



Kentucky Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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Happy Holidays!!!! from Kentucky Board of Pharmacy Board Members and Staff



Continuing Education Reminder

A pharmacist shall complete a minimum of one and five-tenths (1.5) continuing education units (15 contact hours) annually between January 1 through December 31 pursuant to 201 Kentucky Administrative Regulation 2:015 §5(1). A pharmacist first licensed by the Kentucky Board of Pharmacy within twelve (12) months immediately preceding the annual renewal date shall be exempt from the continuing pharmacy education provisions.

2007 Pharmacist Renewals

Pharmacist licenses expire on February 28, 2007. The Board will send out a **postcard** the first week of January 2007 as a reminder. (In addition, a pharmacist that renewed online last year will be sent a reminder via e-mail.) Again, this year you may renew your license online. **Renewal applications will not be mailed out; however, a renewal application may be printed from the Board's Web site: www.pharmacy.ky.gov.**

KASPER Regulation Changes – Pharmacy Action Required

The Interim Joint Committee on Health and Welfare met on July 24, 2006. Among other matters, the Committee approved changes to 902 KAR 55:110, the regulation governing the Kentucky All Schedule Prescription Electronic Reporting (KASPER) program. The following changes became effective at the conclusion of the meeting:

- ♦ Data shall be transmitted within eight (8) days of the date of dispensing unless the cabinet grants an extension.
- ♦ A patient or the person obtaining the controlled substance [CS] on behalf of the patient shall disclose to the dispenser the patient's Social Security number for the purpose of the dispenser's mandatory reporting to KASPER.

Other changes include:

- Additional electronic formats for transmission of data including:
 - 1. Secure file transfer protocol
 - 2. https protocol
 - 3. CD/DVD
 - 4. Secure virtual private network connection

♦ The provision to use "999-99-9999" is no longer an option to identify patients.

The revised 902 KAR 55:110 can be viewed on the Kentucky Legislative Research Commission Web site at www.lrc.ky.gov under the section "Kentucky Law."

If you have any questions about the changes to 902 KAR 55:110 or how they affect you, please contact Drug Enforcement and Professional Practices at 502/564-7985.

Pharmacist Immunization Protocol

A pharmacist that is going to administer adult immunizations must have a prescriber-approved protocol prior to administering these immunizations pursuant to KRS 315.010 (20).

Electronic Signatures by Practitioners

An electronic signature means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record pursuant to KRS 369.102(8). An electronic signature is acceptable for all non-controlled prescriptions in Kentucky; however, a pharmacist should use due diligence in determining the validity of that prescription (as he or she would do so in the filling of any prescription received by phone, fax, or written). At this time the law does not allow electronic signatures for CS prescriptions.

Pharmacist Recovery Network

Submitted by Mike Raque, PharmD Candidate

Being a pharmacist today can be a very rewarding career. Often pharmacists are the most accessible health care professionals, and they possess unique knowledge of both health conditions and medications used to treat those conditions. However, with this knowledge and accessibility comes complications that many pharmacists probably feel on a daily basis, such as being rushed or stressed to the breaking point. Individuals have their own skills to cope with this stress, and they choose the method that works best for them whether it is prayer, meditation, or other relaxation techniques.

Unfortunately, there are also people who turn to alcohol or drugs to help them deal with these stressors on a daily basis. Addicts are no different from anyone else on the surface, but in fact their brain chemistry is very much different from that of the nonaddict. Addicts possess a unique "switch" in their brains that gets turned on at some point in their life from using alcohol or drugs, usually in a legal or prescribed manner. Once this switch is flipped, all they need is another drink or pill to escape reality and their stressors, or to feel normal as some addicts have said. Due to tolerance, the daily requirement of alcohol or drugs needed to

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FDA Launches Consumer Educational Program on the Safe Use of OTCs

The United States Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, in cooperation with the National Council on Patient Information and Education and Maryland's Montgomery County Public Schools, has launched "Medicines in My Home," an interactive educational program aimed at informing middle school students about the safe and effective use of over-the-counter (OTC) medicines. Key concepts students will learn from the program are:

- the Drug Facts label tells you what a medicine treats, if it is right for you and your problem, and how to use the medicine;
- read the label and follow the directions carefully and correctly;
- two medicines with the same active ingredient should not be used at the same time; and
- measure medicines correctly with measuring tools made for medicines.

The program emphasizes that medicines should be used only with permission from an adult and that if there are questions about medicine use, ask a pharmacist or doctor. Materials are provided to encourage students to share what they learn with their families so that all family members can learn to use OTC medicines more safely. Program information can be found at www.fda.gov/medsinmyhome.

HHS Warns Public of Heroin and Fentanyl Deadly Combo

In efforts to warn the public and health care professional communities regarding a recent rash of drug-related deaths due to an illicit street drug combination consisting of the prescription medication fentanyl and either heroin or cocaine, the Department of Health and Human Services (HHS) released a fact sheet containing specific information with the goal of saving lives.

