December 2011

Kentucky Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

State Office Building Annex, Suite 300 • 125 Holmes Street • Frankfort, KY 40601

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

2012 Pharmacist License Renewals

Pharmacist licenses expire on February 28, 2012. The Kentucky Board of Pharmacy will send out a **postcard** the first week of January 2012, as a reminder (in addition, a pharmacist that renewed online last year will be sent an e-mail reminder). This year the Board encourages you to 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*.**

Continuing Education Reminder

A pharmacist shall complete a minimum of 15 contact hours (1.5 CEUs) annually between **January 1 through December 31,** pursuant to 201 KAR 2:015 Section 5(1). A pharmacist first licensed by the Board within 12 months immediately preceding the annual renewal date shall be exempt from the continuing pharmacy education provisions.

HIV/AIDS Continuing Education – Important Update

The Board of Pharmacy at its November 5, 2010 meeting changed the ruling noted in the June 2002 Board *Newsletter* regarding HIV/AIDS continuing education (CE). In that *Newsletter* it was stated that one hour (0.1 CEU) of HIV/AIDS CE must be completed between January 1 to December 31, 2010. The policy is now that a pharmacist must obtain at least one hour (0.1 CEU) every 10 years. This means that if a pharmacist received one hour of HIV/AIDS CE credit in 2004, he or she would have until 2014 to complete the next one hour of HIV/AIDS CE. This also means that if a pharmacist has yet to complete his or her first one hour of HIV/AIDS CE, he or she has until December 31, 2011. **Pursuant to 201 KAR 2:015, a pharmacist must keep his or her HIV/AIDS CE certificate for 10 years.**

2012 Pharmacy Technician Registration Renewals

Pharmacy technician registrations expire on March 31, 2012. The Board will send out a **postcard** the first week of February 2012, as a reminder (in addition, a pharmacy technician that registered online last year will be sent an e-mail reminder). The Board encourages you to renew your registration online. **Renewal applications will not be mailed out; however, a renewal application may be printed from the Board's Web site.**

Board Meeting Dates and Locations 2012

The Board of Pharmacy at its September 2011 meeting approved the following dates and locations for its meetings in 2012:

Wednesday, January 11 ..... Board Office
Wednesday, March 7 ..... Sullivan College of Pharmacy
Wednesday, May 9 ..... Board Office
Wednesday, July 11 ..... Board Office
Wednesday, September 12 ..... University of Kentucky College of Pharmacy
Friday, November 2 ..... To Be Announced
Wednesday, December 12 ..... Board Office

The Board of Pharmacy Retreat for 2012 is:

Friday-Saturday, November 2-3 ..... To Be Announced

2012 CAPTASA Conference

The 2012 Clinical Applications of the Principles in Treatment of Addictions and Substance Abuse (CAPTASA) Conference will be held Friday and Saturday, January 27-28, 2012, at the Embassy Suites in Lexington, KY. For information on this conference please visit *www.CAPTASA.org* or contact Sandy Patrick at sandy@captasa.org or 502/425-7761.

Pharmacist Recovery Network

Submitted by Brian Fingerson, RPh

We all know that we may see patients who come into a pharmacy that are addicted to drugs or alcohol. How do we recognize that they are addicted to these substances? Can we say we would recognize this disease in a colleague? If we do recognize it, then what do we do? Let's begin with one definition and some signs and symptoms:

Addiction is a primary, chronic, neurobiological disease, with genetic, psychosocial, and environmental factors influencing its development and manifestations.

Warning Signs of Abuse and Dependency

- Cravings
- Compulsive/increased use
- Change in personality
- Social withdrawal
- Going to great lengths to obtain prescriptions
- Ongoing use
- Change in appearance
- Desensitized emotions
- Forgetfulness
- Defensiveness

If you recognize any of these signs and symptoms please contact the Kentucky Professionals Recovery Network for information, help, or any concerns you may have for yourself or a colleague. Contact Brian Fingerson, RPh, at 502/749-8385 or kyprn@att.net.

