



Arkansas State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

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

Pharmacist License and Other Permit Renewals

Renewal reminders have been sent out for pharmacists, in-state retail pharmacies, and out-of-state retail pharmacies. This year the Arkansas State Board of Pharmacy sent reminder cards to show once again how to link to the Web site and renew permits. These reminders were sent to the mailing addresses on record with the Board office. As with years past, part of the renewal process will be for pharmacists to report their continuing education (CE) for the last two years. As a reminder, the CE requirements for the current biennium include a total of 30 hours of CE credit with 12 of the hours being live drug therapy or patient care oriented. The newly adopted regulation changes for CE requirements will not be used until renewing your permit in 2011. Specific questions regarding CE should be directed to Board staff. Only CE attained during the 2008-2009 biennium will count toward this requirement. Please remember that Board regulations require pharmacists to retain certificates of participation for proof of continuing education for a period of four years. 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.

Regulation Change Approved During October 2009 Board Meeting

The following regulation change was discussed in a public hearing during the October 14, 2009 Board meeting. This change has been adopted and an updated regulation has been placed on the Arkansas State Board of Pharmacy Web site at www.arkansas.gov/asbp in the Pharmacy Lawbook section where the regulation can be reviewed in its entirety.

Regulation 09 – Pharmaceutical Care/Patient Counseling

Changes to this regulation remove language from Regulation 09 that provides for credentialing in disease state management related to an organization that no longer exists and no longer offers credentialing. By removing this language the regulation accurately describes the process to obtain authority to perform disease state management under Ark. Code Ann. §17-92-316.

Electronic Prescriptions

A topic of discussion for the last several years has centered on electronic prescribing. While Arkansas was one of the first states to adopt a rule for electronic prescribing, many pharmacies are not currently set up to receive electronic prescriptions directly to

a computer in the pharmacy. Because of this, processing companies that transmit the electronic prescriptions to pharmacies must transmit the prescription to the fax machine in the pharmacy much like a computer-generated request for refill authorizations faxed to a prescriber from the pharmacy computer. In previous discussions, the Board decided that electronic prescriptions that are submitted by prescribers electronically and received in a pharmacy on a fax machine are considered electronic prescriptions and do not require a handwritten signature. In these cases, if there are any questions about the legitimacy of the prescription, it should be treated like a phoned-in prescription and the pharmacist must verify it with the prescriber. It is important to note that this process is only for non-controlled medications. Currently, the process for controlled substances using electronic signatures is being determined by Drug Enforcement Administration (DEA); therefore, electronically produced prescriptions for controlled substances should be printed out and signed by the prescriber before being faxed to the pharmacy or given to the patient. Even though DEA sent out a rule for comment in fall 2008, it has not published a final rule to allow electronic signatures on controlled substances. Current DEA rule is cited below:

21 CFR §1306.05 Manner of Issuance of Prescriptions:

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner . . . A practitioner may sign a prescription in the same manner as he would sign a check or legal document (e.g., J.H. Smith or John H. Smith). Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescriptions may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist, including a pharmacist employed by a central fill pharmacy, who fills a prescription not prepared in the form prescribed by DEA regulations.

Anorexiant Medication Guidelines

Recently the Board of Pharmacy requested clarification from the Arkansas State Medical Board on regulations for physicians regarding anorexiant drug guidelines. Below is an excerpt of Medical Board Regulation 21 – Anorexiant Drug Guidelines, as well as the body of our request to the Medical Board. Our questions to the Medical Board are numbered A through D and the answers are in bold.

Continued on page 4



Pharmacy Security and Safety Prove Necessary Component in Pharmacists' Training

Pharmacy robbery – no one ever thinks it will happen to them, but those who have experienced it know it **can** happen to anyone. To address the importance of recognizing actions to follow if faced with a robbery, several boards of pharmacy have included pharmacy safety resources in their state newsletters and on their Web sites. In addition, to keep current licensees aware and up to speed on safety measures, procedures can be directly taught and reiterated in the pharmacy. Likewise, at least one college of pharmacy has begun incorporating pharmacy safety training in its curriculum and recently saw the extreme benefits of doing so.

On Wednesday, July 8, 2009, Dustin Bryan, a P2 doctor of pharmacy candidate at Campbell University College of Pharmacy and Health Sciences, quickly learned how imperative pharmacy safety training really was when he experienced a pharmacy robbery first hand. Just as Bryan and his fellow employees were preparing to close the store, two gunmen entered the North Carolina pharmacy and approached the counter demanding OxyContin®. They left with bags filled with OxyContin and Percocet®, having a retail value of nearly \$10,000.

