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Kentucky Board of Pharmacy

NEWS

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Kentucky's Legislation Restricting Pseudoephedrine Sales Becomes Effective June 20, 2005

By Christine Tham, PharmD Candidate

On June 20, 2005, Senate Bill 63 will take effect and place any non-prescription tablet or capsule preparation or mixture containing ephedrine, pseudoephedrine, or phenylpropanolamine into the pharmacy's guard. These products must be stored in a secure location, such as behind a pharmacy counter or in a locked case, and must not be accessible without assistance from a pharmacist, pharmacist intern, or pharmacy technician. A maximum of nine (9) grams may be sold within a thirty (30)-day period. In addition to the nine (9)-gram restriction, no person shall purchase more than three (3) packages per transaction. No product may be sold to a person less than eighteen (18) years of age. These products are to be dispensed or sold only by a pharmacist, pharmacist intern, or pharmacy technician. At the time of purchase, government-issued photo identification must be shown and the following information recorded in an approved log book: date of the transaction; name of purchaser, date of birth, and address of the purchaser; purchaser's signature; and amount and name of preparation sold. An electronic record may be kept instead of a log book upon approval by the Office of Drug Control Policy. Each transaction needs to be initialed by the seller (pharmacist, pharmacist intern, or pharmacy technician) and kept for a period of two years from the last entry date. The log book is subject to random inspection by any city, county, or state law enforcement officer. Failure to maintain a log book will result in a fine up to one thousand dollars ($1,000) for each violation. Products of pseudoephedrine, phenylpropanolamine, or ephedrine that are in liquid or gel cap dosage form are exempt from this law. For further information, please reference KRS 218A Section 6 or contact the Kentucky Board of Pharmacy.

New KASPER System Premiered

By Dave Sallengs, Branch Manager, Drug Enforcement Branch

On March 16, 2005, the Cabinet for Health and Family Services, Office of the Inspector General, Division of Fraud, Waste and Abuse/ Identification and Prevention, Drug Enforcement and Professional Practices Branch unveiled the Enhanced Kentucky All Schedule Prescription Electronic Reporting (eKASPER) system.

The Web-based eKASPER system was developed over a two-year period following a $1.4 million dollar appropriation from the Kentucky Legislature.

With the new system, KASPER reports are requested via a secure Web-based system. To access the system, an account must be requested using the following steps:

1. Log onto https://ekasper.chfs.ky.gov/accessrequest.
2. Complete and submit the online form.
3. Print the online form and affix copies of all requested licensure information.
4. Send the form and copies to:

Cabinet for Health and Family Services
Office of the Inspector General
Drug Enforcement Branch
275 E Main St HS2CB
Frankfort, KY 40621

Via the Web-based system, reports are available twenty-four (24) hours a day, seven (7) days a week. In most cases reports are delivered within fifteen (15) minutes of a request; however, occasionally a report must be reviewed manually. If that is the case, you will be notified and will receive the report the following business day.

While the information contained in the report may be verbally discussed, a health care provider or any other authorized user may not share the actual report with anyone including the patient. If information from a report is discussed with another health care provider, you may instruct the other provider to request a report, but you may not share your report with him or her.

Pharmacists and emergency room physicians are the two (2) groups projected to benefit most from the Web-based system because their exposure to patients are over a much shorter duration and they do not work by appointment.

As a health care provider, you are on the front line in the fight to prevent the abuse and diversion of prescription medications. KASPER is a useful and powerful tool in this fight. With your diligence, we can turn the tide of this epidemic.

DEA Schedule II Prescription Policy

By Dave Sallengs, Branch Manager, Drug Enforcement Branch

The Drug Enforcement Branch is expecting a statement from the federal Drug Enforcement Administration (DEA) within the next few months clarifying the agency's position on a prescriber preparing multiple Schedule II prescriptions for a patient on the same day with instructions to fill in different dates.

Until DEA states its new policy, the Kentucky Board of Pharmacy and the Drug Enforcement and Professional Practices Branch are enforcing the DEA policy as follows:

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Accutane, Palladone RMPs Designed to Protect Patient Safety

Risk Management Programs (RMPs) are developed by drug manufacturers to meet the requirements of FDA's drug approval process, in conjunction with FDA, to minimize risks associated with specific drug products. To date, several specific drug products have formal risk management programs beyond labeling alone, to further ensure patient safety. Two relevant examples are Accutane® (Roche Pharmaceuticals) and Palladone Capsules (Purdue Pharma LP).

