March 2013

Kentucky Board of Pharmacy News

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Pharmacy Technician Registration Renewal by March 31, 2013

The registration renewal process is available online at *www.pharmacy.ky.gov.* At the completion of the application process and payment of the $25 registration fee, you will print your certificate of registration. If you are unable to complete the process online, you may print a registration renewal application form from the Kentucky Board of Pharmacy's Web site or contact the Board office at 502/564-7910 to obtain an application by mail.

Registrations must be received in the Board office by close of business on Friday, March 29, 2013 (not post-marked). All online registrations must be completed before 12:01 AM (EDT) on April 1, 2013. Your registration will be valid until March 31, 2014.

As a reminder, a pharmacy technician must renew his or her pharmacy technician registration and **must not apply as a new pharmacy technician,** whether he or she has changed pharmacies or is attempting to renew his or her pharmacy technician registration late.

Pharmacists-in-charge, please check that all pharmacy technicians have renewed their pharmacy technician registrations before the March 31, 2013 deadline.

Pharmacy Renewal Deadline: June 30, 2013

Pharmacy permits expire June 30, 2013. A pharmacy permit can be renewed online. A postcard explaining the renewal process will be mailed to each pharmacy on or about May 1, 2013. If you want to send in a paper renewal, this form may be printed off from the Board's 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, relocation within the current premises of the existing permit, or ownership change, 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, 2013. All paper renewal applications must be in the Board office by the close of the day Friday, June 28, 2013.

Lapsed Pharmacy Technician Registration

If an individual is registered as a pharmacy technician and his or her registration has lapsed, the pharmacy technician **must renew his or her pharmacy technician registration before beginning to work in the same or a different pharmacy.** The 30-day window for registration is for initial application only and does not apply to renewal or change of employment.

Board Members and Officers

Joel Thornbury and Larry Hadley were reappointed to serve on the Board. Their terms began January 2, 2013, and will expire January 1, 2017. Joel Thornbury was elected president of the Board at its January 9, 2013 meeting and Cathy Hanna was elected vice-president.

2013 Board Meeting Dates

Following are the meeting dates and locations of the Board meetings for 2013:

- Wednesday, March 27 – Board office
- Wednesday, May 8 – Sullivan University College of Pharmacy
- Wednesday, July 10 – Board office
- Wednesday, September 11 – University of Kentucky College of Pharmacy
- Friday, November 1 – (location to be announced)
- Wednesday, December 18 – Board office

The Board retreat will begin on Friday, November 1, 2013, at the end of the Board meeting, and will continue on Saturday, November 2, 2013. The location will be announced at a later date. If you have any suggestions for topics for the Board to be discussed, please send them to the office for consideration by the Board.

Multiple Prescriptions for an APRN for Schedule III, IV, or V

The Board office has received many inquiries on whether an advanced practice registered nurse (APRN) can issue multiple prescriptions for a Schedule III, IV, or V drug. The answer is **no.**

The Controlled Substances Act (CSA) is unique among criminal laws in that it stipulates acts pertaining to controlled substances (CS) that are permissible. That is, if the CSA does not explicitly permit an action pertaining to a CS, then by its lack of explicit permissibility, the act is prohibited.

Compliance Corner

Vaccine Storage and Handling Guidance

Submitted by Phil Losch, RPh, Pharmacy and Drug Inspector

In December 2011, the Centers for Disease Control and Prevention (CDC) issued a *Vaccine Storage and Handling Guide.* This can be seen at *www.cdc.gov/vaccines/recs/storage/guide/vaccine-storage-handling.pdf.* Then in October 2012, the CDC issued an *Interim Vaccine Storage and Handling Guidance* for vaccine storage and handling that can be seen at *www.cdc.gov/vaccines/recs/storage/interim.htm.*

The subject of this article is to briefly discuss the changes in the interim report. With the explosion of pharmacy-based immunization

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NIH Database Provides Information on Drugs Associated With Liver Injury

The National Institutes of Health (NIH) has launched a free searchable database with information on prescription and over-the-counter (OTC) drugs, herbals, and dietary supplements associated with liver injury. The LiverTox database, *www.livertox.nih.gov*, is a free resource for health care providers and researchers studying liver injury associated with these products. The database provides up-to-date, accurate, and easily accessed information on the diagnosis, cause, frequency, patterns, and management of liver injury attributable to prescription and nonprescription medications, herbals, and dietary supplements. The database currently contains information on 700 medications, and 300 more will be added.

