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News

Arkansas State Board of Pharmacy

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New Pharmacy Statutes = New Pharmacy Regulations

During the 2011 Arkansas General Assembly there were several pieces of pharmacy legislation passed that directly impact the Pharmacy Practice Act. Some of these statutory changes will also precipitate modifications and additions to Arkansas Pharmacy Regulations, which will be considered in June. At the time of submission for this *Newsletter*, the Arkansas State Board of Pharmacy members and staff are working on language changes for these regulations and will be posting them on the Board's Web site at *www.arkansas.gov/asbp* under the Pharmacy Lawbook section.

Here is an overview of some of the new legislative acts passed in the 2011 legislative session. Most of these will become effective in late July, which will be 90 days after the anticipated *sine die* adjournment of the legislature. To view any of these in their entirety, you can go to the Arkansas General Assembly Web site at *www.arkleg.state.ar.us* and type in the bill or act number to view them.

SB902 – Act 597

AN ACT TO MAKE CONSISTENT THE LAW REGARDING LICENSURE FOR PHARMACISTS AND PHARMACIES AND ADVERSE ACTIONS

In summary, these changes to the practice act will do three things. First, this will line up the dates of expiration for pharmacist consultant and preceptor permits to expire on December 31, of each odd numbered year. This will mean that any endorsements on your pharmacist license will expire at the same time as your pharmacist license and will be renewable along with your pharmacist license rather than other times throughout the licensure biennium. Second, this clarifies the ability of the Board of Pharmacy to take action to revoke or suspend an existing certificate of licensure, license, registration, or permit or refuse to issue a certificate of licensure, license, registration, or permit based upon a list of criteria as outlined in the statute. This is another way to show that all permit holders are responsible to uphold the same criteria or can be punished for the same criteria. The third issue defines the Board's ability to take action on a pharmacist who is either physically or mentally incompetent to practice pharmacy to such an extent as to endanger the public. This is a measurable issue for the Board of Pharmacy to consider when a pharmacist is a risk to the public for one of these reasons.

SB437 – Act 588

AN ACT TO CLARIFY THE ROLE OF PHARMACISTS WITH REGARD TO EPHEDRINE, PSEUDOEPHEDRINE, OR PHENYLPROPANOLAMINE

This act adds language in the Pharmacy Practice Act establishing over-the-counter (OTC) products containing ephedrine, pseudoephedrine, and phenylpropanolamine as medications that can only be sold in a pharmacy pursuant to a professional determination by a pharmacist, based on a pharmacist-patient relationship, as to whether or not there is a legitimate medical and pharmaceutical need for the drug. This professional determination may be based on factors including without limitation:

(i) prior medication-filling history;

(ii) patient screening; and

(iii) other tools that provide professional reassurance to the pharmacist that a legitimate medical and pharmaceutical need exists.

These changes also define "proof of age" and "proof of identity" to mean a driver's license or identification card issued by the Arkansas Department of Finance and Administration or an identification card issued by the United States Department of Defense to active duty military personnel that contains a photograph of the person, the person's date of birth, and a functioning magnetic stripe or bar code. These changes keep the current sales limit criteria for these products and also ensure that they will continue to be logged into a statewide sales database when sold as pharmacist-only OTC items.

SB130 – Act 147

AN ACT TO CLARIFY THE AUTHORITY OF PHARMACISTS TO PROVIDE VACCINES AND IMMUNIZATIONS AND TO ADMINISTER CERTAIN MEDICATIONS

Changes from this act will allow pharmacists to administer medications to anyone seven years of age or older as part of written protocols specifically outlined in the act.

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Obtain Your NABP e-Profile ID Online Now, ID Required for ACPE-Accredited CPE

The new National Association of Boards of Pharmacy® (NABP®) CPE Monitor service, a collaborative effort between NABP, the Accreditation Council for Pharmacy Education (ACPE), and their providers, will allow pharmacists and technicians to easily track their ACPE-accredited continuing pharmacy education (CPE) credits beginning in the latter part of 2011. In addition, the service will provide a streamlined reporting and compliance verification process for participating state boards of pharmacy. When pharmacists and technicians complete an ACPE-accredited CPE program, their participation data will be sent electronically from the provider to ACPE, then to NABP for recording into the matching NABP e-Profile. Then, if the board of pharmacy participates in CPE Monitor, the pharmacists' or technicians' CPE credits will be automatically transmitted to the board, saving pharmacists and technicians the trouble and expense of documenting and submitting compliance with state-mandated CPE requirements for license renewal. This eliminates paper forms and the overall need to submit paper copies of CPE statements of credit to the board of pharmacy for CPE activities from ACPE-accredited providers.