Accutane

On November 23, 2004, FDA announced changes to the RMP for isotretinoin (Accutane) that will be implemented in mid-2005 in order to reduce the risk of birth defects associated with fetal exposure to the medication. All of the manufacturers of isotretionin have entered into an agreement with Covance, a drug development services company that currently coordinates the registry for Celgene's thalidomide. Covance's task is to develop and operate a universal enhanced RMP by mid 2005; this program will require patients, dispensing pharmacists, and prescribers to register in a single, centralized clearinghouse. The program will also mandate that a pregnancy test be performed at certified laboratories instead of home or in-office testing. According to the Accutane RMP, System to Manage Accutane Related Teratogenicity, when the registry denies an authorization to fill the prescription, the prescribing physician must explain the reason for denial to the patient; FDA specifically states that the physician is responsible for informing a woman if a pregnancy test result comes back positive.

Palladone

Due to Palladone's (hydromorphone hydrochloride) high potential for abuse and respiratory depression, the drug's manufacturer, Purdue Pharma LP, in conjunction with FDA, developed an RMP for this new extended-release analgesic. Introduced to the market in January 2005, Palladone is approved for the management of persistent, moderate to severe pain in patients requiring continuous, around-the-clock analgesia with a high potency opioid for an extended period of time (weeks to months) or longer. Palladone is to be used in patients who are already receiving opioid therapy, who have demonstrated opioid tolerance, and who require a minimum total daily dose of opiate medication equivalent to 12 mg of oral hydromorphone.

The analgesic's RMP was devised with four goals:

1. Facilitation of proper use (patient selection, dosing)
2. Avoidance of pediatric exposure
3. Minimization of abuse, and
4. Reduction of diversion

Palladone's RMP includes provisions for understandable and appropriate labeling, and proper education of health care professionals, patients, and caregivers. In addition, the manufacturer has offered training sessions to its sales representatives. The RMP provides for the observation and surveillance of abuse and, if abuse, misuse, and/or diversion occur, this program includes an array of interventions. A Medication Guide will be distributed to patients prescribed Palladone.

During the initial 18 months of Palladone's release to the market, the manufacturer will only promote Palladone to a limited number of medical practitioners experienced in prescribing opioid analgesics and will closely monitor and gather data on Palladone's use and any incidences of abuse or diversion, and report this information to FDA on a regular basis.

Metronidazole and Metformin: Names Too Close for Comfort

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, then publishes its recommendations. 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.

A family practice physician in a community health center prescribed metformin 500 mg b.i.d. to a newly diagnosed diabetic man from India who did not speak English. When the patient returned to his office a few months later, he brought his medications with him, as requested. His physician quickly noticed that metformin was missing. Instead, the patient had a prescription bottle labeled as metronidazole with directions to take 500 mg twice a day. The prescription had been refilled several times. Luckily, the patient's diabetes remained stable, and he seemed to suffer no adverse effects from two months of unnecessary antimicrobial therapy. The physician notified the pharmacy of the error and asked the pharmacist to check the original prescription, which had been written clearly and correctly for metformin. Upon further investigation, the pharmacist found that the computer entry screen for selecting these medications included "METF" (for metformin) and "METR" (for metronidazole). Apparently, one of the pharmacy staff members had entered "MET" and selected the wrong medication that appeared on the screen.

In another community pharmacy, the same mix-up happened twice, one day apart. In one case, metformin was initially dispensed correctly, even though the prescription had been entered incorrectly as metronidazole – again, when the wrong mnemonic was chosen. The pharmacist who filled the prescription clearly understood that the physician had prescribed metformin, so he filled the prescription accordingly. However, he failed to notice the order entry error, as he did not compare the prescription vial label to the drug container label. Unfortunately, the initial order entry error led to subsequent erroneous refills of metronidazole, as stated on the label. In the other case, bulk containers of the medication were available from the same manufacturer, both with similar highly stylized labels. Thus, confirmation bias contributed to staff 's selection of the wrong drug. After reading "MET" and "500" on the label, the staff member believed he had the correct drug.