Compliance Corner

Renewal Time in the Commonwealth

Submitted by Steve Hart, RPh, Pharmacy Inspections and Investigations Coordinator

Pharmacists will begin the renewal process in early January and must be renewed by **February 28, 2012, at 11:59:59 PM.** As renewal time approaches the Board and staff would like to give you a few tips. Pharmacists

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2011-2012 Influenza Vaccines Approved by FDA

Food and Drug Administration (FDA) announced that it has approved the 2011-2012 influenza vaccine formulation for all six manufacturers licensed to produce and distribute influenza vaccine for the United States. The vaccine formulation protects against the three virus strains that surveillance indicates will be most common during the upcoming season and includes the same virus strains used for the 2010-2011 influenza season. The Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) recommends that everyone six months of age and older receive an annual influenza vaccination. Details about the new vaccines are available in an FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm263319.htm,* and information about the ACIP recommendations are available on the CDC Web site at *www.cdc.gov/media/pressrel/2010/r100224.htm.*

Another TEAspoon – mL Mix-Up

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes 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 risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

A few weeks ago ISMP heard from a mother whose child was accidentally given an overdose of an antibiotic. A pharmacist accidentally provided instructions on the prescription label for her child to receive 3.5 **TEA**spoonfuls of a liquid antibiotic for 10 days instead of 3.5 **mL.** The medication was dispensed in a 60 mL bottle. The child was given 3.5 **TEA**spoonfuls each day for three days. By the fourth day only one **TEA**spoonful (5 mL) was left in the bottle, so the mother called the pharmacy and learned that the dosage amount on the label was incorrect. The child experienced bouts of diarrhea and a yeast and fungal infection in the vaginal area.

Mix-ups between teaspoons and mL are common and have been happening for many years. ISMP first mentioned the problem in its June 28, 2000 newsletter article, "Oral liquid medications may be more vulnerable to errors than previously recognized" *(www.ismp.org/Newsletters/acutecare/articles/20000628_2.asp).* ISMP has received more than 50 similar errors in recent years, most resulting in patient harm. It is time to standardize to a single way of measuring liquid medications, using the metric system with volumes expressed in mL. If we all used the metric measurement when prescribing, dispensing, and administering medications, these types of mix-ups would no longer happen.

In response to ongoing errors, in June 2009, ISMP called for elimination of **TEA**spoonful and other non-metric measurements to prevent errors *(www.ismp.org/pressroom/PR20090603.pdf).* In May 2011, FDA published a guidance suggesting ways for manufacturers to improve the labeling of over-the-counter (OTC) liquid drug products to minimize the risk of accidental overdoses *(www.fda.gov/Drugs/DrugSafety/MedicationErrors/ucm253715.htm).* Unfortunately, the guidance still mentions both **TEA**spoon and **TABLE**spoon. The Consumer Healthcare Products Association has also published guidelines *(www.chpa-info.org/scienceregulatory/Voluntary_Codes.aspx#volumetricmeasure)* to improve the format for volume measures within the dosing directions for OTC products. The abbreviation "mL" is recommended for use on accompanying dosing devices that measure OTC oral liquid drug products so they match the dosing directions in labeling for children. The group has also told companies to avoid directions that mention tablespoon, cubic centimeters (cc), dram, fluid ounce (Fl Oz), and dropper(ful), and to use mL as the sole unit of measure in the dosing directions or, alternatively, mL **and** the **"TEA**spoonful" equivalent (eg, 5 mL (1 **TEA**spoon)).

While these are excellent moves to improve safety, ISMP would like to see the complete elimination of **TEA**spoonful amounts and the abbreviation "tsp." Doses expressed using mL alone would be the best way to eliminate the risk of mix-ups. The ISMP board fully supports this initiative and is currently in the process of approving a formal ISMP position on this issue. ISMP hopes the health care industry will also support this initiative.

'Know Your Dose' Campaign Aims to Prevent Acetaminophen Overdose

The Acetaminophen Awareness Coalition, has launched *www.KnowYourDose.org,* a Web site aimed to educate consumers about the dangers of acetaminophen overdose and how to ensure that the correct, safe dosage is administered. "Know Your Dose" stresses to patients the importance of checking the labels of both prescription and over-the-counter medications for the amount of acetaminophen contained in order to ensure that they do not exceed recommended maximum dosage levels. Health care providers may order a free Know Your Dose kit that includes materials to help educate patients about safely using medications containing acetaminophen. The kit includes posters, information cards for patients, and a display holder for use in distributing the cards. Members of the Acetaminophen Awareness Coalition include Alliance for Aging Research, American Academy of Nurse Practitioners, American Academy of Physician Assistants, American Pain Foundation, American Pharmacists Association, CHPA Educational Foundation, National Association of Boards of Pharmacy® (NABP®), National Association of Chain Drug Stores, National Community Pharmacists Association, National Consumers League, and the National Council on Patient Information and Education. The campaign was developed under advisement from the American Academy of Pediatrics, CDC, and FDA.

