December 2010

Kentucky Board of Pharmacy News

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

2011 Pharmacist License Renewals

Pharmacist licenses expire on February 28, 2011. The Kentucky Board of Pharmacy will send out a **postcard** the first week of January 2011 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 at *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 rule stated in the June 2002 Board *Newsletter* regarding HIV/AIDS continuing education (CE). In the June 2002 *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 a pharmacist has until December 31, 2011, to complete his or her first one hour of HIV/AIDS CE.

Continuing Education For Pharmacists – Important Update

The Board of Pharmacy at its November 5, 2010 meeting ruled that any Kentucky licensed pharmacist must complete 15 hours of continuing education during the calendar year (January 1-December 31). This includes pharmacists that have a Kentucky pharmacist license and practice in another state. Previously, the Board had accepted the continuing education requirements of the state in which the pharmacist is currently practicing.

2011 Pharmacy Technician Registration Renewals

Pharmacy technician registrations expire on March 31, 2011. The Board will send out a **postcard** the first week of February 2011 as a reminder (in addition, a pharmacy technician that registered online last year will be sent an e-mail reminder). **Renewal applications will not be mailed out; however, a renewal application may be printed from the Board's Web site.**

New Board Member

Governor Steven L. Beshear appointed the following as a member of the Kentucky Board of Pharmacy to serve a term beginning January 2, 2011, and expiring January 1, 2015: Catherine Hanna, Lexington, KY.

Board Meeting Dates and Locations 2011

The Board of Pharmacy at its September 2010 meeting approved the following dates and locations for its meetings in 2011:

Wednesday, January 12	Board Office
Wednesday, March 9	Sullivan University College of Pharmacy
Wednesday, May 11	Board Office
Wednesday, July 13	Board Office
Wednesday, September 14	University of Kentucky College of Pharmacy
Friday, November 4	To Be Announced
Wednesday, December 14	Board Office

The Board of Pharmacy Retreat for 2011:

Friday and Saturday, November 4-5	To Be Announced

2011 CAPTASA Conference

The 2011 Clinical Applications of the Principles in Treatment of Addictions and Substance Abuse (CAPTASA) Conference will be held Friday and Saturday, January 28-29, 2011, 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.

DEA Issues Policy Statement on Role of Agent

Submitted by N. Katie Busroe, RPh, Pharmacy and Drug Inspector

On October 6, 2010, Drug Enforcement Administration (DEA) issued a Statement of Policy titled, "The Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies." This statement does not establish any new laws or requirements, but rather provides guidance under existing law regarding the proper role of an authorized agent of a DEA registered practitioner when communicating a controlled substance prescription to a pharmacy. The need for this policy statement arose from discussions regarding the use of nurses in long-term care facilities as agents of DEA registered practitioners to communicate controlled substance prescriptions to pharmacies, absent an employer-employee relationship. This policy statement applies to any situation involving practitioner use of a non-employee agent and is not restricted to the long-term care setting.

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FDA Alert Regarding Administration of Oral Nimodipine Capsules

Food and Drug Administration (FDA) reminds health care providers that oral nimodipine capsules should be given only by mouth or through a feeding or nasogastric tube and should never be given by intravenous administration. FDA continues to receive reports of intravenous nimodipine use, with serious, sometimes fatal, consequences. Intravenous injection of nimodipine can result in death, cardiac arrest, severe falls in blood pressure, and other heart-related complications.

Nimodipine is a medication intended to be given in a critical care setting to treat neurologic complications from subarachnoid hemorrhage and is only available as a capsule. Prescribing information warns against intravenous use of nimodipine and also provides clear instructions on how to remove the liquid contents from the capsules for nasogastric tube administration in patients who are unable to swallow. The instructions recommend that the syringe used for withdrawal of capsule contents be labeled with "Not for IV Use." FDA will continue working with the manufacturers of nimodipine and with outside groups to evaluate and implement additional ways to prevent medication errors with this product.

An FDA Drug Safety Communication providing additional information for health care providers and patients is available at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm220386.htm.*

FDA Approves Vaccines for the 2010-2011 Influenza Season

FDA approved vaccines for the 2010-2011 influenza season in the United States on July 30, 2010, and some manufacturers began shipping as early as mid-August. The seasonal influenza vaccine protects against three strains of influenza, including the 2009 H1N1 influenza virus, which caused the 2009 pandemic. Last year, two separate vaccines were needed to protect against seasonal flu and the 2009 H1N1 pandemic flu virus because the 2009 H1N1 virus emerged after production began on the seasonal vaccine, but this year, only one vaccine is necessary. The Centers for Disease Control and Prevention has published recommendations for annual influenza vaccination to include all people aged six months and older. The expanded recommendation is to take effect in the 2010-2011 influenza season. More information on the approved vaccine is available in an FDA news release available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm220718.htm.*

FDA Alert Regarding Adverse Effects in Children After Unintentional Exposure to Evamist