In a hospital pharmacy, metronidazole 500 mg and metformin ER 500 mg were accidentally mixed together in the metronidazole storage bin. This resulted in dispensing metformin instead of metronidazole. Fortunately, a nurse recognized the error before giving the patient the wrong medication. Both were generic products, although the brands Flagyl® (metronidazole) and Glucophage®

(metformin) are also available. Unit-dose packages of these drugs contain bar codes, and the printed information is very small, which adds to their similar appearance.

Metronidazole-metformin mix-ups could be serious, considering the different indications and the potential for drug interactions. To avoid selecting the wrong drug from the screen, consider programming the computer to display the specific brand names along with the generic names whenever the "MET" stem is used as a mnemonic. To reduce similarity of the containers, purchase these medications from different manufacturers. Another option in hospital settings is to stock only the 250 mg tablets of metronidazole, since metformin is not available in that strength. This option allows a small risk for nurses who may administer just 250 mg when 500 mg is prescribed, but the potential for harm from giving the wrong drug is greater.

It is also a good idea to separate the storage of these products. During the dispensing process, drug names listed on written prescriptions and hospital orders should be matched to computer labels and manufacturers' products. Since metformin is used to treat a chronic condition, and metronidazole is more likely to be used for an acute condition, outpatient refills for metronidazole are less common and, therefore, bear a second look. Asking physicians to include the drug's indication on the prescription can also help prevent errors.

We have asked FDA to add these drugs to the list of nonproprietary names that would benefit from using "Tall Man" letters. Meanwhile, underline or highlight the unique letter characters in these drug names to make their differences stand out.

'Dietary Supplements' Contain Undeclared Prescription Drug Ingredient

In early November 2004, Food and Drug Administration (FDA) cautioned the public about the products Actra-Rx and Yilishen, which have been promoted via the Internet. These products, purported as "dietary supplements" to treat erectile dysfunction and enhance sexual performance, were actually found to contain the active prescription drug ingredient, sildenafil, the active drug ingredient in Viagra®, which is approved in the United States for the treatment of erectile dysfunction.

The *Journal of the American Medical Association* (*JAMA*) published a research letter that explained the results of a chemical analysis that found that Actra-Rx contained prescription strength quantities of sildenafil. FDA conducted its own analysis, the results of which corroborated the analysis published in *JAMA*.

Sildenafil is known to interact with a number of prescription medications. For example, sildenafil may potentiate the hypotensive effects of medications containing nitrates, which are commonly used to treat congestive heart failure and coronary artery disease.

FDA instructed those who are taking Actra-Rx and/or Yilishen to stop and consult their health care provider and warned that the use of these products could be dangerous to patients' health.

For more information, please visit the following Web site: www.fda.gov/bbs/topics/ANSWERS/2004/ANS01322.html.

NABP Releases Criteria for National Specified List of Susceptible Products, Adds One Drug to List

In late 2004, the National Association of Boards of Pharmacy® (NABP®) Executive Committee finalized the criteria that detail standards and guidance for NABP's "National Specified List of Susceptible Products" (List) based upon recommendations made by NABP's National Drug Advisory Coalition (NDAC). Also, in accordance with NDAC's recommendation, the Executive Committee decided to include Viagra® (sildenafil) on NABP's List. NABP's List, which the Association first released in early 2004, was created to help states reduce redundancy and represented a starting point for states that had an imminent need for such direction. In addition, by adopting NABP's List, states collectively would be able to recognize one national list instead of potentially 50 different lists.

The NDAC is a standing committee that was appointed by NABP's Executive Committee in accordance with the updated Model Rules for the Licensure of Wholesale Distributors, which is a part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*. The Model Rules were released by the NABP Task Force on Counterfeit Drugs and Wholesale Distributors, with the aid of representatives from the pharmacy profession, government, and the wholesale distributor industry, to protect the public from the ill effects of counterfeit drugs and devices. In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandate specific pedigree requirements for products that are particularly prone to adulteration, counterfeiting, or diversion. These products, as defined in the updated Model Rules, are designated as the "National Specified List of Susceptible Products."

