December 2010

Arkansas State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

101 E Capitol, Suite 218 • Little Rock, AR 72201 • Tel: 501/682-0190 • Fax: 501/682-0195

Regulation Changes Approved during October 2010 Board Meeting

The following regulation changes were discussed in a public hearing during the October 13, 2010 Arkansas State Board of Pharmacy meeting. These changes have all been adopted and updated regulations have been placed on the Arkansas State Board of Pharmacy Web site, *www.arkansas.gov/asbp,* in the Pharmacy Lawbook section. Below are summaries of the substantive changes to the regulations, which may be viewed in their entirety on the Board Web site.

Regulation 02 – Pharmacists

Changes to Regulation 2 will:

1. Allow for consideration of a pharmacist's practice history outside a permitted pharmacy when applying for reciprocity.
2. Update language regarding the North American Pharmacist Licensure Examination® (NAPLEX®) to reflect changes made by NAPLEX and to reflect the period of validity for a score transfer.
3. Update requirements for Board of Pharmacy accreditation of pharmacist continuing education. This will decrease the amount of time needed in advance for program approval and will also explain requirements for anyone requesting continuing education so that the Board can verify participation by pharmacists.

Regulation 04 – Pharmacy

Changes to Regulation 4 will:

1. Clarify that both the pharmacist-in-charge and the pharmacy permit holder are responsible for the security and accountability of controlled substances. These changes will describe the different roles of the permit holder and pharmacist-in-charge and give examples of appropriate steps and procedures that pharmacies and pharmacists may take in order to maintain security over controlled substances. The Board developed these changes in response to the suggestions of a Controlled Loss Prevention Task Force which included community pharmacists, drug store owners, the association, Board staff, and other interested parties. This change is necessary in order to give additional guidance to pharmacies and pharmacists regarding appropriate procedures for controlled substances in pharmacies. This regulation is also being pursued in response to cases involving losses of controlled substances and data showing the severe state of prescription drug abuse in Arkansas.
2. Add a section providing guidance on how a pharmacy may provide prescription medications to animals as part of a contractual agreement with the veterinarian. This change was discussed and drafted pursuant to requests from community pharmacists and veterinarians via a Board committee to develop a way for these professionals to work more closely together in treating animal populations.
3. Update requirements for the handling of paper prescription orders by a pharmacy when processed, which will decrease the burden of maintaining paper files of these prescriptions. This regulation change is being pursued at the request of the Arkansas Pharmacists Association as well as community pharmacies.
4. Add language requiring hospitals to develop and routinely evaluate medication error reduction plans to identify medication related errors to increase safety in hospitals. This is something that most hospitals are already doing, but it was suggested for a regulation change by the Advisory Committee for Hospital Pharmacies as a patient safety measure.

Regulation 07 – Drug Products/Prescriptions

Changes to Regulation 7 will delete the prohibition on pharmacy compounding for veterinarian office stock. This will allow pharmacies to prepare customized medications to be administered by veterinarians in their practice, which will give veterinarians additional choices to best treat animals.

Update on September 25, 2010 Drug Take-Back Day

On September 25, 2010, Arkansas participated in the Drug Enforcement Administration (DEA)-sponsored national drug take-back initiative supporting this nationwide effort through local law enforcement and numerous regulatory agencies as part of the state drug director's ongoing efforts to address the proper disposal of expired and unused medications. The Arkansas State Board of Pharmacy has been honored to have participated in this process and would also like to express its appreciation to all of the other regulatory agencies, law enforcement officers, pharmacies, and pharmacists that participated in this event. With information still coming forth on this project at the time of editing the Board thought it would be a good time to update everyone on the success of this program, thus far.

Per DEA, **5,407** pounds of unused medications were collected in Arkansas and returned through DEA for destruction at Clean Harbors in El Dorado, AR. That is well over **2.5** tons of unused medications estimated to represent **seven to nine million dosage units.** According to DEA's Web site, there were 4,094 total return sites registered nationwide with 201 of those sites registered in Arkansas. The average number of registered sites per state was 82

Continued on page 4

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*.

Continued from page 1

showing that Arkansas had roughly 2.5 times the national average of sites. Furthermore, the average number of registered law enforcement agencies per state participating in take-back programs was 60. Arkansas had 186 registered law enforcement agencies participating in this program, which was triple the national average. This project has shown that Arkansas is taking the abuse of prescription drugs seriously and even though its population only represents 2.85 million people, Arkansas is well above average in working toward positive outcomes on this issue. When reviewing this project it is important to note that these millions of pills collected on Sept 25:

- Were no longer wanted or needed by those who possessed them
- Will never be accidentally ingested or poison anyone
- Will never be stolen or sold
- Will never be misused or abused by anyone
- Will never cause an overdose
- Will never be part of teens' experimentation with prescription drugs
- Will never start or feed anyone's addiction
- Will never be the catalyst for a criminal diversion case
- Will not harm the environment via flushing and will not contaminate waterways or leach into the water table from landfills.

Once again, please continue to support this project by informing your patients to increase their awareness regarding what medications they have in their homes, informing them how to secure their medications, and informing them how to appropriately dispose of their medications when they are no longer needed. These three steps could help prevent countless problems and potential injuries or death from prescription drug abuse. Please refer to the Web site *www.ioit2me.com* for information regarding drug abuse that may be beneficial to parents and teens. You can also help educate patients on the SMARxT Disposal program, which they can follow at any time to dispose of their medications at home.

For more information, please visit *www.ioit2me.com* and *www.smarxtdisposal.net.*

Technician Permit Renewals

The Arkansas State Board of Pharmacy sent out pharmacy technician permit renewals in October. These permit renewal reminders are sent directly to pharmacy technicians at their address of record and it should be noted that technician permits that are not renewed will expire on December 31, 2010. The Arkansas State Board of Pharmacy allows a grace period until March 31, on permits. However, there is a $20 penalty on a technician permit renewal if not renewed by February 1, a $40 penalty if not before March 1, and if a permit is not renewed by April 1, then the permit is void. The Board strongly encourages you to use the Board's Web site to renew technician permits via the Internet as it will speed up the renewal process for your technicians and it will also reduce the turn around time for technicians to receive their new permits. This is also the only way that the Board can accept credit card payments for renewal of these permits.

Business Permit Renewals

The following additional permits are also in their renewal cycle at this time: charitable clinic pharmacies, institutional pharmacies, wholesale distributors, List 1 chemical distributors, hospital pharmacies, nursing home consultants, and durable medical equipment permits. Charitable clinic permits and institutional 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 turn around time for delivery of the new permits.

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

870/636-0923

The *Arkansas State Board of Pharmacy News* is published by the Arkansas State 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.

John Kirtley, PharmD - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Larissa Doucette - Communications Manager

National Association of Boards of Pharmacy Foundation, Inc
1600 Feehanville Drive
Mount Prospect, IL 60056

ARKANSAS STATE BOARD OF PHARMACY

Presorted Standard
U.S. Postage
PAID
Chicago, Illinois
Permit No. 5744