FDA advises patients and health care providers of reports regarding adverse effects from Evamist® in children who may have been unintentionally exposed to the drug through skin contact with women using this product. Evamist contains estradiol, an estrogen hormone, and is a topical product, sprayed on the skin on the inside of the forearm between the elbow and the wrist. Children unintentionally exposed to Evamist may experience premature puberty. FDA is currently reviewing these reported adverse events and is working with the company to identify any factors that may contribute to unintended exposure and to evaluate ways to minimize the risk. FDA advises that patients should make sure that children are not exposed to Evamist and that children do not come into contact with any skin area where the drug was applied, and for those who cannot avoid contact with children to wear a garment with long sleeves to cover the application site. Additional information for patients is provided in an FDA Drug Safety Communication available at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm220185.htm.*

Safeguards to Implement with 'High Alert' Medications

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 a 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.*

While most medications have a large margin of safety, a small number of drugs have a high risk of causing injury when they are misused. ISMP calls these "high-alert medications" to draw attention to this characteristic so that all involved in their use will treat them with the care and respect that they require. Errors may or may not be more common with these drugs than with the use of any others; however, the consequences of the errors are more devastating. For this reason, special considerations are required. These medications often need to be packaged differently, stored differently, prescribed differently, and administered differently than others. Examples of high-alert medications in community pharmacy include warfarin, insulin, methotrexate, and fentanyl patches. Whenever possible, "forcing functions" – methods that make it impossible for the drug to be given in a potentially lethal manner – should be developed and instituted. Forcing functions are procedures that create a "hard stop" during a process to help ensure that important information is provided before proceeding. For example, a pharmacy computer system that prevents overriding selected high-alert messages without a notation (eg, patient-specific indication must be entered if high-alert medication selected) is a forcing function.

An independent double-check of a high-alert medication is a procedure in which two pharmacists, alone and apart from each other, separately check each component of dispensing and verifying the high-alert medication, then compare results before giving it to the patient to self-administer. While technological solutions such as bar coding systems have great potential to detect human error, manual redundancies such as independent double checks still play an important role in error detection. Studies show that manual redundancies detect about 95% of errors. Independent double checks serve two purposes: to prevent a serious error from reaching a patient; and just as important, to bring attention to the systems that allow the introduction of human error. In retail pharmacies, with only one pharmacist per shift, the independent double check can be performed via a "will call" bag

check or by another pharmacist at the beginning of the next shift. If the medication has been dispensed, serious harm can be avoided or mitigated if the error is discovered within one or two doses.

The following information must be verified during the double-check process:

Comparison to prescriber's order:

- Is this the prescribed drug?
- Is this the prescribed dose/strength/rate and route of administration?
- Is this the right patient (use two patient identifiers)?
- Is this the prescribed frequency?

Additional cognitive checks:

- Does the drug's indication correspond to the patient's diagnosis?
- Is this the right drug formulation?
- Are dose calculations correct?
- Is the dosing formula (eg, mg/kg) used to derive the final dose correct?
- Is the prescribed dose/frequency/timing appropriate for this patient?
- Is the route of administration safe and proper for this patient?
- Has patient been educated on appropriate monitoring?

ASCO/FDA Program Provides Information on Expanded Access for IND Applications

Developed in partnership with FDA, the American Society of Clinical Oncology (ASCO) offers an online interactive educational program to help providers understand FDA regulations regarding expanded access programs for individual-patient investigational new drug (IND) applications. The program provides an introduction from the viewpoint of various involved stakeholders, including physicians, FDA, industry, and patients and may assist pharmacists in providing patient counsel regarding expanded access.

This interactive module consists of:

- A thorough explanation of all expanded access programs available
- Links to key references and resources that are relevant to the slide content
- Selected virtual meeting presentations from ASCO Annual Meetings
- Helpful resources to use with patients

The program is available at *http://university.asco.org/Expanded Access* and participants may earn a certificate of participation or completion.

Rise in Prescription Pain Pill Abuse Documented in Latest SAMHSA Data

Abuse of prescription pain medications continues to rise, according to the latest data from the Substance Abuse and Mental Health Services Administration (SAMHSA). The agency's Treatment Episode Data Set showed that the proportion of substance abuse treatment admissions for individuals aged 12 and older rose 400% from 1998 to 2008. SAMHSA data also showed an increase in emergency room visits involving the non-medical use of a prescription narcotic pain reliever, which have tripled in proportion since 1998. SAMHSA Administrator Pamela S. Hyde, JD, stressed that the non-medical use of prescription pain relievers is now the second most prevalent form of illicit drug use. Hyde emphasized the importance of raising awareness about this public health threat and educating the public on the "critical importance of properly using, storing, and disposing of these powerful drugs" as reported in a SAMHSA press release available at *www.samhsa.gov/newsroom/advisories/1007140544.aspx*.