The updated "National Specified List of Susceptible Products" is available on NABP's Web site at www.nabp.net. NABP's List criteria that detail standards and guidance (eg, under what circumstances a product will be considered for addition to NABP's List) are also available on the Association Web's site and detailed in the February 2005 *NABP Newsletter*.

FDA Announces New CDERLearn Educational Tutorial

The US Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) recently announced that its new online educational tutorial "The FDA Process for Approving Generic Drugs" is now available at http://www.connectlive.com/events/genericdrugs/.

This seminar provides viewers with an overview of FDA's role in the generic drug process. The tutorial also discusses various aspects of the Abbreviated New Drug Application (ANDA) process, including how FDA's approval assures that generic drugs are safe, effective, and high quality drug products.

This program meets the criteria for up to one Accreditation Council for Pharmacy Education contact hour (or 0.1 CEU).

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1. According to Code of Federal Regulations (CFR) 1306.05, a prescription for a Schedule II controlled substance must be dated and signed on the date issued.
2. A prescriber may still write "do not fill until" a certain date on the prescription; however, he/she may not write more than one prescription for the exact same Schedule II controlled substance at one time.
3. If the prescriber writes "do not fill until" a certain date on the prescription, the date written and the "do not fill until" date should not be far enough apart to imply that multiple prescriptions were written on the same date.
4. This does not apply to the partial filling of a Schedule II controlled substance for a patient in a long-term care facility or for a patient with a documented terminal illness provided that the requirements of 902 KAR 55:095 are met.

As with any prescription-filling issue when a professional judgment is involved, documentation should be included as a reminder when questions arise.

Board of Pharmacy Web Site

The Kentucky Board of Pharmacy unveiled its new Web site on December 28, 2004. With the new Web site, the Board office has the capabilities of providing timely notification and information on current issues (such as the pseudoephedrine bill). Most of the Board forms can be printed from your computer. Hopefully, in the near future you will have the option of filling out certain forms online and submitting them to the Board office. The Board's Web site is www.pharmacy.ky.gov.

2005 Pharmacy Renewals

Pharmacy permits expire on June 30, 2005. Renewal applications were mailed out the first week of May to all pharmacies or corporate coordinators in order to allow time for processing. All incomplete applications will be returned.

Board Examinations Scheduled for July 9-10, 2005

The Kentucky Board of Pharmacy will be administering the Pharmacist Licensure Examinations on July 9-10, 2005, at the University of Kentucky College of Pharmacy and the College of Nursing. All applicants must have completed and submitted all necessary forms and fee payments to the Board office by June 15, 2005.

2005 Legislative Session Results

The 2005 session of the Kentucky Legislature has ended with the enactment of several changes to the practice of pharmacy.

Senate Bill 63

Senate Bill 63 amends KRS 315.0351 to require out-of-state pharmacies who are delivering prescription medications to citizens of the Commonwealth to have a pharmacist-in-charge who holds a Kentucky pharmacist license. It further amended KRS 315.035 to include a requirement for any pharmacy conducting business primarily or exclusively within the Commonwealth by use of the Internet to obtain a Kentucky pharmacy permit. The amendment requires the Internet pharmacy to be accredited by the Verified Internet Pharmacy Practice Sites™ (VIPPS®) program of the National Association of Boards of Pharmacy® (NABP®). The VIPPS accreditation process begins with the submission of a completed VIPPS Application Form and supporting documentation. As a VIPPS-accredited site, the Internet pharmacy may display the VIPPS hyperlink Seal of Approval on its Web site. For more information about VIPPS, contact NABP at 847/391-4406, or visit NABP's Web site at www.nabp.net.

Senate Bill 107

This bill changes the name of the Impaired Pharmacist Committee to the Kentucky Recovery Network. Also, it allows for staggered terms of the Kentucky Board of Pharmacy Advisory Council members. It also clarifies the expiration dates for pharmacist license renewal and pharmacy permit renewals.

The *Kentucky Board of Pharmacy News* is published by the Kentucky 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.

Michael A. Burleson, RPh - State News Editor

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

Reneeta C. "Rene" Renganathan - Editorial Manager

KENTUCKY BOARD OF PHARMACY

1600 Feehanville Drive
Mount Prospect, IL 60056

National Association of Boards of Pharmacy Foundation, Inc

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