*Continued on page 4*



## 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](http://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!**<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: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: [ismpinfo@ismp.org](mailto: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<sup>®</sup> (error reports indicating mistaken as Lasix<sup>®</sup>) to Prilosec<sup>®</sup>,
- ◆ Levoxine (error reports indicating mistaken as Lanoxin<sup>®</sup>) to Levoxyl<sup>®</sup>,
- ◆ Reminyl<sup>®</sup> (error reports indicating mistaken as Amaryl<sup>®</sup>) to Razadyne<sup>™</sup> (and unfortunately new error reports show Razadyne being mistaken as Rozerem<sup>™</sup>)



◆ 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](http://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](http://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](http://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](http://www.cfsan.fda.gov/~dms/dscgmps7.html) and a fact sheet at [www.cfsan.fda.gov/~dms/dscgmps6.html](http://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](http://www.fda.gov/cder/drug/unapproved_drugs/default.htm).

Continued from page 1

functioning of the disaster team. Pharmacists who focus on doing what is best for the patient at the time should not have any concerns about the Board looking over their shoulders.

OMRC provides the opportunity to help your community when it is needed the most. OMRC offers free trainings, hands-on drills and exercises, professional continuing education units, and networking with fellow health care professionals. The time commitment is minimal, but the reward is great. You can make a difference. Join OMRC.

### Make a Difference!

#### How to Join:

- ◆ Sign up at the Ohio Medical Reserve Corps Web site: [www.serveohio.org](http://www.serveohio.org)
- ◆ For more information you may also e-mail David O'Reilly at [david.oreilly@ocsc.state.oh.us](mailto:david.oreilly@ocsc.state.oh.us) or Paul Bender at [paul.bender@ocsc.state.oh.us](mailto:paul.bender@ocsc.state.oh.us)

### New Pharmacy Board Rules Effective

By the time this *Newsletter* arrives, the Board should have new rules that have become effective. The full text of these rules can be found on the Board's Web site. Click on "What's New" and you will find the full text of the rules, showing changes. A major change this year deals with the immunizations that pharmacists may administer to patients, including influenza vaccine to patients 14 years of age and older. In addition, properly trained and certified pharmacy interns are now able to administer influenza vaccine to patients 18 years of age and older under the direct supervision of a pharmacist. Senate Bill 58 passed both the House and the Senate, was signed by the governor, and became law on August 30, 2007. The process of finalizing the rules meant that the implementation of the law was delayed until the rules could go through the state's approval system. All of that is complete and the implementation of the law can now proceed.

Pharmacists may now administer influenza vaccine to patients 14 years of age or older. For patients 18 years of age or older, pharmacists may administer vaccines for pneumonia, tetanus, hepatitis A, hepatitis B, meningitis, diphtheria, and pertussis. In addition, pharmacists may have epinephrine or diphenhydramine available for administration in emergency situations.

As stated above, pharmacy interns may administer influenza vaccine to patients 18 years of age or older when they are directly supervised by a pharmacist who is able to administer immunizations.

One other change made in the law deals with the notification of the patient's physician or the local board of health. It is no longer

necessary to notify the physician or the board of health for influenza vaccines administered to patients 18 years of age or older. Even though notification is still required for the other injectables, this should cut down on the pharmacy's paperwork requirements tremendously.

Please note that pharmacists who were trained prior to the recent changes to the laws and rules must receive additional training before they may begin to administer the new immunizations or administer influenza vaccine to patients in the 14- through 17-year-old age group. The Board has been approving programs that incorporate the new injections and many of them have indicated that they will offer a somewhat shorter course for those who were previously certified to be sure they are knowledgeable about the approved new injections.

As usual, if you have any questions about this, please call the Board office and speak with one of the pharmacists in the office.

### Disciplinary Actions

Anyone with a question regarding the license status of a particular prescriber, nurse, pharmacist, pharmacy intern, or dangerous drug distributor in Ohio should contact the appropriate licensing board. The Web sites listed below may include disciplinary actions for their respective licensees.

**State Dental Board** – 614/466-2580, [www.dental.ohio.gov](http://www.dental.ohio.gov)

**State Medical Board** – 614/466-3934, [www.med.ohio.gov](http://www.med.ohio.gov)

**State Nursing Board** – 614/466-3947, [www.nursing.ohio.gov](http://www.nursing.ohio.gov)

**State Optometry Board** – 614/466-5115, [www.optometry.ohio.gov](http://www.optometry.ohio.gov)

**State Pharmacy Board** – 614/466-4143, [www.pharmacy.ohio.gov](http://www.pharmacy.ohio.gov)

**State Veterinary Medical Board** – 614/644-5281,

[www.ovmlb.ohio.gov](http://www.ovmlb.ohio.gov)

**Drug Enforcement Administration** – 1-800/230-6844,

[www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov)

Page 4 – November 2007

The *Ohio State Board of Pharmacy News* is published by the Ohio State 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.

William T. Winsley, MS, RPh - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor  
& Executive Editor

Larissa Doucette - Editorial Manager

Presorted Standard  
U.S. Postage  
PAID  
Chicago, Illinois  
Permit No. 5744

OHIO STATE BOARD OF PHARMACY

National Association of Boards of Pharmacy Foundation, Inc  
1600 Feehanville Drive  
Mount Prospect, IL 60056