A letter from H. Westley Clark, director of HHS Center for Substance Abuse Treatment, to health care professionals warned that in "just one week, an estimated 33 individuals in the Detroit, MI area are reported to have died after using this fatal mix of drugs; the same drug combination may have been responsible for more than 100 deaths in the same region last September [2005]." Philadelphia, PA; Chicago, IL; St Louis, MO; and Camden, NJ have also recently experienced similar clusters of drug-related deaths.

Fentanyl, an injectable Schedule II prescription opioid analgesic, is roughly 50 to 80 times more potent than morphine but can also be produced in clandestine laboratories in powder form and then mixed with or substituted for heroin. Fentanyl-related overdoses can result in sudden death through respiratory arrest, cardiac arrest, severe respiratory depression, cardiovascular collapse, or severe anaphylactic reaction. In some cases, heroin or cocaine users are aware they are purchasing this dangerous combination of drugs and in other cases, they are not. Because the potency of street-sold heroin or cocaine is amplified markedly by fentanyl and because the inclusion of fentanyl

may not be disclosed, any use, even a reduced dose, can result in overdose or death. The fact sheet advises that suspected overdoses should be treated rapidly with a naloxone injection, 0.4 to 2 mg intravenously, subcutaneously, or intramuscularly every two to three minutes, which should rapidly reverse symptoms related to a narcotic overdose; if there is no response after 10 minutes, then a different diagnosis should be considered.

For additional information, contact Kenneth Hoffman at the Substance Abuse and Mental Health Services Administration at 240/276-2701 or via e-mail at Kenneth.Hoffman@samhsa.hhs.gov.

Pharmacy Technicians and Medication Error Prevention



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 po-

tentially 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.

In an October 2005 article in the *American Journal of Health-System Pharmacists*, the results of a random nationwide survey of more than 800 pharmacy technicians' views about their medication errors was published (Desselle SP. Certified pharmacy technicians' views of their medication preparation errors and educational needs. *Am J Health-Syst Pharm*. October 1, 2005; 62:1992-97). Most of the technicians worked in community pharmacies, but more than a quarter (27%) were employed in hospitals.

As one might expect in both settings, interruptions and inadequate staffing were among the most frequent factors perceived to contribute to technician medication preparation errors. Inadequate staffing was perceived as especially problematic in chain pharmacies, while inadequate supervision by pharmacists was cited as a factor more frequently by hospital technicians. It also may come as no surprise that the pharmacists' most frequently cited response to an error that was caught during the checking process was to make the technician aware of the error and require him or her to correct it. However, only about 17% of the technicians reported that the pharmacist had used the error as an opportunity to provide instructions on how to avoid the same or similar errors in the future.

While many of these respondents attributed this responsibility to the organization as a whole, not necessarily the individual pharmacist who detects an error, it appears technicians may not be receiving guidance about system and process changes that can help avert errors. After an

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error is corrected, the checking pharmacist should find time that same day (or the next day, if necessary) to review the error with the technician and suggest ways to avoid it, including safer behavioral choices if applicable. Later, during pharmacy staff meetings or other forms of intradepartmental communication, errors, their causes, and ways to prevent them should be shared with all staff in a way that does not embarrass those who were possibly involved in the errors.

One or Both Nostrils?

Submitted by ISMP

Although many nasal sprays are intended for administration in each nostril for a single dose, there are notable exceptions. For example, some medications are meant to be delivered via the nasal passage but **not** sprayed into each nostril. Calcitonin salmon (**Fortical**®, **Micalcin**®) is a prime example. Patients should administer a single spray (200 international units) into one nostril daily, using alternate nostrils each day. Other examples in metered-dose or unit-dose nasal spray containers include butorphanol, desmopressin (**DDAVP**®), sumatriptan (**Imitrex**®), and zolmitriptan (**Zomig**®).

Some pharmacy and/or physician electronic prescribing systems have been preprogrammed to print directions that default to "spray in each nostril" when nasal sprays are selected. For the previously mentioned drugs, this would result in the administration of a double dose of medication. One health care facility recently reported that about 50 patients, who had been prescribed medications intended to be given into one nostril, had prescription container labels that instructed the patients to administer the spray into both nostrils. Some physicians might anticipate patients' confusion and write the prescription for "half" doses in each nostril. Even if instructed to use the spray in one nostril, patients who administer other nasal medications in both nostrils may spray these medications into both nostrils without thinking.

Explicit verbal directions and written instructions that emphasize administration via one nostril only are critical to avoid an overdose.

FDA/ISMP National Campaign to Help Eliminate Ambiguous Medical Abbreviations

FDA and the ISMP have launched a national education campaign that focuses on eliminating the use of potentially harmful abbreviations by health care professionals, medical students, medical writers, and the pharmaceutical industry. The campaign addresses the use of error-prone abbreviations in all forms of medical communication, including written medication orders, computer-generated labels, medication administration records, pharmacy or prescriber computer order entry screens, and commercial medication labeling, packaging, and advertising. For more information visit www.fda.gov/cder/drug/MedErrors.

