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Kentucky Board of Pharmacy News

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Pharmacy Renewal Deadline June 30, 2011

Pharmacy permits expire June 30, 2011. A pharmacy permit can be renewed online. A postcard explaining the renewal process was mailed to each pharmacy around May 1, 2011. If you want to send in a paper renewal, this form may be printed from the Kentucky Board of Pharmacy's Web site at *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, relocation within the current premises of the existing permit, or change in 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, 2011. All paper renewal applications must be in the Board office by the close of the day June 30, 2011.

HIV/AIDS Continuing Education – Important Update

The Board of Pharmacy at its November 5, 2010 meeting changed the ruling printed 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 a pharmacist has until December 31, 2011, to complete his or her first one hour of HIV/AIDS CE. **Pursuant to 201 KAR 2:015 a pharmacist must keep his or her HIV/AIDS CE certificate for 10 years.**

Board Retreat Location 2011

The Griffin Gate Marriott Resort in Lexington, KY, will be the site of the 2011 Kentucky Board of Pharmacy Retreat to begin on Friday, November 4, 2011, at the end of the Board meeting that begins at 9 AM. The meeting will continue on Saturday, November 5, 2011, from 8 AM until 5 PM.

The Board would request any individual or organization to submit topics to be discussed at the Board Retreat. Please submit any suggestion(s) to the Board office either by mail, fax, or e-mail. The Board will set the agenda at a later date. If you have any questions, please contact the Board office.

Pseudoephedrine to Methamphetamine: A Pharmacy Problem

Submitted by Phil Losch, RPh, Pharmacy and Drug Inspector

Now that the 2011 Kentucky Legislative Session is over and there have been no laws passed to address the rising methamphetamine problem in Kentucky, maybe it is time that pharmacies embrace the fact that this truly may be a pharmacy problem. And, for the next year there will be no new laws to fix the problem. As for the facts, let's review some of them.

The only place that pseudoephedrine (PSE) is legally sold in Kentucky is from a pharmacy (with the exception of liquid and gel caps). So when you read the headlines that a methamphetamine lab has been found in your county or a person is arrested with possession of meth, consider where the PSE came from to make the meth. Was it from your pharmacy? Are you part of the problem and not part of the solution?

Illegal meth labs have risen from 225 in 2007 to 1,080 in 2010. How can this be? After all, the Drug Enforcement Administration's Combat Methamphetamine Epidemic Act of 2005 took effect in 2006. Was not this to be the answer? Then Kentucky mandated the use of MethCheck to further reduce the illegal manufacturing of PSE to methamphetamine, but the illegal labs have had a fourfold increase in as many years. Is MethCheck not working? No, that is not the case. MethCheck works well for what it was intended to do. It prevents any sale larger than 3.6 grams of PSE at any one time and prevents sales of over 9 grams in a 30-day period. What MethCheck does not do is identify "smurfers."

Smurfers are people that are sent in to pharmacies to purchase PSE and do not intend on using it. Instead, they are reselling their PSE to someone else that will ultimately get it into the hands of a meth cook. The economics of this is surprising. A smurfer may be given up to $50 with instructions to go in and buy PSE for as little as $8 and told the remaining money is theirs ($42). And, they can do this several times a month turning a profit well over $100.

Now, what does a smurfer look like? The fact is they can look like your neighbor, your mother, your son, or daughter. There may even be a carload of individuals driven to a pharmacy and each goes into a pharmacy to purchase PSE. They do not wear badges or flowers in their hair. They are nearly impossible to spot from a distance. That is where pharmacists, interns, and technicians must step up to be part of the solution instead of part of the problem.

Just what is the responsibility of the pharmacist, intern, or technician? It is clear in KRS 315.121 that these pharmacy personnel have a responsibility to "not allow any drug or chemical to get into an illegal traffic when they know or should have known of their intended use in illegal activities." What this means is that pharmacy personnel have a responsibility that goes further than MethCheck if they question the potential for illegal activity. This may mean questioning the patient about why they need the product or who it is for. In order for a pharmacy to be part of the solution, more effort must be extended by pharmacy personnel to identify legal and illegal sales. It has become painfully obvious that due to the increasing illegal labs, we in pharmacy have not been as prudent in PSE as maybe we should have been.

One might also ask, just what has the Kentucky Board of Pharmacy done to address the problem. First, the Board voted at the February 9, 2011 meeting to endorse the scheduling of PSE thus making it a controlled

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FDA Asks Manufacturers to Limit Acetaminophen Strength

In the interest of patient safety, Food and Drug Administration (FDA) asked drug manufacturers to limit the strength of acetaminophen in prescription drug products – which are predominantly combinations of acetaminophen and opioids – to 325 mg per tablet, capsule, or other dosage unit. In addition, FDA reports that the labels of all prescription drug products that contain acetaminophen will now include a boxed warning that highlights the potential for severe liver injury and a warning that highlights the potential for allergic reactions. FDA has taken these actions to reduce the risk of severe liver injury and allergic reactions associated with acetaminophen. FDA notes that over-the-counter products containing acetaminophen are not affected by this action.