Coalition Urges Consumers to 'Double Check, Don't Double Up' on Acetaminophen

With the start of cold and flu season in October 2012, the Acetaminophen Awareness Coalition began urging consumers to double check their medicine labels to make sure they do not double up on medicines containing acetaminophen. The coalition's "Double Check, Don't Double Up" message is aimed to reach the more than 50 million Americans who use acetaminophen every week, encouraging them to take three simple steps to avoid acetaminophen overdose: (1) know if your medicine contains acetaminophen; (2) never take two medicines with acetaminophen at the same time; and (3) always read your medicine label. The coalition also wants to educate consumers that taking more acetaminophen than directed is an overdose and can lead to liver damage. Health care providers can join the effort by educating patients about safe use of acetaminophen, and can refer patients to the *KnowYourDose.org* Web site for more information. The Acetaminophen Awareness Coalition is made up of a diverse group of organizations representing health care providers and consumers who have joined forces through the Know Your Dose campaign to inform consumers about safe acetaminophen use and preventing liver damage that can result from unintentional overdose.

Root Cause Analysis

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.*

To assist pharmacists in the process of minimizing the occurrence of medication errors, many state boards of pharmacy are contemplating or already requiring community pharmacies to have a continuous quality improvement program in place. Many of these state's regulations include the requirement of root cause analysis (RCA) in the case of sentinel events. The Joint Commission defines a sentinel event as an "unexpected occurrence involving death or serious physical or psychological injury or risk thereof," and recommends completing an RCA for all sentinel events for health care organizations in which they accredit. It is anticipated that RCA for sentinel events may be required as part of an accreditation program for community/ambulatory pharmacies.

RCA is a process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or risk of occurrence of a sentinel event. RCA focuses primarily on systems and processes, not individual performance. Finding and identifying root causes during an investigation adds considerable value by pointing out significant, underlying, fundamental conditions that increase the risk of adverse consequences. These analyses can be of enormous value in capturing both the big-picture perspective and the details of the error. They facilitate system evaluation, analysis of need for corrective action, and tracking and trending.

The RCA process starts by creating a team, holding a meeting, and stating the problem. The team gathers documentation (prescriptions, labels, computer reports, etc) and interviews staff involved in the error to determine the sequence of events.

The RCA team will review the documentation and review the sequence of events and continue asking themselves "Why did this happen?" until they arrive at each root cause.

The team must assume that any problem is preventable and caused by weak or vulnerable systems rather than individual incompetence. Even in the case of a person making a mistake, the team must ask "Why do our systems allow these types of mistakes to happen so easily?" or "What factors set this person up to make this error?"

The heart of the process is the analysis itself. Table 1 lists basic questions that should be answered during RCA.

Table 1. Basic Questions to Answer During RCA
1. What happened?
2. What normally happens?
3. What do policies/procedures require?
4. Why did it happen?
5. How was the organization managing the risk before the event?

It is important to answer "What normally happens?"(Question 2, in the above table). The difference between "What normally happens?" and "What do the policies and procedures require?" (Question 3) helps determine the reliability of processes and how often staff cut corners to get the work done.

RCA also includes a method to measure the effectiveness of these strategies over time. Targeting corrective measures at the identified root causes is the best way to ensure that similar problems do not occur in the future.

USP Releases Universal Standards for Prescription Labels

New United States Pharmacopeial Convention (USP) standards for a universal approach to the format, appearance, content, and instructions for medicines in containers dispensed by pharmacists have been released. "Wide variability in prescription container labels exists today across individual prescriptions, pharmacies, retail chains and states. The USP standards provide specific direction on how to organize labels in a 'patient-centered' manner that best reflects how most patients seek out and understand medication instructions," as explained in a USP press release. Lack of universal standards for medication labeling can contribute to patients

misunderstanding dosage instructions and can lead to medication errors. Elements of the new USP standards, contained in General Chapter <17> Prescription Container Labeling, of the USP and the National Formulary, include:

- Emphasizing instructions and other information important to patients
- Improving readability
- Giving explicit instructions
- Including purpose for use
- Addressing limited English proficiency
- Addressing visual impairment

Descriptions of each standard including examples, as well as more information about the development of the standards, are provided in a USP press release, available at *http://us.vocuspr.com/Newsroom/ViewAttachment.aspx?SiteName=USPharm&Entity=PRAsset&AttachmentType=F&EntityID=109587&AttachmentID=5dc9eb96-5706-4e61-b0fa-ce9673fb3010*.

