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News

Arkansas State Board of Pharmacy

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Pharmacist License and Other Permit Renewals

The Arkansas State Board of Pharmacy sent out pharmacist and pharmacy permit renewals during October 2009. While these renewals are sent directly to the individual's mailing address on record, the Board has had a number of pharmacists who have called saying that they have not received a renewal notice. In most cases this has been due to a change of address that the Arkansas State Board of Pharmacy has not been notified of. This is a violation of pharmacist registration requirements and may be subject to disciplinary action. Furthermore, it should be noted that the permits that were not renewed expired on December 31, 2009. The Arkansas State Board of Pharmacy allows a renewal grace period until March 31 on permits; however, there is a $20 penalty on permit renewals 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 license or permit is void. This means that in order to get a pharmacist license reactivated, an individual must apply for reinstatement and undergo a criminal background check, which includes fingerprinting and payment of reinstatement fees. While pharmacists are responsible for keeping their license current, it is the responsibility of the pharmacist-in-charge of any pharmacy or other facility to be sure that all employees including pharmacists, pharmacy interns, and pharmacy technicians have current licenses in good standing with the Arkansas State Board of Pharmacy. Any pharmacist who works after April 1, without renewing his or her pharmacist license will be called before the Board for disciplinary action. **Once again, the best way to renew your license will be through the Internet.** This is the fastest way to renew your permit and is also the only way to use a credit card to renew any permit or license with the Arkansas State Board of Pharmacy. To renew your pharmacist or pharmacy permit, go to the Board of Pharmacy Web site at *www.arkansas.gov/asbp* and click on the heading CURRENT RENEWAL INFORMATION for full instructions to renew your permit. Please remember to have your pharmacist or facility license or permit number when calling the Board office to ensure faster service.

Immunization Certification

As a reminder to Arkansas pharmacists, if you are planning to administer immunizations and vaccines, or other approved medications, you must have met all of the requirements set forth in the statute and Board Regulation 09-00-0002 (b) Authority to administer medications/immunizations. These requirements must be met before a pharmacist may administer immunizations and vaccines, regardless of the route of administration (injectable or inhalation). The pharmacist must possess a Certification for the Authority to Administer Medications/Immunizations issued by the Board to be qualified to accept an Authority to Administer contract with a physician and must maintain a current certification in Cardiopulmonary Resuscitation or Basic Cardiac Life Support. The Authority to Administer Medications/Immunizations expires on the same date as your pharmacist license and must be renewed each biennium. The certificate should be displayed in the pharmacy along with your pharmacist license and must be current in order to administer any medications.

Additionally, the Authority to Administer is discussed in Board Regulation 09-00-0002 and ACA §17-92-101 (16) and ACA §17-92-101 (22) (B). Here are a few things to remember:

- The administration of medications shall not include the administration of medications to any person under the age of 18.
- The administration of medications shall be limited to the following classifications of medications: immunizations, vaccines, allergy medications, vitamins, minerals, antihyperglycemics, and antinausea medications.
- An Authority to Administer for **immunizations and vaccinations** may be a general protocol.
- An Authority to Administer, once granted, is valid for a time period not to exceed one year.

Please contact the Board office at 501/682-0190 if you have any questions regarding vaccinations, immunizations, or the Authority to Administer.

Continuing Education Update

The Board of Pharmacy continuing education (CE) requirements for the 2010-2011 biennium have been updated and are now in effect for renewing your pharmacist license that will expire December 31, 2011. During this biennium you must obtain 30 hours of total CE. In the 30 hours of required CE, 12 hours must be live of any type of CE (Board-approved or Accreditation Council for Pharmacy Education (ACPE)-approved) and 12 hours must be ACPE-accredited hours.

The individual requirements for 12 live and 12 ACPE requirements are not mutually exclusive and as long as in the 30-hour total, 12 live hours are obtained and 12 hours of the 30 are ACPE-accredited, the criteria will be met by the pharmacist.

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FDA and ISMP Warn of Potential Medication Errors for Dosing and Emergency Compounding of Tamiflu

Food and Drug Administration (FDA) issued a Public Health Alert regarding potential dosing errors with Tamiflu® (oseltamivir) for oral suspension. While United States prescriptions for liquid medicines are generally written in milliliters or teaspoons, Tamiflu is dosed in milligrams and packaged with a dispenser marked in milligram dosages. Errors where dosing instructions for the patient do not match the dosing dispenser have been reported to FDA. FDA advises that providers should write doses in milligrams if the dosing dispenser with the drug is in milligrams. Pharmacists should ensure that prescription instructions and the dosing device use the same unit of measure. More information can be accessed at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm183714.htm.*