While the maximum amount of acetaminophen in a prescription tablet, capsule, or other dosage unit will be limited to 325 mg, the total number of tablets or capsules that may be prescribed and the time intervals at which they may be prescribed will not change as a result of the lower amount of acetaminophen. Additional information for health care providers and patients is included in an FDA Drug Safety Communication available on the FDA Web site at *www.fda.gov/Drugs/DrugSafety/ucm239821.htm.*

Looking for Risk

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.*

Health care organizations focused on improving patient safety must first identify, ascertain the causes of, and employ strategies to reduce risk. Everyone on staff in an organization has responsibility for risk assessment and, therefore, risk management.

This includes involving patients in their care and seeking their help to identify risk in the system. Assessing risk in an organization is important to understanding and prioritizing areas of highest risk and for discovering which improvements will have the greatest overall impact on patient safety.

FMEA

The Failure Mode and Effects Analysis (FMEA) process is a "systematic method of identifying and preventing product and process problems before they occur." FMEA is the tool that has the potential to be an integral part of any risk assessment and, therefore, the risk management process.

FMEAs focus on identifying and removing defects, enhancing safety, and increasing customer satisfaction.

AROC

Assessing Risk and Opportunities for Change (AROC) is designed to help community pharmacy personnel identify potential medication safety risks and prevent errors. Pharmacists can use these materials and tools to pinpoint specific areas of weakness in their medication delivery systems and to provide a starting point for successful organizational improvements.

Pharmacists' Role

Pharmacists are often assumed to be the "guardians" in ensuring that medication errors do not occur. This expectation is unrealistic, because avoiding error is a health care team effort. It has, however been suggested that pharmacists should assume a leadership role in implementing safe medication use efforts in their organization.

Objectives for the pharmacist and other pharmacy staff who participate in the assessment process:

- Explain the important processes and sub-processes of medication use from prescription through administration.
- Participate in identifying failure modes and risk throughout the entire medication process, especially in information that should be available to the prescriber and nurse, as well as describing the steps in the process

that occur after the medication order is transferred to the pharmacy.

- Offer possible causes for medication errors because of breakdowns in the prescription to administration process.
- Identify effects, as well as their severity and probability, when a system failure occurs.
- Offer suggestions, along with all team members, for actions that should be taken to prevent medication errors.

Pharmacists are an integral part of any medication safety assessment process. They not only offer information – as do the other disciplines in the organization – they can also expand their knowledge through participating in these risk assessments. Pharmacy participation should include frontline staff, pharmacists, pharmacy technicians, and pharmacy support staff. It is important to have multilevel involvement so that all system enhancements are discussed and identified.

To learn more about assessing risk in acute care pharmacy visit *www.ismp.org/Tools/pathways.asp.*

To learn more about assessing risk in community pharmacy visit *www.ismp.org/communityRx/aroc/.*

NABP Launches New and Improved NAPLEX/MPJE Application in March

In March 2011, NABP launched a new and improved application process for the North American Pharmacist Licensure Examination® (NAPLEX®) and the Multistate Pharmacy Jurisprudence Examination® (MPJE®). The online application was upgraded to be more user friendly, allowing candidates to perform more registration tasks and providing status information to examination candidates.

In addition to providing the basic features of registering for the NAPLEX, NAPLEX score transfer, and MPJE, the new application also allows candidates to make changes to, add to, or withdraw an application, eliminating the need for candidates to call NABP for this service. Changes that can be made to an application include registering for the MPJE in additional jurisdictions and adding NAPLEX score transfer requests until the time of the examination. Technological enhancements to the application allow for the elimination of the previous requirement that candidates submit score transfer requests five business days prior to sitting for the NAPLEX.

The new application also gives candidates who miss sitting for an examination or who do not cancel within two business days of their appointment the ability to submit resitting fees online rather than having to send a payment to NABP via mail. This expedites the receipt of the candidate's new Authorization to Test so that he or she may schedule another examination appointment more quickly.

An additional benefit to candidates is the ability to monitor the status of their profile. After submitting an application, candidates can log in to their profile and see if the application has been received; if eligibility has been requested, granted, denied, or expired; if Authorization to Test has been generated; if the application has been withdrawn or expired; and history of examinations taken.