Luckily, all employees involved remained unharmed and despite the situation, Bryan was able to remain calm, focusing on lessons he recently learned during his pharmacy management course at Campbell.

Bryan shared his experience in the university's college of pharmacy alumni e-Newsletter. In the article Bryan states, "I crouched down hoping they hadn't seen me so I could get to a safe place in an office behind the pharmacy to call the police. They saw me as I was crawling and made me come to the front of the pharmacy. My mind was running through a class Dr Cisneros taught dealing with a robbery," he explains. "I knew what type of questions the police would be asking from our lecture, and I was asking myself those very questions while the robbery was happening. It was a very intense and scary moment . . . but I am thankful for the class I had and that nobody was hurt during the whole ordeal."

In December 2008, a safety DVD, *Pharmacy Security – Robbery*, accompanied the shipments of the National Association of Boards of Pharmacy® 2009 Survey of Pharmacy Law that were sent to the schools and colleges of pharmacy. The DVD was an educational offering from Purdue Pharma L.P. provided to the schools as part of an initiative to promote pharmacy safety education. Endorsed by National Association of Drug Diversion Investigators, Federal Bureau of Investigation Law Enforcement Executive Development Association, and National Community Pharmacists Association, the 15-minute video contains information that may be critical to preparing pharmacists in the event that they are faced with a robbery.

It was this DVD that Robert Cisneros, PhD, assistant professor at the university, implemented in his pharmacy management

course – the very same course that helped Bryan stay calm during the robbery. Cisneros went a step further by arranging for the head of campus security to speak during the course.

"One of the biggest values of the DVD was pointing out things to focus on during a robbery such as the robber's appearance – clothes, height, weight – and not just focusing on the gun," states Cisneros. He was glad to have received the DVD, explaining that, "it was just the right length, added a lot to the class, and led to great discussions." Cisneros went on to share that he was surprised to learn only 50% of the students in his class this past spring had some form of training on what to do if robbed, though this was a significant increase from the less than 5% who indicated so a few years prior.

Pharmacy robberies may not be avoidable; however, with the proper knowledge, individuals faced with these frightening situations may be better prepared to avoid harm and to assist law enforcement officials in catching criminals before additional robberies occur.

The safety DVD mentioned above may be viewed on the RxPatrol® Web site at www.rxpatrol.org. RxPatrol is a collaborative effort between industry and law enforcement designed to collect, collate, analyze, and disseminate pharmacy theft information. The safety DVD, along with a variety of other non-branded educational materials, is also available through the Purdue Pharma Medical Education Resource Catalog, accessible at www.partnersagainstpain.com under Pain Education Center.

Concerns with Patients' Use of More than One Pharmacy



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.

Perhaps it is not readily apparent, but medication safety could be compromised if patients practice polypharmacy to take advantage of widely publicized programs offering discounted or free medications. With tough economic times, patients may choose to fill or refill their prescriptions at multiple pharmacy



locations to save money, since taking advantage of such offers may cost less than filling their prescription at their usual pharmacy and paying the insurance co-pay.

Normally, when a customer presents a prescription, the pharmacy sends information about the drug and the patient to third-party payers and/or the patient's pharmacy benefit managers (PBM) for reimbursement.

If patients are paying out of pocket for the prescription, the pharmacy can notify the PBM so the medication can be tracked, but notification is not required. In these circumstances, the PBM and insurer may not be made aware that the prescription has been dispensed and no adjudication or drug utilization clinical screening of the prescription will be performed. Normally, medications are screened by the PBM's computer system, which includes all prescription medications regardless of where they were dispensed, and dispensing pharmacists are alerted to drug duplications, drug interactions, and some other unsafe conditions. This checking process will not occur if the prescription is not sent to the PBM. This also has an impact on hospitals that use outside vendors that obtain PBM data through Surescripts in order to populate patient medication profiles upon admissions to the emergency department or hospital. This could decrease the accuracy of drug lists collected for medication reconciliation since these vendors access their information from PBMs and insurers.