For convenience, the NABP e-Profile will be available 24/7 for viewing a comprehensive list of the CPE activities completed. All information will be maintained in a highly secure environment. NABP does not distribute any personal information for commercial purposes without consent.

To prepare for the new process, pharmacists and technicians are encouraged to obtain their NABP e-Profile identification to ensure their e-Profile is properly set up. Beginning in the latter part of 2011, all pharmacists and technicians will be able to provide their NABP e-Profile ID, plus their birth date (mmdd) to receive credit for any accredited CPE activities from ACPE-accredited providers. Providers will ask CPE participants to provide the ID either when registering or when submitting participation data to the provider. Please note that CPE Monitor will not initially track CPE from non-ACPE-accredited providers. This feature will be added in Phase 2 of the CPE Monitor service, and, until then, pharmacists and technicians will need to submit non-ACPE-accredited CPE directly to their board of pharmacy when required to do so.

NABP and ACPE will work with CPE providers to ensure an adequate amount of time is allotted to implement this new service.

Pharmacists can obtain their ID by creating an NABP e-Profile using the portal in the Pharmacists section of the NABP Web site at *www.nabp.net/pharmacists*. Technicians can obtain their ID by creating an NABP e-Profile using the portal in the Technicians section of the NABP Web site at *www.nabp.net/technicians*. Visit *www.MyCPEmonitor.net* for more information.

FDA Asks Manufacturers to Limit Acetaminophen Strength

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

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

Looking for Risk

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also a FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

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

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

FMEA

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

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

AROC

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

Pharmacists' Role

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

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

- Explain the important processes and sub-processes of medication use from prescription through administration.
- Participate in identifying failure modes and risk throughout the entire medication process, especially in information that should be available to the prescriber and nurse, as well as describing the steps in the process that occur after the medication order is transferred to the pharmacy.
- Offer possible causes for medication errors because of breakdowns in the prescription to administration process.
- Identify effects, as well as their severity and probability, when a system failure occurs.
- Offer suggestions, along with all team members, for actions that should be taken to prevent medication errors.

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

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

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

NABP Launches New and Improved NAPLEX/ MPJE Application in March

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

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

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

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

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

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

In addition, the score results for the NAPLEX and MPJE are also accessible when candidates log in to the application, provided that the board for which the candidate tested participates in the online score interface. Currently, 25 boards utilize this service.

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

New FDA Drug Info Rounds Training Video

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

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SB973 – Act 1019

AN ACT TO AUTHORIZE INTERSTATE RECIPROCITY FOR LICENSURE OF PHARMACISTS AND PHARMACIES

This act adds the following language in the statute: "The Arkansas State Board of Pharmacy *may* adopt rules applicable to a pharmacy or a pharmacist licensed in another state that renders services in Arkansas that mirror qualifications, requirements, prerogatives, prohibitions, and limitations imposed by the other state on Arkansas pharmacies and pharmacists rendering services in the other state."

HB2186 – Act 839

AN ACT TO ENSURE THAT AT LEAST FIVE MEMBERS OF THE ARKANSAS STATE BOARD OF PHARMACY ARE ACTIVELY ENGAGED IN THE PRACTICE OF PHARMACY

SB345 – Act 304

AN ACT TO ESTABLISH A PRESCRIPTION DRUG MONITORING PROGRAM

SB789 – Act 1007

TO PRESERVE THE PROFESSIONAL INDEPENDENCE OF A PHARMACIST AND A PHARMACY; TO PROHIBIT INTERFERENCE WITH THE PHARMACIST-PATIENT RELATIONSHIP OR THE PRACTICE OF MEDICINE

SB722 – Act 517

AN ACT TO CLARIFY THE PROCEDURES FOR RECOUPMENT OF COSTS UNDER THE ARKANSAS PHARMACY AUDIT BILL OF RIGHTS

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 were not renewed expired on December 31, 2010. The Board would like to remind pharmacists that any permits that were not renewed by April 1, are void. This means that in order to get a technician permit again, an individual must apply for reinstatement and undergo a criminal background check, which includes fingerprinting and payment of reinstatement fees. More importantly, if a technician's permit was not renewed then they cannot legally perform technician duties until they have a new registration approved and a new permit to display in the pharmacy. As a reminder to pharmacists, past action by the Board regarding the employment of technicians without a valid permit or technicians who have allowed their permit to lapse has resulted in a $500 fine for the pharmacist-in-charge, a $1,000 fine for the pharmacy, and the technician being put on probation. The Board encourages you to check the permits posted in your facility to be sure that they are current as posted.

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 (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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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.

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