

March 2008



Kentucky Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Board Newsletter

The Kentucky Board of Pharmacy voted at its July 11, 2007 meeting to allow the *Kentucky Board of Pharmacy News* to be sent via an e-mail link beginning 2008. Therefore, around the first of March 2008 each pharmacist will receive an e-mail from the National Association of Boards of Pharmacy® with a link to the *Kentucky Newsletter*. If you wish to continue to receive the *Newsletter* by mail, please notify the Board in writing. If you have further questions, please contact the Board office at your convenience.

Board Officers for 2008

W. Michael Leake was sworn in as president, and Catherine Leake was sworn in as president-elect to the Kentucky Board of Pharmacy on Wednesday, January 9, 2008.

Board Meeting Dates 2008

At the January 9, 2008 Board meeting, the Board approved Louisville as the site for the November Board meeting and Board Retreat. The Board meeting will be on Friday, November 14, 2008, and the Board Retreat will be held on Saturday and Sunday, November 15-16, 2008. The exact location of the meeting will be announced at a later date.

Topics for Discussion at the 2008 Board Retreat

If you or your organization would like to submit topics to be considered for the Board of Pharmacy's 2008 Board Retreat, Saturday and Sunday, November 15-16, 2008, please forward them to the Board office. The Board will review these suggestions and prepare an agenda at a later date. If you have any questions, please contact the Board office at your convenience.

Pharmacy Renewal Deadline June 30, 2008

Pharmacy permits expire June 30, 2008. A pharmacy permit can be renewed online. A postcard explaining the renewal process will be mailed to each pharmacy on or about April 20, 2008. If you want to send in a paper renewal, this form may be printed from the Board's Web site: www.pharmacy.ky.gov. If you have any questions concerning the renewal process, please contact the Board office. Please be reminded that if your pharmacy has an address change, relocating within the current premises of the existing permit or changing ownership, you must complete a new pharmacy application. A pharmacy application with a United States Post Office box address only will **not** be accepted and will be returned. All incomplete applications will be returned. Remember the deadline is June 30, 2008. All paper renewal applications must be in the Board office by the close of the day June 30, 2008.

Continuing Education Changes

Submitted by Jeffrey Osman, RPh, PharmD, Inspections and Investigations Coordinator

The Board office received information from the Accreditation Council for Pharmacy Education (ACPE) concerning a recent change in its Universal Program Number (UPN) codes. Effective August 1,

2007, a new "topic designator" was added to the existing list of UPN codes. The new designator is "05" and it tells you that the program contents are about patient safety. List of current and new designator codes found in the UPN are as follows:

L	Live Program
H	Home Study
C	Both Live and Home Study
P	Pharmacists
T	Pharmacy Technician
01	Disease State Management/Drug Therapy
02	AIDS Related Therapy
03	Pharmacy Law
04	General Pharmacy Topics
05	Patient Safety: The prevention of health care errors, and the elimination or mitigation of patient injury caused by health care errors.

Additionally, educational material provided should clearly identify the target audience, whether it is exclusively for pharmacists (P) or exclusively for pharmacy technicians (T) or both. If a continuing pharmacy education (CPE) program or activity includes both pharmacists and pharmacy technicians, specific and separate performance objectives should be described for each group.

For example, a program or activity assigned 022-000-99-098-L03P would indicate a live (L) program regarding a pharmacy law topic (03) and exclusively for pharmacists (P). On the other hand, a program or activity assigned 022-000-99-098-H02T would be a home study (H) program regarding AIDS (02) and exclusively for pharmacy technicians (T). If the program or activity is intended for both pharmacists and pharmacy technicians, providers must be able to demonstrate needs assessments, performance objectives, and learning assessments for each group. The CPE program or activity would be assigned two UPNs specific to each group. For example, a live program titled "Safety & Quality Pearls for 2008" intended to include both pharmacists and pharmacy technicians would be assigned 022-000-99-098-L05P and 022-000-99-098-L05T.

Remember, the CPE credits required for pharmacist license renewal must be earned between January 1 and December 31 of each year with no carry over.

KASPER Data Collection Update

Submitted by Dave Sallengs, RPh, Branch Manager, Office of Drug Enforcement and Professional Practices Branch of the Cabinet for Health and Family Services

On February 18, 2008, all Kentucky All Schedule Prescription Electronic Reporting (KASPER) data collection will be through

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NABP Testifies in Support of Proposed BTC Class of Drugs

NABP testified at the Food and Drug Administration (FDA) meeting November 14, 2007, stating its support for the proposed creation of a behind-the-counter (BTC) class of drugs. The meeting was held to solicit input on the public health benefits of certain medications being available BTC without a prescription but only after intervention by a pharmacist.