Methylene Blue and Linezolid May Interact With Certain Psychiatric Medications

FDA has issued two safety communications regarding adverse drug reactions in patients taking certain psychiatric medications, and also given methylene blue or linezolid (Zyvox®). Specifically, FDA has received reports of serious central nervous system reactions in patients taking serotonergic psychiatric medications who are also given methylene blue, a product commonly used in diagnostic procedures. FDA explains that "[a]lthough the exact mechanism of this drug interaction is unknown, methylene blue inhibits the action of monoamine oxidase A – an enzyme responsible for breaking down serotonin in the brain. It is believed that when methylene blue is given to patients taking seroto-

nergic psychiatric medications, high levels of serotonin can build up in the brain, causing toxicity. This is referred to as Serotonin Syndrome. Signs and symptoms of Serotonin Syndrome include mental changes (confusion, hyperactivity, memory problems), muscle twitching, excessive sweating, shivering or shaking, diarrhea, trouble with coordination, and/or fever." FDA has published a list of the serotonergic psychiatric medications that can interact with methylene blue, available at *www.fda.gov/Drugs/DrugSafety/ucm263190.htm#table,* and advises that "Methylene blue should generally not be given to patients taking serotonergic drugs." Exceptions and more information for health care providers and patients are available in an FDA Drug Safety Communication available at *www.fda.gov/Drugs/DrugSafety/ucm263190.htm.*

Similar reports of interactions between certain serotonergic psychiatric medications and the antibacterial drug, linezolid (Zyvox) have also been reported to FDA. FDA has published a list of the serotonergic psychiatric medications that can interact with linezolid, available at *www.fda.gov/Drugs/DrugSafety/ucm265305.htm#table,* and advises that "Linezolid should generally not be given to patients taking serotonergic drugs." Exceptions and more information about the linezolid interaction for health care providers and for patients are available in an FDA Drug Safety Communication available at *www.fda.gov/Drugs/DrugSafety/ucm265305.htm.*

NABP Looking For Item Writers to Develop New Questions for NAPLEX, MPJE, FPGEE, and PCOA

NABP is seeking individuals to serve as item writers for the North American Pharmacist Licensure Examination® (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), and the Pharmacy Curriculum Outcomes Assessment® (PCOA®).

Pharmacists in all areas of practice and faculty from schools and colleges of pharmacy are encouraged to apply. To be considered as an item writer for the NAPLEX and MPJE, pharmacists must have at least two years of pharmacy practice experience.

Item writers will be selected based on the specific needs of the programs. Those who are chosen will be asked to attend a workshop at NABP Headquarters with travel, lodging, and ancillary expenses paid by NABP.

Attendees will receive detailed instructions and training materials describing the item-writing process and content-related requirements for their designated examination. Item writers will then be asked to develop new test items that will be considered for inclusion in NABP licensure and certification and assessment examination programs.

The NAPLEX is an examination consisting of 185 selected-response and constructed-response test questions, the majority of which are asked in a scenario-based format, that covers important information about the knowledge, judgment, and skills an entry-level pharmacist is expected to demonstrate. The three competency areas of the examination are:

- Assess pharmacotherapy to ensure safe and effective therapeutic outcomes
- Assess safe and accurate preparation and dispensing of medications
- Assess, recommend, and provide health care information that promotes public health

The MPJE is a computer-based examination that consists of 90 select-response items. It combines federal and state-specific questions that test the pharmacy jurisprudence knowledge of prospective pharmacists on the following areas:

- Legal aspects of pharmacy practice, including responsibilities with regard to the distribution and dispensing of pharmaceuticals and for the care of patients
- Licensure, registration, certification, and operational requirements
- Regulatory structure and terms of the laws and rules that regulate or affect pharmacists, pharmacies, manufacturers, and distributors

The FPGEE is a comprehensive examination consisting of 250 multiple-choice questions that measures four major pharmacy content areas:

- Basic biomedical sciences
- Pharmaceutical sciences
- Social/behavioral/administrative pharmacy sciences
- Clinical sciences

The PCOA is a 220-question, multiple-choice assessment that is administered to pharmacy students in all four professional years. The assessment follows a blueprint that reflects actual curriculum hours established through a national sample of PharmD programs in the US and is broken down into the following four areas:

- Basic biomedical sciences
- Pharmaceutical sciences
- Social, behavioral, and administrative pharmacy sciences
- Clinical sciences

Interested individuals should mail or fax a letter of interest indicating their current practice/educational setting, specialties/certifications, and years of experience, along with a resume or curriculum vitae via mail to NABP Executive Director/Secretary Carmen A. Catizone at 1600 Feehanville Drive, Mount Prospect, IL 60056; via e-mail at exec-office@nabp.net; or via fax at 847/391-4502.