Enforcement of the standards will be the decision of individual state boards of pharmacy, which may choose to adopt it into their regulations, notes USP. The National Association of Boards of Pharmacy® (NABP®) member boards adopted Resolution 108-1-12 at the NABP 108th Annual Meeting stating that the Association should support state boards of pharmacy in efforts to require a standardized prescription label. NABP also convened a task force on this issue in December 2008. The resolution and the Report of the NABP Task Force on Uniform Prescription Labeling Requirements are available in the Members section of the NABP Web site.

New Law Increases Penalties on Medical Cargo Theft

New legislation signed into law by President Obama on October 5, 2012, increases penalties for medical product cargo theft, a significant problem that threatens patient safety when these stolen products are reintroduced into the legitimate supply chain. The Strengthening and Focusing Enforcement to Deter Organized Stealing and Enhance Safety Act of 2012 (SAFE DOSES Act) prohibits theft of medical products as well as trafficking, buying, selling, or distributing illegally obtained pre-retail medical products. The law "prescribes criminal and civil penalties for violations, including a civil penalty of up to the greater of 3 times the economic loss attributable to the violation or $1 million." According to the Coalition for Patient Safety and Medicine Integrity, "current federal criminal laws do not distinguish between stealing a load of insulin and stealing a truck full of paper clips." By increasing the penalties for medical theft, the SAFE DOSES Act should help deter such theft. The text of the new law is available for download from the Government Printing Office Web site at *www.gpo.gov/fdsys/pkg/BILLS-112hr4223enr/pdf/BILLS-112hr4223enr.pdf*.

NABP Implements Action Plan to Assist States in Regulating Compounding Pharmacies

Supporting state board of pharmacy efforts to enforce compounding regulations, NABP is implementing a four-part action plan centered around inspection of nonresident compounding pharmacies and creating an information-sharing network of regulatory details on such pharmacies. Focusing on inspections of nonresident compounding pharmacies and sharing this data among boards of pharmacy nationwide was determined by NABP and its member state boards of pharmacy to be key to preventing future tragedies like the current meningitis outbreak.

NABP developed the action plan at a November 2012 meeting of board of pharmacy executive directors where the attendees expressed a strong commitment to correcting system failures that allowed the meningitis outbreak to occur, and implementation began quickly thereafter. The Iowa Board of Pharmacy recently requested NABP to develop an inspection program for entities that are licensed by the state as nonresident pharmacies and dispensing compounded drugs in Iowa. Those in attendance expressed their support of this inspection initiative, which became a cornerstone of the four-part action plan.

In the first part of its action plan, NABP shared the list of nonresident compounding pharmacies provided by the Iowa Board with other NABP member boards of pharmacy and began coordinating the collection of information on these pharmacies. The boards' collaboration on this data helped NABP identify the initial pharmacies to inspect. NABP believes that the list provided by Iowa represents a significant number of nonresident pharmacies dispensing compounded drugs across the country.

Implementing the inspection program is the second part of the action plan and is currently underway. Initial results will reveal whether the selected pharmacies are compounding pursuant to a prescription in compliance with state regulations, or instead are engaging in manufacturing. Entities that refuse inspection may be subject to disciplinary action by the Iowa Board and such actions will be shared with all of NABP's member boards.

The third part of the action plan includes NABP collecting and maintaining data on the compounding pharmacies identified by the Iowa Board and by other boards of pharmacy. Initial data collected from the boards and the inspection reports will be stored in an NABP Pharmacy e-Profile, allowing the Association to disseminate pertinent public information among state boards. Ultimately, states will be able to submit inspection reports and other related information to NABP for inclusion in pharmacies' e-Profiles. The network will be made available at no cost to boards for use in making licensure and registration determinations for pharmacies, and may also help to identify pharmacies whose operations are more akin to manufacturing than compounding.