DEA Provides Retail Training Materials

Drug Enforcement Administration (DEA) recently announced the availability of training materials regarding self-certification training for regulated retail sellers of non-prescription drug products containing

ephedrine, pseudoephedrine, and phenylpropanolamine as required by the Combat Methamphetamine Epidemic Act of 2005 (Title VII of Public Law 109-177).

Two sets of training materials have been developed: one for regulated persons who are mobile retail vendors, and one for regulated persons who are not mobile retail vendors. Both sets of training materials may be found on the Diversion Control Program Web site, www.deadiversion.usdoj.gov, under "Combat Methamphetamine Epidemic Act of 2005."

DEA notes that regulated sellers must use the content of these training materials in the training of their employees who sell scheduled listed chemical products. A regulated seller may utilize additional content in its training program, but DEA's posted material must be included.

DEA is continuing to work to promulgate regulations to implement the Combat Methamphetamine Epidemic Act of 2005.

FDA Announces Release of Guidance on Useful Written Consumer Medication Information

In the July 18, 2006 Federal Register, FDA announced the availability of a guidance entitled "Useful Written Consumer Medication Information (CMI)." This guidance is intended to assist individuals or organizations (eg, pharmacies, private vendors, health care associations) in developing useful written consumer medication information to comply with Public Law 104-180. CMI is written information about prescription drugs developed by organizations or individuals, other than a drug's manufacturer, that is intended for distribution to consumers at the time of dispensing. Since neither FDA nor the drug's manufacturer reviews or approves CMI, FDA recommends that the developers of written medication information use the factors discussed in this guidance to help ensure that their CMI is useful to consumers.

This guidance can be accessed at www.fda.gov/cder/guidance/7139fnl.htm.

2007 Survey of Pharmacy Law Available Soon

NABP's 2007 Survey of Pharmacy Law CD-ROM will be available in early December 2006. New topics include whether or not licensure for wholesale distributors of non-prescription drugs is required and the recognition of Verified-Accredited Wholesale Distributors® accreditation.

The *Survey* consists of four sections: organizational law, licensing law, drug law, and census data. The *Survey* can be obtained for \$20 from NABP by downloading the publication order form from www.nabp.net and mailing in the form and a money order to NABP. The CD-ROM is provided free of charge to all final-year pharmacy students through a grant from AstraZeneca Pharmaceuticals. If you do not have Web access or would like more information on the *Survey*, please contact NABP at 847/391-4406 or via e-mail at custsery@nabp.net.

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escape reality can skyrocket. In the case of addiction to prescription drugs this can lead to illegally obtaining them, either from the street or in the case of most pharmacists, through theft from their employers. Sadly, the problem of addiction is not recognized in the individuals until some type of criminal action is brought against them for theft or buying them off the street.

The unfortunate thing is that no one knows for sure who will become an addict; no one plans on becoming addicted to a substance. There are clues that can be found in family history that may suggest a likelihood that someone could become addicted to alcohol or drugs, but until that switch in the brain is turned on there is no guarantee that someone will or will not become an addict.

There is help out there for people who are addicted to alcohol or drugs. Within our own profession we have the Kentucky Pharmacist Recovery Network (KYPRN). The purpose of this network is to help addicts become clean and sober initially, and to teach them the coping skills necessary to deal with stress and live a clean and sober lifestyle. KYPRN will help you build a foundation upon which you can have a successful recovery. For more information on KYPRN and the help it may provide, call Brian Fingerson, RPh, at 502/749-8385 or e-mail him at kyprn@insightbb.com.

Prescriptive Authority for ARNP for Controlled Substances

If you continue to have questions about prescriptive authority for CS for advanced registered nurse practitioners (ARNP), please visit the Board's Web site at www.pharmacy.ky.gov, click on the link titled "Kentucky Coalition of Nurse Practitioners and Midwives," then click on "Explanation of SB 65." At this link you will be able to read the law and see explanations of certain aspects.

Plan B Available OTC

Duramed Pharmaceuticals, Inc announced that new packaging for Plan B® over-the-counter (OTC) for ages eighteen (18) and older was made available the first week of November. Please review the following:

- ♦ Prescription needed for women ages 17 and younger
- ♦ Government-issued identification required for age verification
- ♦ Stock behind pharmacy counter
- Current prescription package (national drug code [NDC] number 51285-038-93) cannot be dispensed without a prescription

♦ New single package will be used for both prescription and OTC – NDC number for new package: 51285-769-93
For more information, please call the Plan B Information Center at 1-800/330-1271.

Contact Numbers of State Boards and Federal Agencies

Board of Dentistry	502/429-7280(o) .502/429-7282(fax)
Board of Medical Licensure	502 429-7150(o) .502/429-7158(fax)
Board of Nursing	502/429-3300(o) .502/429-3311(fax)
Board of Optometric Examiners	859/246-2744(o) .859/246-2746(fax)
Board of Respiratory Care	859/246-2747(o) .859/246-2750(fax)
Office of Drug Enforcement	502/564-7985(o) .502/696-3880(fax)
Food and Drug Administration (Cincinnati)	
Drug Enforcement Administration (Louisville)	502/582-5905(o)

For more information on these and other state agencies please visit www.ky.gov, click on "Government," and then click on "State Agency List."

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