June 2007

Kentucky Board of Pharmacy

NEWS

Published to promote voluntary compliance of pharmacy and drug law.

Spindletop Administration Building
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Pharmacy Renewal Deadline June 30, 2007

Pharmacy permits expire June 30, 2007. A pharmacy permit can be renewed online. A postcard explaining the renewal process was mailed to each pharmacy on April 19, 2007. If you want to send in a paper renewal, this form may be printed from the Kentucky Board of Pharmacy 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, is relocating within the current premises of the existing permit, or is 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, 2007. All paper renewal applications must be in the Board office by the close of the day June 30, 2007.

Plan B

Submitted by Katie Busroe, Pharmacy and Drug Inspector

Plan B® has been available by prescription only since 1999. On August 24, 2006, Food and Drug Administration (FDA) approved Plan B as the first dual status drug, available as a prescription only for women 17 years old and younger and over-the-counter (OTC) for consumers (male or female) at least 18 years old. Plan B, an emergency contraceptive, differs from RU-486 (mifepristone), the abortion pill. Plan B consists of two levonorgestrel 0.75 mg tablets. Levonorgestrel is a synthetic progestin hormone that has been used in oral contraceptives for over 35 years. The mechanism of action is very similar to oral contraceptives in that Plan B prevents pregnancy primarily by preventing or delaying ovulation. The fact that Plan B can be taken any time during the menstrual cycle, however, indicates that it may also work by changing the pH of the uterine cavity and/or thickening cervical mucous. Plan B does not have any effect on a fertilized egg already attached to the uterus, thus the pregnancy will continue. Nor does Plan B protect against sexually transmitted diseases.

According to FDA, the first tablet of Plan B should be taken orally within 72 hours of known or suspected contraception failure or unprotected sex. The second tablet should be taken 12 hours after the first tablet. Plan B is manufactured by Duramed Pharmaceuticals, Inc, which offers an FDA-approved Convenient Access, Responsible Education (CARE) program. CARE will provide health care professional and consumer education, ensure appropriate distribution and packaging, and monitor the effectiveness and safety of the OTC and prescription only distribution to patients. Because of the dual status of Plan B, the OTC version will only be available at pharmacies staffed by a pharmacist and clinics staffed with a licensed health care practitioner. The only requirement for OTC purchase of Plan B is that the purchaser (male or female) provide personal identification demonstrating proof of age (18 years or older). FDA does not specify that a pharmacist make the transaction or that a pharmacist must provide counseling. FDA does specify that the transaction must be made when a pharmacist is on duty, should the purchaser have questions. There is no requirement that the purchaser sign a log or register. There is no limit on the number of Plan B packages that may be purchased in one transaction.

For more information, contact Duramed at *www.go2planB.com* or 1-800/330-1271.

ARNP Controlled Substance Prescription Limitations

Beginning March 9, 2007, additional limitations were placed on the prescriptive authority of advanced registered nurse practitioners (ARNP) for controlled substances (CS) by the Kentucky Board of Nursing. Following are the additional limitations pursuant to 201 KAR 20:059:

1. Diazepam (Valium®), clonazepam (Klonopin®), lorazepam (Ativan®), and alprazolam (Xanax®): prescriptions for these medications written by an ARNP shall be limited to a fourteen (14)-day supply without any refills.
2. Carisoprodol (Soma®): prescriptions for this medication written by an ARNP shall be limited to a thirty (30)-day supply without any refills.
3. Combination hydrocodone products in liquid or solid dosage form: prescriptions for these medications written by an ARNP shall be limited to a fourteen (14)-day supply with no refills.

Prescriptions for diazepam, clonazepam, lorazepam, or alprazolam written or dispensed prior to March 9, 2007, for a quantity higher than a fourteen (14)-day supply with refills may be filled one additional time, limited to a fourteen (14)-day supply, and all remaining refills are void.

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FD&C Act Holds Manufacturers Accountable for Availability of Medication Guides

Under the Federal Food, Drug, and Cosmetic (FD&C) Act, Food and Drug Administration (FDA) requires that Medication Guides be dispensed with products the agency deems a serious and significant public health concern. Medication Guides provide consumers with information about the risks and benefits of these drugs and are necessary for patients to use these products safely and effectively.