As the final part of the action plan, NABP plans to schedule immediate and ongoing training of board of pharmacy inspectors and compliance officers via Webinar and field training opportunities. NABP will also continue cooperative efforts with Food and Drug Administration and legislators to address the regulatory quagmire that exists when traditional compounding is exceeded and manufacturing may be occurring.

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programs, the storage of vaccines in pharmacies has become a critical component to providing a quality service to the communities we serve. The appropriate handling of the vaccines used is critical for positive outcomes for our patients.

The goal in the CDC interim guidance is to improve the way providers store and handle vaccines nationwide with several changes being recommended including:

1. Use of biosafe glycol-encased probe or a similar temperature buffered probe rather than measurement of ambient air temperatures;
2. Use of digital data loggers with detachable probes that record and store temperature information at frequent programmable intervals for 24-hour temperature monitoring rather than non-continuous temperature monitoring;
3. Use of stand-alone refrigerator and stand-alone freezer units suitable for vaccine storage rather than combination (refrigerator/freezer) or other units not designed for storing fragile biologics such as vaccines;
4. Discontinuing use of dorm-style or bar-style refrigerator/freezers for any vaccine storage, even temporary storage; and
5. Weekly review of vaccine expiration dates and rotation of vaccine stock.

More detailed information can be found at the aforementioned Web sites, but it is clear that CDC has recommended the use of digital, biosafe glycol-encased probe thermometers or similar probes that more closely approximate the internal temperature of the products stored. Additionally, the temperature should be monitored by data loggers that are continuously (24/7/365) monitoring, and alarms should be issued if temperature excursions occur.

If you are a current provider of vaccines in your pharmacy, it is strongly urged that you view the CDC Web sites listed above. There is much more information about proper storage and handling provided there. This article was only intended to be a springboard for identifying a best practice of storage of vaccines. It appears that dorm-style refrigerators belong in dorms, and bar-style refrigerators belong in bars. These no longer have a place in pharmacy for the storage of vaccines or biologicals.

Kentucky Pharmacist Recovery Network

Submitted by Brian Fingerson, RPh, Chairperson, Pharmacist Recovery Network Committee

We are fortunate here in Kentucky that we have options in dealing with someone who has addiction or alcoholism affecting his or her ability to safely practice pharmacy. Yes, here in Kentucky, a pharmacist or student pharmacist may call for assistance from the Pharmacist Recovery Network Committee before a complaint is made to the Board that may result in the opening of an investigation into that person's activities.

We do understand why an intervention with a colleague, or even recognizing this in yourself, may be difficult. This is one definition of alcoholism (or you may substitute drug addiction) that may help us to understand a bit better why the alcoholic or addict acts the way he or she does. **Alcoholism (or addiction) is a disease, the very nature of which renders the victim incapable of recognizing the severity of the symptoms, the progression of the disease, and of accepting any ordinary offers of help.** This definition comes from Father Vernon Johnson, the founder of the Johnson Institute. It says the disease itself renders the victim incapable of recognizing the severity of the symptoms, how bad it is getting, and how much it is progressing. This may well be why it is so difficult to say to the alcoholic/addict, "Don't you see how bad your drinking is?" or "Don't you see how much worse your drinking is?" They do not see this. The disease has rendered them incapable of seeing this. It is contrary to the nature of the disease for them to see this.

So, what do you as a concerned loved one or colleague do when you see this happening? You may make the **extraordinary** offer of help and contact the Kentucky Professionals Recovery Network at 502/749-8385 or kyprn@att.net and speak with Brian Fingerson about how to obtain help for the person for whom you care about. We are most fortunate here in Kentucky that pharmacists and student pharmacists have options for help.

Official Method of Notification

The *Kentucky Board of Pharmacy Newsletter* is considered an official method of notification to pharmacists, pharmacist interns, pharmacies, wholesalers, and manufacturers credentialed by the Board. **These *Newsletters* will be used in administrative hearings as proof of notification.** Please read them carefully. The Board encourages you to store them electronically in a folder or keep them in the back of the *Kentucky Pharmacy Law Book* for future reference.

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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