Please note, applications are accepted on a continuous basis and kept on file for a period of five years. For more information about item writing, contact NABP at custserv@nabp.net.

Clarification Regarding Pradaxa Storage and Handling Requirements

An FDA alert released in March 2011 details important storage and handling guidelines for Pradaxa® (dabigatran etexilate mesylate) capsules, as reported in the third quarter NABP *National Pharmacy Compliance News.* As a point of clarification, the FDA-approved Pradaxa label states that once opened, the product must be used within 30 days. FDA is currently reviewing data that indicate no significant loss of potency up to 60 days after the bottle is opened as long as Pradaxa is stored in the original bottle and the handling requirements are met. An FDA Drug Safety Communication available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm249005.htm* provides more details, and the manufacturer's Pradaxa safety information is available at *www.pradaxa.com* by clicking on the link for "Important Storage & Handling Information" at the top of the page.

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To subscribe, visit the Newsroom on the NABP Web site at *www.nabp.net/news/* and click the subscribe button located along the top right of the page titled "Sign Up to Receive NABP E-News." Questions? Contact custserv@nabp.net.

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should review the CE requirements for 2012 renewal. 201 KAR 2:015 Section 5 requires:

(1) a pharmacist shall:
  (a) Complete a minimum of one and five-tenths (1.5) CEU (fifteen contact hours) **annually between January 1 and December 31;**
  (b) Not transfer or apply excess hours or units for future years.

(2) A pharmacist may be granted a deferral on a year-to-year basis at the discretion of the board for illness, incapacity, or other extenuating circumstances.

(3) A pharmacist first licensed by the board within twelve (12) months immediately preceding the annual renewal date shall be exempt from the continuing pharmacy education provisions.

Section 9: (1) At least once every ten (10) years a pharmacist shall successfully complete a continuing education course of not less than one (1) contact hour (0.1 CEU) concerning HIV/AIDS that complies with KRS 214.610(1).

(2) The continuing education course shall be:
  (a) Approved by the Cabinet for Health and Family Services HIV/AIDS Branch; or
  (b) Conducted by a provider approved by the Accreditation Council for Pharmacy Education (ACPE).

Pharmacy Technician Registration

Pharmacy technician renewal will begin in early February and on-time renewal will conclude on March 31, 2012, at 11:59:59 PM. The Board experienced a very high number of delinquent renewals in 2011. The Board recommends using the online verification on the Web site *(pharmacy.ky.gov)* to confirm the status of all employees.

As of April 1, 2009, anyone assisting in the practice of pharmacy is required to be registered as a pharmacy technician. This statute was passed and implemented to aid in curbing the controlled substance diversion across the Commonwealth. Since the registration has begun, the Board has revoked over 50 registrations for drug diversion. Are there more? Most of these diversion cases have been discovered in reviewing Drug Enforcement Administration (DEA) 106 forms submitted to the Board office. Each of these cases should have been reported by any pharmacist, pharmacist intern, or pharmacy technician pursuant to **KRS 315.121:**

(1) The Board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, or place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons:

(j) Knowing or having reason to know that a pharmacist, pharmacist intern, or pharmacy technician has engaged in or aided and abetted the unlawful distribution of legend medications, and failing to report any relevant information to the board

Please follow through on reporting these violations in a timely fashion.

Contact Numbers of State Boards and Federal Agencies

Board of Dentistry.....502/429-7280
502/429-7282 (fax)

Board of Medical Licensure.....502/429-7150
502/429-7158 (fax)

Board of Nursing.....502/429-3300
502/429-3311 (fax)

Board of Optometric Examiners.....859/246-2744
859/246-2746 (fax)

Board of Respiratory Care.....859/246-2747
859/246-2750 (fax)

Office of Drug Enforcement.....502/564-7985
502/696-3880 (fax)

Food and Drug Administration (Cincinnati, OH).....513/684-3501

DEA (Louisville, KY).....502/582-5905

For more information on these and other state agencies please visit *www.ky.gov,* and click on the Agencies icon along the top of the page.

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 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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