February 2013

News

Arkansas State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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New Web Site – PharmacyBoard.Arkansas.Gov

The Arkansas State Board of Pharmacy has a new Web site: *http://pharmacyboard.arkansas.gov.*

Board Plans for Move of Board Offices

The Board is planning to change locations in the summer of 2013. With this projected move, the Board will have office space that is more functional for its staff and meetings, and will include a boardroom sufficient to hold interested parties for Board meetings as well as interprofessional workgroups as the Board partners with others on issues such as prescription drug abuse, prescription drug take-back programs, law tests, law reviews, and educational opportunities delivered from the Board staff. The Board will also have a conference room that will function very well for smaller meetings with Board staff and committee meetings for the Board. While the Board has been in its current space since 1993, its workload and space needs have increased greatly. This has been a great place to be, but the Board is truly looking forward to the opportunities this move will provide in delivering more services to the public as well as the Board's permit holders while remaining in downtown Little Rock, AR. With this move, the Board anticipates updating all permit holders with the Board in respect to its new address once the move is confirmed and a date is set.

Compounding Pharmacy Issues

Most everyone has heard of the recent tragedy surrounding the inappropriate compounding of products that has affected so many people around the nation with fungal meningitis. In the aftermath of this tragedy, the Board has seen numerous responses and emergency changes to pharmacy rules around the nation. In Massachusetts, the home state of the pharmacy with the tainted products, one of the state's immediate responses was to order its board to conduct regular, unannounced inspections. The Arkansas Board is proud to say that it has done regular inspections of its pharmacies for years and it makes every effort to inspect each one at least once annually. The Board's review of the 2012 inspections shows that 667 of the 748 pharmacies in Arkansas were inspected between January 1 and December 7. This number does not include additional site visits for changes of location, new openings, or the multiple visits and walk-throughs the Board does routinely for its major compounding pharmacies. It is also important to note that all of the Board's pharmacy inspectors as well as executive and assistant directors are licensed pharmacists with experience and expertise in various areas of pharmacy practice. Board staff has sought out and received training in regard to United States Pharmacopeia standards such as Chapter 797 and has incorporated sterile compounding inspection surveys into the Board's workflow for any pharmacies that are preparing sterile products. While the Board does not claim this to be an absolute safety net, the Board continues to pursue additional opportunities for training and learning opportunities to continually improve its efforts in inspecting compounding pharmacies.

As a reminder to any pharmacies that are preparing compounded products for distribution in or into Arkansas, be sure to review Regulation 07-02: COMPOUNDING, pertaining to pharmacy compounding, which details Board requirements for sterility, potency, and endotoxin testing that must be followed prior to dispensing or administration of products.

Renewals Continue

Renewals are underway for the following permits/registrations that expired December 31, 2012: pharmacy technicians, charitable clinic pharmacies, institutional pharmacies, wholesale distributors, List 1 chemical distributors, hospital pharmacies, and durable medical equipment permits. Charitable clinic permits and charitable clinic pharmacy technician permits cannot be renewed via the Internet, but all others may be renewed through the Board's Web site. Once again, renewing these permits via the Internet will allow use of a credit card for payment and will also greatly reduce the turnaround time for delivery of the new permits. Please also remember to update your contact information when renewing as well as throughout the year whenever a change of address or other contact information occurs. Penalties apply for late renewal in February and March, and any permit that is not renewed by April 1, 2013, is void.

Arkansas's Sixth Prescription Drug Take-Back Day to Be Held April 27, 2013

The next Arkansas Prescription Drug Take-Back Day will occur as part of the Drug Enforcement Administration (DEA) sponsored National Take-Back Initiative on April 27, 2013. Please use this opportunity to educate your patients and your community regarding the importance of **monitoring** their medications, **securing** prescription drugs, and **disposing** of unused and unneeded medications properly. Previous Arkansas take-back efforts collected 47,352 pounds of unused medications reflecting an estimated 65.9 million pills and dosage units of medications that are no longer wanted or needed that have been properly disposed.