A long-time advocate of this measure, NABP passed a resolution in 1993 advocating a third class of drugs that would be dispensed without a prescription only by licensed health care professionals authorized to prescribe and/or dispense prescription drugs. Continuing its support of this concept, NABP passed a resolution in 1995 stating that medications being converted from prescription-only to over-the-counter status that pose serious risks and require patient education for effective use should be placed in a special class requiring sale only by licensed health care professionals after counseling the patients on proper use.

More information is available in the *Federal Register* (Docket No. 2007N-0356).

A Rose by Any Other Name . . . Might Be Safer



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.

What's in a name? Well, if the name is referring to a pharmaceutical compound getting ready to go to market, a lot goes into that name.

In order for a drug manufacturer to test its drug chemicals in animals, it must submit three possible generic names to the United States Adopted Names (USAN) Council, the organization responsible for assigning generic drug names. USAN Council selects a generic drug name, based on safety, consistency, and logic and then refers this name to the World Health Organization to check for similar generic names being used in other countries.

There is a method to this naming madness. For instance, drug name "stems" group therapeutically-related drugs. An example would be the stem *-vastatin* for drugs that lower cholesterol, and is used in the generic names of atorvastatin (Lipitor®) and lovastatin (Mevacor®). Another example of the use of stems is *-mab* used in anticancer drugs. MAB stands for 'monoclonal antibodies' and is used in the generic drug names alemtuzumab and cetuximab. The stem gives clues about what a drug is used for; however, drug names that share a common stem can contribute to medication errors because they may sound or look alike. This is especially problematic if the products share common dosage forms and other similarities.

Additionally, USAN Council guidelines call for generic names to be simple to pronounce with only one way to say it and have no more than four syllables. Yet, the names mentioned in the preceding paragraph are difficult to pronounce and some have five syllables.

After a drug has completed phase-I clinical trials, the manufacturer submits potential brand names to FDA as well as the US Patent and Trademark Office.

Drug manufacturers often work with drug naming companies to help them develop unique brand names. A report in the January-February 2004 issue of the *Journal of the American Pharmacists Association* stated that there are more than 9,000 generic drug names and 33,000 trademarked brand names in use in the US. Although the drug names may be unique, more and more often they are leading to miscommunications and are resulting in errors.

According to USP-ISMP Medication Errors Reporting Program (MERP) data, 25% of the errors reported relate to the products generic or brand name. To help combat this problem, in 1990 FDA established the Labeling and Nomenclature Committee (LNC) to review proposed trade names. The LCN, which has evolved into the Division of Medication Errors and Technical Support of the Office of Surveillance and Epidemiology, formerly the Office of Drug Safety, has been actively reviewing drug names.

Although prescribers and consumers would like drug names to give an indication of the intent of the drug in the name itself, FDA prohibits trade names associated with the product's intended use and will not approve names that imply efficacy. Yet there are many exceptions to this "intended" rule. A drug such as Celebrex® (pain treatment) connotes "celebration" and Halcion® (sleep aid) conjures up images of restfulness (halcyon). Perhaps naming drugs for their intended purpose would decrease the number of medication errors associated with confusing and sound-alike/look-alike drugs. Until prescribers conform to writing the indication or purpose on the actual prescription, the drug name itself may give a clue to the patient as to what is being prescribed. The patient may read the prescription before handing it to the pharmacist and question why he or she is being prescribed "Oncocure" when he or she does not have cancer.

Studies estimate that anywhere from 7,000 to 20,000 people die or are injured each year in the United States because of drug name confusion. What can pharmacists do? Go to the Med-E.R.R.S.® Web site www.med-errs.com and register to become a drug name reviewer. Although not required, many drug companies seek the consultant advice of Med-E.R.R.S. to test their potential generic and brand names before submitting these names to FDA. Med-E.R.R.S., Inc, a wholly owned subsidiary of ISMP, assists pharmaceutical and health care technology companies in evaluating the safety of their products and services. Med-E.R.R.S., Inc has tested more than 600 names for over 35 pharmaceutical companies in 2006. Med-E.R.R.S. integrates knowledge and experience with the input of clinicians in the field to systematically analyze potential trademarks, packaging, and technology.

Med-E.R.R.S. pharmacist reviewers participate in online surveys to review names of potential drugs handwritten by a number of "prescribers" to determine if any of the tested names look like medical terms or other current drugs on the market. They are also asked to review the potential drug names to compare if the potential name sounds like another drug or like another medical term.

