



Oklahoma State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

4545 N Lincoln Blvd, Suite 112 • Oklahoma City, OK 73105-3413

Seasons Greetings

The members and staff of the Oklahoma State Board of Pharmacy would like join in wishing everyone happiness and all the best for the coming year.



Board Members and Staff

Dorothy Gourley, DPh.....	President
John Lassiter, DPh.....	Vice-President
Gordon Richards, DPh.....	Member
James O. Spoon, DPh.....	Member
Greg Adams, DPh.....	Member
Stephen Dudley.....	Member
John A. Foust, DPh.....	Executive Director
Mary Ann Terral.....	Business Manager
Susan Dozal.....	Administrative Programs Officer
Rhonda Jenkins.....	Registration Secretary
Erin Richardson.....	Administrative Technician
Cindy Hamilton, DPh.....	Chief Compliance Officer
Betty Beil, DPh.....	Senior Compliance Officer
Gary LaRue, DPh.....	Senior Compliance Officer
Chelsea Church, DPh, BCPS.....	Compliance Officer
Brinda White.....	Assistant Attorney General

From the Inspector's Desk

- ◆ **13.01. Faxed Refill Authorization Forms:** Drug Enforcement Administration (DEA) has ruled that pre-populating faxed refill authorization forms for physicians is not allowed. Pharmacists are not agents of the physician and may not prepare **controlled substance** prescriptions for the physician's signature. The pharmacist may communicate a refill request and the patient prescription history to the physician via fax but the physician must rewrite the prescription completely before faxing to the pharmacy. Further questions may be directed to DEA at 405/475-7500.
- ◆ **13.02. Hospital ERs and PMP:** Hospital emergency room (ER) departments need to be aware that they are required to submit all **dispensing** of controlled substances to the Prescription Monitoring Program (PMP). This does not include administration to inpatients or to ER patients while in the hospital. For further information, please contact Kelly Couch or Don Vogt at the Oklahoma Bureau of Narcotics and Dangerous Drugs (OBND) at 405/521-2885.
- ◆ **13.03. PSE Must Be Submitted to PMP:** All medications containing any amount of pseudoephedrine (PSE) sold **by prescription** are considered to be Schedule V drugs and must be submitted to the PMP. Also, for prescription PSE sales, make sure that you verify independently that the patient is not on the Meth Registry on the OBND Web site. This is updated information since the December 2, 2012 law seminar.
- ◆ **13.04. PSE Sales Effective January 1:** The OBND Web site will no longer be supporting over-the-counter PSE sales reporting, effective January 1, 2013. Your pharmacy should be signed up with the National Precursor Log Exchange (NPLEx). If your pharmacy or patients have any problems after January 1, please do not call OBND as they will not be able to assist you. Pharmacies should contact NPLEx at 1-855/656-7539 or OKNPLEx@appriss.com. Citizens should be directed to visit www.nplexanswers.com.
- ◆ **13.05. 2012 Pharmacy Law Book:** A PDF version of the 2012 *Pharmacy Law Book* containing the pharmacy laws and rules effective November 1, 2012, will soon be available for download at www.pharmacy.ok.gov. The online PDF version is searchable and you may print a copy if you choose. Access to the online copy counts toward your pharmacy library as the Board does not plan to print the 2012 *Pharmacy Law Book* for distribution and sale.
- ◆ **13.06. Disposal of Medications:** Patients often ask pharmacies how to dispose of their medications or ask the pharmacy to take them back. The Board has approved some medication disposal programs for non-controlled medications. Check the Board Web

Continued on page 4



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



Compliance News to a particular state or jurisdiction should not be assumed (regarding the law of such state or jurisdiction.)

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.



Pharmacists & Technicians:
Don't Miss Out on Valuable CPE Credit.
Set Up Your NABP e-Profile and
Register for CPE Monitor Today!

CPE Monitor™ integration is underway. Most Accreditation Council for Pharmacy Education (ACPE)-accredited providers should now be requiring you to submit your NABP e-Profile ID, assigned when you set up your NABP e-Profile, along with your date of birth (MMDD), in order to obtain continuing pharmacy education (CPE) credit for any ACPE-accredited activity.

Visit www.MyCPEmonitor.net to set up your e-Profile, obtain your e-profile ID, and register for CPE Monitor and avoid possible delays in your CPE reporting.

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.

site for more information. Federal guidelines recommend mixing medications with something undesirable such as kitty litter or coffee grounds before disposal.

Under no circumstances should a pharmacy take back controlled substances. A pharmacy may direct a consumer to dispose of controlled medications in the take-back boxes provided by the OBNDD in several locations around the state. They do not accept liquids, syringes, or inhalers. The nearest take-back box location may be found by visiting www.ok.gov/obnndd/documents/TakeBackBoxes.pdf.

Pharmacies or other registrants may not use take-back boxes for disposal of medications. They must use their wholesaler or a reverse distributor for proper documentation.

Disciplinary Actions

For more information you may view hearing minutes at www.pharmacy.ok.gov.