Candidates who registered for the NAPLEX or MPJE before the new application was launched will need to create a user name and password through the new application so that they can view the historical data of their NAPLEX and MPJE registrations. Upon creating a new user account, the system will match the newly created account with applications previously submitted or currently in progress so that all the information will be viewable by the candidate.

The new application also allows users to update their profiles as needed and review past orders.

In addition, the score results for the NAPLEX and MPJE are also accessible when candidates log in to the application, provided that the board for which the candidate tested participates in the online score interface. Currently, 24 boards utilize this service.

Overall, candidates can expect a clearer and smoother registration process because both front and back-end functionality of the application has been streamlined and tightly integrated.

New FDA Drug Info Rounds Training Video

FDA Drug Info Rounds, a series of online training videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest Drug Info Rounds video, pharmacists discuss the role of FDA in responding to and mitigating drug shortages. Drug Info Rounds is developed with contributions from pharmacists in the FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information. FDA Drug Info Rounds training videos may be accessed on the FDA Web site at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

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substance prescription item. As stated previously, the Kentucky Legislature did not take this direction. Additionally, as of November 2010 the Board has begun working with the Kentucky Office of Drug Control Policy to identify trends in the sale of PSE. One such trend is that the data strongly suggest that more sales per capita are made in several Kentucky counties than other counties within Kentucky. The Board staff is planning on comparing sales data per county with identified illegal labs in the same counties to ascertain if there is a direct correlation between sales per capita and illegal labs.

With all this said, the main point of this article is to ask the question: is methamphetamine a pharmacy problem? Have we in pharmacy been waiting for a new law to "fix" a problem that we in pharmacy can truly impact if we take the time to more closely monitor the sales in our pharmacies? The Board encourages you to be part of the solution to this issue and not be part of the problem. If you have any questions about how to address this problem in your pharmacy, you can contact your pharmacy and drug inspector or the Board office for further advice.

Brian Fingerson Receives Award at APhA Annual Meeting

Congratulations to Brian Fingerson, RPh, as he received the 2011 American Pharmacists Association (APhA) Academy of Pharmacy Practice and Management Distinguished Achievement Award in Specialized Pharmacy Practice. He was selected for his dedication to the wellness of pharmacists, student pharmacists, and other health professionals, who are suffering from or recovering from alcoholism or other drug dependencies. He has become a recognized leader at both the state and national level in the area of substance abuse education and assistance.

Legislation Update 2011

SB 40 was passed during the 2011 Legislative Session and signed into law by Governor Steve Beshear. This bill authorizes pharmacists to **administer flu vaccines only** to individuals nine to 13 years old pursuant to a prescriber-approved protocol and with consent of parent or guardian. Upon request of the individual, parent, or guardian, the pharmacist must provide notice to the primary care provider.

SB 71 was passed during the 2011 Legislative Session and signed into law by Governor Beshear. This bill establishes a licensure board for individuals providing diabetes education; however, it exempts pharmacists and some other licensed health care providers from being licensed by this new board.

HB 311 was passed during the 2011 Legislative Session and signed into law by Governor Beshear. This bill updates Kentucky's Controlled Substances Act to allow electronic prescribing of controlled substance prescriptions (Schedule II, III, IV, and V).

Even though HB 311 becomes effective June 8, 2011, software provider applications prior to use for e-prescribing must undergo independent audit or certification by a certification organization approved by Drug Enforcement Administration (DEA). The audit or certification must determine whether an application meets DEA requirements (both prescriber and pharmacy). As of this date no organizations have been approved. DEA will announce approvals via *Federal Register* notices and its Offices of Diversion Control Web site at *www.deadiversion.usdoj.gov*. Until these software applications have been approved, e-prescriptions of controlled substances will not be valid.

All these bills will become effective June 8, 2011.

Regulation Update 2011

201 KAR 2:330 (Emergency Pharmacy Powers) became effective October 20, 2010. This administrative regulation sets out the **conditions whereby a prescription may be refilled pursuant to an executive order issued by the governor as authorized by KRS 315.500** when the prescriber is unavailable and sets out the **conditions whereby a pharmacy may operate temporarily in an area not designated on the pharmacy permit** pursuant to an executive order issued by the governor as authorized by KRS 315.500.

201 KAR 2:165 (Transfer of Prescription Information) became effective February 4, 2011. This administrative regulation establishes the procedures by which a prescription may be transferred between pharmacies within the Commonwealth or between a pharmacy and an establishment located in a state or US territory or district outside the Commonwealth and similarly credentialed as a pharmacy by that state or US territory or district for the purpose of dispensing.

To review the entire regulation, please visit the Board's Web site at *www.pharmacy.ky.gov*, click on Statutes and Regulations, and then click on 201 KAR and proceed to Chapter 2 and click on .330 for emergency pharmacy powers and .165 for transfer of prescription information.

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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