To further national efforts to manage drug name confusion, ISMP hosted an invitational summit on October 9-10, 2007, in Philadelphia. This meeting brought together a full range of pharmacy professionals



and representatives from standard-setting organizations, regulatory agencies, the pharmaceutical industry, and the payer community. During the meeting, the attendees discussed post-marketing strategies to identify and reduce name confusion and ways to improve upon their scope and effectiveness. ISMP believes that the health care industry can significantly reduce the risk to patients from otherwise preventable product mix-ups due to look-alike and sound-alike names. A report from the summit will be available online soon.

So a rose by any other name may smell as sweet, but Reminyl® renamed Razadyne™, (see *ISMP Medication Safety Alert!® Community/Ambulatory Edition*, Volume 4, issue 5, May 2005, **Reminyl®/Amaryl® Your Reports at Work.**) may “smell” safer, and therefore “sweeter.” Sweeter, that is until recently when MERP started receiving errors involving confusion between Razadyne and Rozerem™. Stay tuned.

FDA Study Suggests Consumers are Seeking Meds Online to Avoid Rx Rules

FDA recently announced the results of a year-long investigation, which suggest that consumers are buying drugs online to avoid the need for prescriptions from their physicians.

The investigation, comprising surveys conducted from September 2006 to August 2007 in international mail and courier facilities across the country, found 88% of the 2,069 drug packages examined appeared to be prescription medicines available in the US. More than half (53%) of the products sampled have FDA-approved generic versions, likely sold at lower costs, according to earlier studies that have shown generics in the US to be generally less expensive than comparable drugs in Canada or Western Europe. Other products included dietary supplements, foreign products with “illegible or incomprehensible” labeling, and medications not available in the US.

FDA warns that products from unregulated Internet drug sellers may contain the wrong ingredients or toxic substances. Earlier this year, FDA learned that 24 apparently related Web sites operating outside the US may be involved in the distribution of counterfeit prescription drugs.

FDA Posts Drug Safety Newsletter, Labeling Changes

FDA released the first issue of its new *Drug Safety Newsletter* in late 2007. The quarterly online newsletter provides information for health care professionals about the findings of selected post-marketing drug safety reviews, emerging drug safety issues, and recently approved new drugs.

The newsletter is available on the FDA Web site at www.fda.gov/cder/dsn/default.htm and will be sent electronically to *Drug Safety Newsletter* and/or MedWatch subscribers.

FDA also provides monthly updates on medication labeling changes, such as boxed warnings, contraindications, warnings, precautions, adverse reactions, and patient package insert/medication guide sections. The Safety-Related Drug Labeling Changes page is accessible at www.fda.gov/medwatch/safety.htm.

NABP Awards DMEPOS Accreditations Representing Over 11,000 Pharmacies

NABP accredited several independent pharmacies and chains, representing over 11,000 pharmacies, through its durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) accreditation program during fourth quarter 2007.

The DMEPOS program ensures that pharmacies supplying DMEPOS products meet the Centers for Medicare and Medicaid Services’ (CMS) quality and accreditation standards. Those pharmacies that are accredited through the program are doing their part to ensure that Medicare beneficiaries receive the appropriate products, services, and patient care associated with DMEPOS.

A full listing of pharmacies accredited through the NABP DMEPOS program is available under Accreditation Programs on the NABP Web site, www.nabp.net.

FDA Acts to Ensure Thyroid Drug Potency until Expiration

FDA is tightening the potency specifications for levothyroxine sodium to ensure the medication retains its potency over its entire shelf life. FDA is taking this action in response to concerns that the potency of the drug may deteriorate prior to its expiration date.

The revised potency specifications require levothyroxine sodium drug products to maintain 95% to 105% potency until their expiration date. Previously, these products were allowed a potency range of 90% to 110%. FDA has given manufacturers and marketers two years to comply with the revised specification.

More information is available on the FDA Web site at www.fda.gov/cder/drug/infopage/levothyroxine/default.htm.

FDA Reform Law Provides for Establishment of Tracking Standards

President Bush signed HR 3580, the Food and Drug Administration Amendments Act of 2007, into law on September 27, 2007. Among other provisions, the law reauthorizes and expands the Prescription Drug User Fee Act and the Medical Device User Fee and Modernization Act.

The legislation expands FDA authority to regulate marketed drugs, establish a surveillance system to monitor and assess the safety profile of drugs on the market, reauthorize and modify programs that evaluate the use of drugs and devices by children, and expand federal databases that track information on certain clinical trials.