FDA is interested in receiving reports about all instances in which manufacturers, distributors, or packers are not complying with the Medication Guide distribution requirements as set forth in Title 21, Code of Federal Regulations (CFR), section 208.24, Distributing and dispensing a Medication Guide.

The regulation requires manufacturers, distributors, or packers to provide authorized dispensers with Medication Guides – or the means to produce Medication Guides – in sufficient numbers to provide one to each patient who receives the drug. The manufacturer is responsible for ensuring that pharmacists have the Medication Guides they need when dispensing these drugs to consumers.

Problems related to the availability of Medication Guides are a labeling concern to FDA, and pharmacists are often the first to become aware of these problems. Voluntary reporting by pharmacists of these instances would assist FDA in ensuring manufacturer, distributor, and packer compliance with the Medication Guide regulatory requirement.

In addition to reporting to FDA, the agency advises pharmacies to contact the manufacturers directly to discuss problems associated with the availability of Medication Guides.

More information is available at *www.fda.gov/medwatch/report/hcp.htm*. Reports can also be made by phone at 1-800/FDA-1088.

Infant Deaths Attributed to Cough and Cold Medications

The Centers for Disease Control and Prevention (CDC) issued a Morbidity and Mortality Weekly Report article describing three deaths of infants ranging in age from one to six months associated with cough and cold medications. These medications were determined by medical examiners or coroners to be the underlying cause of death.

According to the report, the three infants – two boys and one girl – had what appeared to be high levels (4,743 ng/mL to 7,100 ng/mL) of pseudoephedrine in postmortem blood samples. One infant had received both a prescription and an over-the-counter (OTC) cough and cold combination medication at the same time; both medications contained pseudoephedrine.

During 2004-2005, an estimated 1,519 children younger than two years were treated in emergency departments in the United States for adverse events, including overdoses, associated with cough and cold medications.

Because of the risks, parents and caregivers should consult a health care provider before administering cough and cold medications to children in this age group. Clinicians should use caution when prescribing cough and cold medications to children younger than two years. In addition, clinicians and pharmacists should always ask caregivers about their use of OTC combination medications to avoid overdose from multiple medications containing the same ingredient.

The complete article is available at *www.cdc.gov/mmwr/preview/mmwrhtml/mm5601a1.htm.*

Changes in Medication Appearance Should Prompt Investigation

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.

As the number of generic products continues to increase, it seems that both patients and practitioners have become desensitized to changes in medication appearance. So much so that patients may not question a change or, when they do, practitioners may simply reassure them that it was due to a change in manufacturer without actively investigating the reason. It is not uncommon for ISMP to receive reports from both practitioners and consumers where a change in medication appearance was not fully investigated and subsequently contributed to an error.

In one case, a man shared an account of what his 86-year-old father experienced over the course of nine days after his prescription for minoxidil was mistakenly refilled with another medication. He had been taking minoxidil 2.5 mg for years at a dose of 5 mg (2 tablets) twice daily. Due to failing vision, he did not realize that his minoxidil tablets looked different. His daughter noticed the change, but was unconcerned since the tablets had previously changed appearance. Within a few days of taking the medication, his appetite began to fade, he complained of a sore throat, and felt like he was coming down with a cold. Soon after, he developed a red rash on his face, had trouble maintaining his balance, needed assistance with his daily activities, and wished to remain in bed. When a family friend (a nurse) came to see him, she noticed a very red, raised rash on his abdomen that looked like a medication rash. She asked his daughter if he was taking any new medications and was informed that there were no new medications, but the minoxidil tablets looked different than before. The pharmacy was contacted about the change and a staff member explained that it was a different generic for minoxidil, and that the pills could be exchanged for those that he usually received. There was no mention of a mistake being made when the medication was exchanged. He was taken to the hospital the following day, when he could barely walk.

After this incident was explained to hospital staff, they contacted the pharmacy. It was then revealed that he was given methotrexate by mistake because the bottles were stored next to each other. By this time, the man had taken 36 methotrexate 2.5 mg tablets, his white blood cell and platelet counts were extremely low, and he was in critical condition. We later learned that he passed away during that hospital visit.