The Institute for Safe Medication Practices (ISMP) issued an alert to all health care professionals regarding a risk of dosing errors related to the concentration of pharmacy-compounded Tamiflu (oseltamivir phosphate) oral suspension being dispensed due to shortages of the manufacturer's oral suspension. The base concentration for the commercially manufactured Tamiflu oral suspension is 12 mg/mL. The directions for emergency compounding of Tamiflu oral suspension from Tamiflu powder capsules result in a 15 mg/mL oseltamivir base concentration. Incidents have occurred resulting in too large of a dose being dispensed to children. ISMP advises that prescribers communicate suspension doses in milligrams rather than by volume, and that, if experiencing shortages of commercial Tamiflu oral suspension, pharmacists communicate with area medical practices regarding the dosage error risk. More information may be found at the ISMP Web site at *www.ismp.org/safetyalerts/20091015-Tamiflu.asp*.

FDA Authorization for Use of Outdated Tamiflu Products Remains in Effect until April 2010

On October 30, 2009, FDA issued an Emergency Use Authorization (EUA) allowing pharmacists to dispense certain lots of expired Tamiflu for oral suspension as part of the federal government's response to the 2009 H1N1 influenza public health emergency. The declaration of emergency justifying the EUA remains in effect until April 26, 2010, unless it is terminated earlier, or extended. The authorized lots of Tamiflu for oral suspension, which were tested through the federal government's Shelf-Life Extension Program, are part of the Strategic National Stockpile and are listed on the FDA Web site at *www.fda.gov/NewsEvents/PublicHealthFocus/ucm154962.htm*. Additional information for health care professionals and the EUA letter are also available on the FDA Web site.

HIPAA and Quality – The Seven-Year Itch

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.*

On April 24, 2003, an article in the *Wall Street Journal* noted that many health care providers "are going overboard to avoid violations" of the Health Insurance Portability and Accountability Act (HIPAA) privacy rule, which took effect on April 14 of that year. In fact, initial concern was that the rule might actually slow the transfer of protected health information and place patients at risk for harm, certainly the opposite of HIPAA's intended goal.

One particularly troubling area of confusion is whether listing the drug's intended purpose on a prescription violates the privacy rule. Initially, numerous organizations reported that physicians were reluctant to include this crucial information on prescriptions. But according to the US Department of Health and Human Services (HHS), listing a medication's purpose or the patient's diagnosis on a prescription does not violate the privacy rule. Although a patient's diagnosis or purpose for using a medication would qualify as protected health information, communicating this information on a prescription does not require separate, special authorization because the information is used for the purposes of treating the patient. A violation would occur only if the prescription form was then used for a purpose not defined by the HIPAA privacy rule, such as copying it for a marketing company.

Concerns were also raised that listing a purpose on prescriptions did not meet qualifications of providing only the minimum amount of information necessary to treat the patient. However, the "minimum necessary" rule does not apply when protected health information is disclosed between providers treating the same patient. ISMP firmly believes that the drug's intended purpose should be part of the "minimum amount of information necessary" on a patient's prescription. Pharmacists should never be expected to dispense a medication without knowing its intended use, which is typically the case in many community pharmacies. Knowing the

medication's purpose helps pharmacists avoid confusion between products with look-alike names, as most products with similar names are used for different purposes. It also allows a double check to occur because the pharmacist is able to verify that the medication is being used appropriately for the patient's condition, and that it is dosed properly for its intended use.

The same arguments hold true for medication reconciliation. It is not a violation of the HIPAA privacy rules for community pharmacies to share patient information for the purposes of reconciling a patient's medication profile with hospitals because the minimum necessary rule does not apply when protected health information is disclosed between providers treating the same patient.

Seven years later, the best advice is still to use common sense when applying the HIPAA rules so that patient privacy and safety are not compromised.

USP Standards for Heparin Products May Require Dosage Adjustments

Heparin products using new standards began shipping on October 8, 2009, and may require that dosages are adjusted to achieve consistent potency, according to a FDA alert. New manufacturing controls issued by United States Pharmacopeia (USP) were adopted for heparin to guard against potential contamination. Included in the new controls were changes in the unit dose, making heparin about 10% less potent than the former unit used. More information can be found at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm184674.htm*.

FDA Issues Alert, Seeks Assistance in Tracking Stolen Tylenol Arthritis and Tylenol PM Caplets

FDA has issued an alert regarding stolen Tylenol® Arthritis and Tylenol® PM products. Pharmacists should be wary of the following Tylenol products:

- Tylenol Arthritis Pain Caplet 150 count bottles with the following identifying information: UPC number 30300450838155, code number 8381500, and lot number 09XMC112.
- Tylenol PM 2-caplet packets with the following identifying information: UPC number 30300450482304, code number 4823000, and lot number 09XMC110.

The theft took place at a cargo terminal at the Jacksonville Port Authority in Jacksonville, FL on September 25, 2009.