USP Recommends Patient-Centered Standards for Prescription Labels

To address the problem of patient misinterpretation of medication instructions, the United States Pharmacopeial Convention (USP) Health Literacy and Prescription Container Labeling Advisory Panel developed and recently released recommendations for standardizing the format, appearance, content, and language of prescription labels. The panel, on which the National Association of Boards of Pharmacy® (NABP®) participated, developed the patient-centered recommendations in response to a call for such standards from the Institute of Medicine. More details about the panel's recommendations are available in a USP press release at *http://vocuspr.vocus.com/vocuspr30/ViewAttachment.aspx?EID=2WSh2u7neSpIu2bXW1HJ5VQ48HGFAOGH1NdNBeuPwJE%3d*.

Seven Pharmacy Organizations Respond to AMA Scope of Pharmacy Practice Document

Seven national pharmacy organizations, including NABP, collaborated on the analysis and responded to the AMA Scope of Practice Data Series: Pharmacists, a document published by the American Medical Association (AMA) that describes the scope of the practice of pharmacy as viewed by the AMA authors. The pharmacy organizations identified significant opportunities for enhanced understanding by the AMA of contemporary pharmacy practice and urged the AMA to correct the identified issues noted in the document. AMA responded that meaningful dialogue will be pursued to examine ways pharmacists and physicians can collaboratively address the health care needs of patients. Collaborating on the pharmacy organizations' review and response were the American Pharmacists Association (APhA), American Association of Colleges of Pharmacy, American College of Clinical Pharmacy, Accreditation Council for Pharmacy Education, American Society of Consultant Pharmacists, National Alliance of State Pharmacy Associations, and NABP. The letter and materials sent to AMA are available at the following links from the APhA Web site:

- Recommendations: AMA Scope of Practice Data Series: Pharmacists, *www.pharmacist.com/AM/Template.cfm?Section=Home2&CONTENTID=23148&TEMPLATE=/CM/ContentDisplay.cfm*.
- Response Letter: AMA Scope of Practice Data Series: Pharmacists, *www.pharmacist.com/AM/Template.cfm?Section=Home2&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=23149*.
- Scope of Contemporary Pharmacy Practice, *www.pharmacist.com/AM/Template.cfm?Section=Home2&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=23150*.

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The policy statement emphasizes that it is the responsibility of the DEA registered practitioner to determine the legitimate medical need for a controlled substance and that this act of determination cannot be delegated. The elements of a valid controlled substance prescription must be specified by the practitioner and cannot be delegated. These elements are patient name and address, drug name and strength, quantity, directions for use, and name, address, and DEA number of issuing practitioner. Furthermore, the pharmacist has a corresponding responsibility for the proper prescribing and dispensing of controlled substances and should only fill valid controlled substance prescriptions.

DEA regulations permit a practitioner to use an authorized agent to perform certain basic acts in connection with communicating prescription information to a pharmacy. These acts allow an agent to:

1. Prepare for practitioner signature a written controlled substance prescription.
2. Telephone the pharmacy and convey the prescription information for a Schedule III through V controlled substance to the pharmacist.
3. Fax a practitioner signed controlled substance prescription to the pharmacy. Kentucky law permits the faxing of Schedule II controlled substance prescriptions in limited situations, such as for a Hospice or long-term care patient, as long as the original prescription is delivered to the pharmacy within seven days.

This policy statement provides guidance on who is an agent. Per the Controlled Substances Act (CSA), an agent is defined as, "an authorized person who acts on behalf of or at the direction of a manufacturer, distributor or dispenser." (The CSA definition of dispense includes prescribing, 21 U.S.C. 802(3) and (10).) The common law definition of agency is a relationship that arises when a principal (in this case the DEA registered practitioner) declares an agreement with another person (the nurse) that the nurse shall act on the practitioner's behalf and subject to the practitioner's control and the nurse consents to this agreement. When the CSA definition is taken in context of the common law definition of agency, the employer-employee relationship is not necessary. This allows for a nurse in a long-term care facility (or other setting) to act as the agent of the practitioner. There must be an explicit and transparent relationship between the practitioner and agent. It must be clearly identified who the agent is and the activities the agent is allowed to perform, which are subject to the practitioner's control and cannot exceed the legal limits of the agent's role under the CSA. For example, an agent cannot make a medical determination as to the patient's need for the controlled substance or how long the patient may need the controlled substance.

DEA suggests one way in which to clearly define the practitioner-agent relationship may be to outline such relationship in writing, documenting the name of the agent and the scope of that agent. The policy states, "DEA believes it is in the best interests of the practitioners, agents and pharmacists" that the nature of the relationship be designated in writing and maintained on file by all three parties.

In some respects the Kentucky Controlled Substances Act is more stringent than federal law. This federal policy statement does not change 902 KAR 55:095, which states that a Schedule II prescription for a Hospice or long-term care patient may be transmitted via a facsimile to a pharmacy, however, the original Schedule II prescription must be delivered to the pharmacy within seven days. Also, Kentucky law does not allow an emergency oral communication of a Schedule II prescription from a practitioner to a pharmacist.

The entire Statement of Policy and a sample of the written agreement between the practitioner and agent are available on the DEA Web site, *www.deadiversion.usdoj.gov.*

Contact Numbers for 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)
Drug Enforcement and Professional Practices Branch of the Cabinet for Health and Family Services	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 Agencies 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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