In another case, a breast cancer patient went to her pharmacy to pick up a refill for **Femara**® (letrozole) but instead received the estrogen replacement product **femhrt**® (norethindrone and ethinyl estradiol). The patient recognized that the tablets were different, but after she read the label on the prescription bottle, which indicated Femara, she proceeded to use the tablets thinking the pharmacy used another manufacturer's product. After some time, she began to experience bloating, low back pain, and menstrual spotting. The error was discovered when she visited the clinic and the practitioner asked to see her medication. It is believed that disease progression had occurred secondary to the estrogen exposure, as evidenced by increased tumor markers. As a result of the error, chemotherapy was restarted.

The nature of these errors (wrong product dispensed on a refilled prescription despite a correct interpretation of the prescription) reinforces the need for the prescription verification process to be standardized. Verification should include comparisons of the pharmacy label with the selected manufacturer's product and the original prescription (whenever possible). In addition, the national drug code (NDC) number on the manufacturer's product should be compared to the NDC number in the pharmacy computer system. Pharmacies that utilize drug-imaging technology or bar code scanners as part of their verification process experience fewer of these errors.

Patients should be made aware of what their medication will look like and be educated to always question any change in its appearance. Pharmacies could consider software that allows a description of the medication's appearance to be printed on either the pharmacy label or receipt. Staff and patients should then be educated about proper use of this method. Ideally, pharmacists should proactively communicate with patients about the appearance of their medication by showing the medication to them during counseling and alerting them whenever a change occurs. Pharmacists should thoroughly investigate questions raised by patients or caregivers. Consider making it mandatory for pharmacists to investigate all inquiries related to changes in medication appearance. Although an auxiliary label can be placed on the medication container or the pharmacy receipt to alert the patient or caregiver that a change in appearance has occurred, the label may go unnoticed.

FDA Launches CDERLearn Educational Tutorial on MedWatch

FDA's Center for Drug Evaluation and Research (CDER) has launched its new Web-based self-learning tutorial, FDA MedWatch and Patient Safety, available at *www.connectlive.com/events/fdamedwatch*. This tutorial is intended to teach students in the health care professions and practicing health care professionals about FDA's Safety Information and Adverse Event Reporting Program, known as MedWatch.

The module explains how MedWatch provides important and timely clinical safety information on medical products, including prescription and OTC drugs, biologics, medical and radiation-emitting devices, and special nutritional products (eg, medical foods, dietary supplements, and infant formulas). It also describes how the reporting of serious adverse events, product quality problems, and product use errors to MedWatch is essential to FDA's safety monitoring process and to improving patients' safe use of medical products. The module consists of a 30-minute video and PowerPoint program with optional quiz and certificate of completion.

Three additional free programs for health professionals are available on the CDERLearn site, on the topics of the drug development and review process, the generic drug review process, and osteoporosis. Continuing education credit for these three programs may be awarded after completion of a quiz and evaluation form.

More information is available at *www.fda.gov/cder/learn/CDERLearn/default.htm*.

ONDCPRA Increases Patient Limit for Physicians Authorized under DATA 2000

The Office of National Drug Control Policy Reauthorization Act of 2006 (ONDCPRA) has modified the restriction on the number of patients a physician authorized under the Drug Addiction Treatment Act of 2000 (DATA 2000) may treat.

Under DATA 2000, physicians were restricted to treating no more than 30 patients at any one time. Under ONDCPRA, which became effective on December 29, 2006, physicians meeting certain criteria may notify the Secretary of Health and Human Services of their need and intent to treat up to 100 patients at any one time.

To be eligible for the increased patient limit: (1) the physician must currently be qualified under DATA 2000; (2) at least one year must have elapsed since the physician submitted the initial notification for authorization; (3) the physician must certify his or her capacity to refer patients for appropriate counseling and other appropriate ancillary services; and (4) the physician must certify that the total number of patients at any one time will not exceed the applicable number.