Once again, through the efforts of our law enforcement and partner agencies in Arkansas, our state has made a tremendous effort to address the prescription drug abuse problems that we face, especially with our youth. The Board looks forward to future efforts in this endeavor and hopes that you will encourage law enforcement in your own area to continue working with the Arkansas Prescription Drug Take-Back initiatives and that you will visit *www.artakeback.org* for more information.

Disposal of Controlled Substances

The December 21, 2012 *Federal Register* included DEA's Notice of Proposed Rulemaking, which was followed up on the DEA Web site with the following release:

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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.

Continued from Page 1

DEA Publishes Proposed Regulations for Disposing of Controlled Substance Prescription Drugs

DEC 26 (WASHINGTON, D.C.) – The Drug Enforcement Administration (DEA) published its Notice of Proposed Rulemaking for the Disposal of Controlled Substances in the Federal Register Dec. 21. The proposed regulations seek to implement the Secure and Responsible Drug Disposal Act of 2010.

According to the 2011 Substance Abuse and Mental Health Services Administration's National Survey on Drug Use and Health, more than six million Americans abuse prescription drugs. That same study revealed more than 70 percent of people abusing prescription pain relievers got them through friends or relatives, a statistic that includes raiding the family medicine cabinet. Medicines that languish in home medicine cabinets are highly susceptible to diversion, misuse, and abuse. Rates of prescription drug abuse in the U.S. are alarmingly high—more Americans currently abuse prescription drugs than the number of those using cocaine, hallucinogens, and heroin combined.

This rule proposes requirements to govern the secure disposal of controlled substance medications by both DEA registrants and what the Controlled Substances Act refers to as "ultimate users" of these medications (patients and animals). The proposed regulations seek to expand the options available to collect these medications from ultimate users for the purpose of disposal, to include take-back events, mail-back programs, and collection box locations. The proposed regulations contain specific provisions that:

- Continue to allow law enforcement agencies to voluntarily conduct take-back events, administer mail-back programs, and maintain collection boxes;
- Allow authorized manufacturers, distributors, reverse distributors, and retail pharmacies to voluntarily administer mail-back programs and maintain collection boxes;
- Allow authorized retail pharmacies to voluntarily maintain collection boxes at long term care facilities.

The public can review an electronic copy of this document at *http://www.gpo.gov/fdsys/pkg/FR-2012-12-21/pdf/2012-30699.pdf* and has 60 days to submit comments, until February 19, 2013. DEA encourages interested parties to comment on this important proposed rule.

The Board would encourage you to take a look at these proposed regulations and consider providing comments to DEA regarding this issue.

This information was obtained on January 9, 2013, from *www.justice.gov/dea/divisions/hq/2012/hq122612.shtml.*

Newsletter/Notification Changes

The Arkansas State Board of Pharmacy periodically sends out updates, *Newsletters*, current topics, and notifications by mail and/or e-mail. During the June 2012 meeting, the Board voted to phase out the mailing of these *Newsletters* in favor of sending electronic reminders of current issues as well as links to the quarterly *Newsletter* as posted on the Board Web site. As part of this process, it is important to ensure that your contact information is current with the Board office including your e-mail address as a point of contact.

If you would like to check your contact information you may do so through the Board Web site by clicking on the License Maintenance link. Once you reach that screen, enter your license number, which includes PD as a designator for pharmacists and PT for technicians, followed by a five-digit number. If your license only has four numbers then put a zero in front of those four digits such as PD01234 for the number 1234. Also, do not forget to update your information if you move or change jobs. Printed *Newsletters* will end after the May 2013 *Newsletter* and will switch to electronic format, which will be available on the Board's Web site.

Special Notice About the Arkansas State Board of Pharmacy Newsletter

The Arkansas State Board of Pharmacy has designated this *Newsletter* as an official method to notify pharmacists licensed by the Board about information and legal developments. Please read this *Newsletter* and keep it for future reference because this *Newsletter* will be used in hearings as proof of notification of the *Newsletter's* contents. Please contact the Board office at 501/682-0190 if you have questions about any of the articles in this *Newsletter.*

Arkansas Pharmacy Support Group Help Line
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