The law also requires the US Department of Health and Human Services to establish a standardized numerical identifier that must be applied to prescription medications at the point of manufacture, and to develop standards to serve as guidelines in the implementation of track-and-trace and package-level identification technology to monitor prescription medications through the supply chain.

2008 Survey of Pharmacy Law Now Available

The NABP 2008 *Survey of Pharmacy Law* CD-ROM is now available. The *Survey* consists of four sections including organizational law, licensing law, drug law, and census data. New topics include whether or not states recognize Verified Internet Pharmacy Practice Sites™ accreditation and if the boards of pharmacy require compliance with United States Pharmacopeia Chapter 797, “Pharmaceutical Compounding – Sterile Preparations.”

To order the *Survey*, visit www.nabp.net and download an order form; the cost is \$20.

The CD-ROM is provided free of charge to all final-year pharmacy students through a grant from Purdue Pharma LP. For more information on the *Survey*, please contact NABP via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

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RelayHealth. Recent communications to dispensers of controlled substances in Kentucky have highlighted the new data collection vendor and process. All dispensers were requested to begin sending KASPER data to both Atlantic Associates and RelayHealth by January 14, 2008. Beginning February 18, 2008, dispensers **must** send KASPER data to RelayHealth, and discontinue sending data to Atlantic Associates.

Kentucky statues and regulations require each dispenser of controlled substances to report as specified in:

KRS 218A.202(3). Every dispenser within the Commonwealth or any other dispenser who has obtained a license, permit, or other authorization to operate from the Kentucky Board of Pharmacy shall report to the cabinet for Health and Family Services the data required by this section in a timely manner as prescribed by the Cabinet.

902 KAR 55:110(3). The data identified in subsection (2) of this section shall be transmitted within eight (8) days of the date of dispensing.

If you have not already registered with RelayHealth, you need to register and begin reporting to RelayHealth immediately. All dispensers will be asked to sign a RelayHealth Data Authorization Agreement that permits RelayHealth to collect your data under the Health Insurance Portability and Accountability Act. There are no costs to you to report your data to RelayHealth. For technical questions or to complete the registration process you should call or e-mail the RelayHealth customer care center at kypmp@relayhealth.com or 1-800/892-0333.

Your cooperation and support in helping implement the new KASPER data collection process are greatly appreciated. For questions regarding compliance with Kentucky law you may call the Drug Enforcement and Professional Practices Branch of the Cabinet for Health and Family Services, Office of the Inspector General at 502/564-7985.

Revisions to USP Chapter 797 (Sterile Compounding)

Submitted by Phil Losch, RPh, Pharmacy and Drug Inspector

After nearly thirty (30) months in revision, United States Pharmacopeia (USP) posted the final update for USP General Chapter 797, "Pharmaceutical Compounding – Sterile Preparations." Information for obtaining a copy of this revised chapter can be obtained at www.USP.org. It was posted in early 2007 and will take effect June 1, 2008. Under KRS 317.015(31), USP is defined as Kentucky's official compendium. Therefore, these revisions will affect any pharmacy in Kentucky that compounds sterile products.

Due to the magnitude and length of the revisions, a summary of the changes cannot be addressed in this article. Some of the major changes involve new definitions, new risk categories, hazardous drugs, radiopharmaceuticals, environmental controls, and personnel cleansing and garbing. These changes have tried to address the fact that direct contact is the principal source of contamination of compounded sterile products. Needless to say, these changes are far reaching and will affect all sterile compounding pharmacies.

It is urged that all sterile compounding pharmacists review these changes. The new chapter is over sixty (60) pages in length and not an easy read. The last three (3) pages of the revision are check lists that greatly assist the pharmacy in implementation of some of the environmental requirements. Time and concentration will be necessary to understand what areas will have direct impacts on your pharmacy practice site. The Kentucky Board of Pharmacy has previously appointed a committee to review these changes and assess the impact to Kentucky pharmacies. This committee will report to the Board on its findings and all pharmacists will be notified. If you have any comments regarding the changes in USP Chapter 797, please forward your comments to the Board office. We encourage you to contact your pharmacy inspector with any questions you might have.

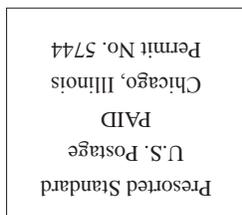
Official Method of Notification

The *Kentucky Board of Pharmacy News* is considered an official method of notification to pharmacists, pharmacist interns, pharmacies, wholesalers, and manufacturers credentialed by the Board. **These Newsletters will be used in administrative hearings as proof of notification.** Please read carefully. The Board encourages you to keep them in the back of the *Kentucky Pharmacy Law Book* for future reference.

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