DATA 2000 allows qualified physicians to dispense or prescribe specifically approved Schedule III, IV, and V narcotic medications for the treatment of opioid addiction in treatment settings other than the traditional opioid treatment program (ie, methadone clinics). In addition, DATA 2000 allows qualified physicians who practice opioid addiction therapy to apply for and receive waivers of the registration requirements defined in the Controlled Substances Act.

More information is available by phone at 866/287-2728, via e-mail at info@buprenorphine.samhsa.gov, or online at *www.buprenorphine.samhsa.gov*.

Contingency Plan Allows Extension for NPI Compliance

Pharmacies that missed the May 23, 2007 deadline for using the National Provider Identifier (NPI) required by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) may be able to take an extension of up to one year. To be eligible, pharmacists must demonstrate "good faith" effort to come into compliance by developing and implementing a plan to enable them and their trading partners to move toward compliance. More information is available at *www.cms.hhs.gov/nationalprovidentstand*.

Continued from page 1

Prescriptions written for carisoprodol prior to March 9, 2007, and having refills may be dispensed one additional time, limited to a thirty (30)-day supply, and all remaining refills are void.

These new limitations only apply to the above drugs. ARNP may continue to prescribe other CS as allowed by Kentucky Revised Statute (KRS) 314. Please visit the Board's Web site at *www.pharmacy.ky.gov* and click on "Kentucky Coalition of Nurse Practitioners and Nurse Midwives," then click on "Prescribing," then click on "Guide for KY ARNPs" (page two of this guide shows the original law, and page 17 shows the additional limitations).

When dispensing a CS prescription written by an out-of-state ARNP, a pharmacist must follow the Kentucky statute/regulation regarding the limitations on CS prescriptions.

Legislation Update 2007

Sentate Bill (SB) 88 (sponsored by Senator Robert Stivers) was signed into law by Governor Ernie Fletcher on April 5, 2007. This bill will strengthen the current Internet pharmacy law. This law requires that any out-of-state pharmacy shipping **one (1)** prescription into Kentucky must have a valid Kentucky pharmacy permit and must have a Kentucky licensed pharmacist-in-charge (the incidental definition in KRS 315.010 (12) was deleted by SB 88). Two new definitions were included in KRS 218A.010 regarding "Good Faith Prior Examination," which means an in-person medical examination of the patient by the prescribing practitioner routinely relied upon in practice, at which time the patient is physically examined; and "Practitioner-patient relationship," which means a medical relationship that exists between a patient and practitioner or designee, after practitioner has conducted at least one good faith prior examination. This new law makes falsifying, altering, creating, selling, or unlawfully transferring medical records a Class D felony. Also, a pharmacy shipping a prescription into the state shall use the same address on the return label that is on the prescription label. SB 88 also changes KRS 218A.1446 to:

an electronic record-keeping mechanism may be required in lieu of the written log or record described in subsection (2)(b) of this section if the costs of establishing and maintaining the mechanism are borne by the Commonwealth of Kentucky.

House Bill (HB) 533 (sponsored by Representative Robin Webb) regarding the registration of pharmacy technicians was introduced in the House and was assigned to the Health and Welfare Committee; however, it was not presented in committee.

Other bills that were introduced in the House or Senate this 2007 legislative session pertained to prescriptive authority for pharmacists (HB 233), importation (HB 252 and HB 256), substitution of anti-epilepsy drugs (SB 102), allowing the Board per diem to be set by regulation (SB 112), prescriptive authority for CS by physician assistants (SB 97), and wholesaler/pedigree (SB 215). None of these bills became law. SB 112 (sponsored by Senator Richard "Dick" Roeding) passed the Senate and was on the House floor the last day of the session; however, it did not come before the House for a vote.

Continuing Education

The Board would like to suggest that a pharmacist keeps a copy of his or her continuing education (CE) certificate at both the place of employment and home. Each year it seems that a pharmacist leaves employment of one pharmacy and forgets to take his or her CE certificates, and when pharmacist renewal time begins they cannot find the certificates at the original employer. Therefore, the pharmacist has to find duplicate copies of the CE certificates from the sponsor of the CE program.

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.

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