13.07. October 3, 2012 Board Hearing

Dustin Hunt, Technician #16147 – Case No. 1116: Admitted to theft and possession of a controlled dangerous substance (CDS) without a valid prescription. **Revoked.** (Agreed Order)

Clayton Barton, Technician #15924 – Case No. 1127: Found guilty of theft of money. **Revoked.**

Cassidy Climer, Technician #13553 – Case No. 1128: Found guilty of theft and possession of a CDS without a valid prescription. **Revoked.**

Jennifer Cook, Technician #10353 – Case No. 1129: Admitted to theft; possession of a CDS without a valid prescription; and abusing alcohol or drugs, using an illegal CDS substance, and/or testing positive for such substance or its metabolite. **Revoked.** (Agreed Order)

Kelly Jackson, Technician #14917 – Case No. 1131: Admitted to theft; possession of a CDS without a valid prescription; and abusing alcohol or drugs, using an illegal CDS substance, and/or testing positive for such substance or its metabolite. **Revoked.** (Agreed Order)

Victor Romero, Technician #16257 – Case No. 1134: Admitted to theft. **Revoked.** (Agreed Order)

Sharon Denmark, Technician #1269 – Case No. 1138: Found guilty of abusing alcohol or drug, using an illegal CDS substance, and/or testing positive for such substance or its metabolite. Failure to notify the Board, in writing, within 10 days of change of employment. **Letter of reprimand and suspension of permit until a fit for duty assessment from an Oklahoma Pharmacists Helping Pharmacists (OPHP)-approved provider is obtained.**

13.08. November 7, 2012 Board Hearing

Lindsey Hagood, Technician #5057 – Case No. 1130: Admitted to theft of CDS. **Revoked.** (Agreed Order)

Rebecca Johnson, Technician #14458 – Case No. 1132: Admitted to forgery of CDS prescription. **Revoked.** (Agreed Order)

Mercy Szalaj, Technician #11564 – Case No. 1133: Admitted to taking new prescriptions over phone and authorizing new and refill CDS prescriptions without prescriber authorization. **Revoked.** (Agreed Order)

Larry's Pharmacy, #55-4503 – Case No. 1135: Admitted to three violations of the Oklahoma Pharmacy Act including failing to ensure prescriptions had been issued for legitimate medical purpose; failing to guard against diversion; and failing to supervise technician. **Nine-thousand dollar fine and updated policy and procedure manual due to the executive director of the Board for review by December 7, 2012.** (Agreed Order)

Larry Hobbs, DPh, #8240 – Case No. 1136: Admitted to 11 violations of the Oklahoma Pharmacy Act including failing to ensure prescriptions had been issued for legitimate medical pur-

pose; failing to guard against diversion; and failing to supervise technician. **Five years probation; \$16,500 fine; eight-hour law seminar in 2012 and 2013 in addition to required 15 hours of continuing education (CE); and must complete all live CE during probation.** (Agreed Order)

Russell Hobbs, DPh, #14375 – Case No. 1137: Admitted to five violations of the Oklahoma Pharmacy Act including failing to ensure prescriptions had been issued for legitimate medical purpose; failing to supervise technician. **Five years probation; \$7,500 fine; eight-hour law seminar in 2012 and 2013 in addition to required 15 hours of CE; and must complete all live CE during probation.** (Agreed Order)

Cameron Crupper, Technician #13406 – Case No. 1139: Admitted to receiving a positive drug screen. **Revoked.** (Agreed Order)

Cameron Perkins, Technician #10996 – Case No. 1142: Found guilty of theft of CDS. **Revoked.**

New England Compounding Center, #99-722 – Case No. 1143: Admitted to failing to maintain original license in resident state in good standing. **Revoked.** (Agreed Order)

Calendar Notes

The Board will meet on **January 16**. The Board will be closed Monday, **January 21**, for Martin Luther King, Jr, Day; and Monday, **February 18**, for Presidents' Day. Future Board dates will be available at www.pharmacy.ok.gov and will be noted in the April Newsletter.

Change of Address or Employment?

Please be diligent in keeping your information up to date and if possible, remind your coworkers and employees. This continues to be an ongoing problem and failure to notify the Board is a violation of Oklahoma pharmacy law. All pharmacists, technicians, and interns must notify the Board in writing within 10 days of a change of address or employment. Online updates through the license renewal page are also accepted as official notification.

Special Notice About the Newsletter

The *Oklahoma State Board of Pharmacy Newsletter* is an official method of notification to pharmacies, pharmacists, pharmacy interns, and pharmacy technicians registered by the Board. Please read them carefully. The Board encourages you to keep them for future reference.

Oklahoma Pharmacists Helping Pharmacists

If you or a pharmacist you care about is suffering from chemical dependency, there is a solution. OPHP is readily available for help. Pharmacists in Oklahoma, Texas, and Louisiana may call the OPHP help-line at 1-800/260-7574, ext. 5773. All calls are confidential.

“This publication is issued by the Oklahoma State Board of Pharmacy as authorized by Title 59 O.S. 353.7. Copies have not been printed but are available through the agency website.”