FDA seeks assistance in tracking this theft and is asking pharmaceutical drug distributors and pharmacies that may receive offers for the stolen drug products, or that may have been sold stolen product, to contact FDA's Office of Criminal Investigations (OCI) by phone at 800/551-3989 or on the OCI Web site at *www.fda.gov/ICECI/CriminalInvestigations/ucm123025.htm*. Pharmacists should verify pedigrees they receive with any wholesale drug purchases. News regarding the alert can be found at *www.fda.gov/ICECI/CriminalInvestigations/ucm186269.htm*.

FDA Warns Companies to Stop Marketing Unapproved Codeine Sulfate Tablets

On October 13, 2009, FDA warned four companies to stop marketing unapproved codeine sulfate tablets. The manufacturers and distributors that received warning letters are as follows:

- Lehigh Valley Technologies Inc in Allentown, PA
- Cerovene Inc in Valley Cottage, NY
- Dava International Inc in Fort Lee, NJ
- Glenmark Generics Inc USA in Mahwah, NJ

FDA regulations allow manufacturers 90 days to cease manufacturing of new product, and distributors 180 days to cease further shipment of existing products. Previously manufactured unapproved products may still be found on pharmacy shelves for a period of time. FDA advises that Roxane Laboratories markets FDA-approved codeine sulfate tablets and is able to meet the demand for the drug. For additional information about the warning letters, visit *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm186418.htm*.

2010 Survey of Pharmacy Law Now Available

Serving as a convenient reference source for individuals seeking an overview of the state laws and regulations that govern pharmacy practice, the updated 2010 *Survey of Pharmacy Law* is now available.

The *Survey*, produced as a CD, consists of four sections including a state-by-state overview of organizational law, licensing law, drug law, and census data. Newly added this year, a question in Section 17, "Wholesale Distributor Licensure Requirements," asks whether or not states license or register manufacturers separately from wholesalers.

Updates for the *Survey* were graciously provided by the state boards of pharmacy. In addition to the state boards of pharmacy's support, this year NABP requested data from numerous outside organizations for the *Survey's* prescribing authority and dispensing authority laws in Sections 24 and 25.

The *Survey* can be purchased for $195 by visiting the publications section of the NABP Web site at *www.nabp.net*, downloading the publications order form, and mailing it to NABP Headquarters with a check or money order made payable to NABP. Credit card payments are accepted by phone.

All final-year pharmacy students receive the *Survey* free of charge through the generous sponsorship of Purdue Pharma L.P.

For more information on the *Survey*, please contact customer service via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

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With this you could have live hours that were ACPE-approved and it would apply toward both the ACPE requirement and the live requirement.

You could also have live hours that were Board-approved and home study ACPE hours. It can work out many different ways so here is an example.

- One hour live ACPE
- One hour live Board-approved
- Four hours live ACPE
- Six hours ACPE home study (non-live)
- One hour ACPE home study (non-live)
- Three hours Board-approved non-live

In this example, you would have 16 hours total CE so far with six hours being live format and 12 hours of ACPE-accredited CE.

So with these 16 hours you have already met the ACPE requirement but in your final 14 hours you would still need to attend six live hours in some setting. Please remember that Board regulations require pharmacists to retain certificates of participation for proof of continuing education for a period of four years.

Disease State Management Programs Underway

Regulation 09 – Pharmaceutical Care/Patient Counseling was modified during the October 2009 Board meeting to remove language from the regulation that provides for credentialing in disease state management related to an organization that no longer exists and no longer offers credentialing. During the October meeting, the Board of Pharmacy approved the colleges of pharmacy in Arkansas to deliver a program for disease state management for pharmacists. Since that time, this program has been developed with a targeted date of January 31, for a CE program which will be presented by University of Arkansas for Medical Sciences (UAMS) College of Pharmacy faculty. There are also plans to present this program during the Arkansas Pharmacists Association Annual Convention in Fort Smith, AR, this June. For information regarding future dates for this program, please contact the UAMS College of Pharmacy – Office of Continuing Pharmacy Education at 501/686-5396.

FDA Adverse Events Toll-Free Number

The Board of Pharmacy would like to remind community pharmacists that every prescription dispensed after July 1, 2009, is required by Food and Drug Administration (FDA) to contain the statement, "Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088." This statement may be distributed to patients in one of five ways.

- on a sticker attached to the unit package, vial, or container of the drug product;
- on a preprinted pharmacy prescription vial cap;
- on a separate sheet of paper;
- in consumer medication information; or
- in the appropriate FDA-approved medication guide that contains the side effects statement.

Combat Methamphetamine Epidemic Act

Please remember that your self-certification through the Drug Enforcement Administration (DEA) for selling pseudoephedrine and ephedrine containing products must be renewed annually. This can be completed through the DEA Web site at *www.deadiversion.usdoj.gov/meth/index.html*.

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
870/636-0923

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