For these reasons, patients need to be educated about the importance of sharing insurance information wherever they have their prescriptions filled, even when the insurance is not being billed. Community pharmacists can help by submitting claims to insurance carriers, as cash, to keep an accurate medication profile for the patient. This is especially necessary if the patient is only filling a prescription for a drug on the \$4 list from your pharmacy, but you suspect they may be taking other medications and obtaining them elsewhere. It is also important to expand our efforts to encourage patients to keep a complete list of medications, herbals, nutritional supplements, vitamins, and prescription drugs and to show this list to every provider of care they visit. Community pharmacies can also update patient medication profiles in their computer systems to include prescription and over-the-counter medications obtained at other pharmacies, including mail-order, and promoting and providing a written copy of this list to the patient upon request.

CDC Launches Get Smart Web Site to Help Decrease Antibiotic Resistance

Centers for Disease Control and Prevention (CDC) launched the Get Smart Web site to teach about the potential danger of antibiotic resistance and what can be done to prevent it. Because antibiotic resistance is one of the world's most pressing public health problems, CDC also held Get Smart Week on October 5-11 to emphasize its public health effort to decrease antibiotic resistance, including how pharmacists can become involved.

The Web site contains patient education materials, updated guidelines for health care providers, campaign materials, and additional resources, including information in Spanish, to help increase the public health awareness of antibiotic resistance and the importance of obtaining influenza vaccines in time for the upcoming flu season. As most states now allow pharmacists to immunize, they can help contribute to public health awareness on who should get flu shots and appropriate antibiotic use in the community. The Get Smart Web site can be accessed at www.cdc.gov/getsmart/.

FDA Approves Vaccine for 2009-2010 Seasonal Influenza and H1N1

Food and Drug Administration (FDA) has approved a vaccine for 2009-2010 seasonal influenza in the United States. FDA has also approved four vaccines against the 2009 H1N1 influenza virus. The seasonal influenza vaccine will not protect against the 2009 H1N1 influenza virus. More information is available at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements.

ISMP: Do Not Store Insulin Vials in Open Cartons – Risk of Mix-up High

ISMP warns that storing insulin vials inside their cardboard cartons after the packages have been opened can lead to mix-ups, and potential medical emergencies, if vials are accidentally returned to the wrong carton after being used. The next patient care worker looking for a particular insulin product could read the label on the carton, assume that it accurately reflects what is inside, and end up administering the wrong product. To avoid such a mishap, ISMP recommends that the cartons be discarded, either in the pharmacy before the insulin is dispensed, or when it is received at the nursing station.

FDA Takes Actions on Pain Medications Containing Propoxyphene

FDA announced in July that it will require manufacturers of propoxyphene-containing products to strengthen the label, including the boxed warning, emphasizing the potential for overdose when using these products. FDA will also require manufacturers to provide a medication guide for patients stressing the importance of using the drugs as directed. In addition, FDA is requiring a new safety study assessing unanswered questions about the effects of propoxyphene on the heart at higher than recommended doses. Findings from this study, as well as other data, could lead to additional regulatory action. In its July 7 denial of a citizen petition requesting a phased withdrawal of propoxyphene, FDA said that, despite "serious concerns . . .", the benefits of using the medication for pain relief at recommended doses outweighs the safety risks at this time." Additional information can be found at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm170769.htm.

Medical Board Regulation 21 – Anorexiant Drug Guidelines

- 4. The treating physician shall prescribe a daily dosage that does not exceed the dosage recommended in the manufacturer’s prescribing information for the drug prescribed or dispensed.
- 5. The treating physician shall not dispense or prescribe more than a 30-day supply for a patient on the first visit. Thereafter, not more than a 30-day supply shall be dispensed or prescribed at the time of each visit. The patient shall be weighed at each visit prior to dispensing or prescribing an additional supply of the drug and the weight shall be entered in the patient’s record.

Arkansas State Board of Pharmacy Request to Medical Board

When our inspectors and investigators reviewed Medical Board Regulation 21 – Anorexiant Drug Guidelines, the regulations seemed clear but we had a number of pharmacists being asked to compound a phentermine 45 mg extended release dosage form for weight loss or being asked for twice daily dosing of phentermine 37.5 mg. Since the manufacturer’s Food and Drug Administration (FDA)-approved labeling only indicates 37.5 mg of phentermine to be given no more than once daily, the Pharmacy Board is requesting guidance to give pharmacists in filling these prescriptions. Numerous pharmacists have also called asking about physicians calling in refills for these prescriptions when the patient has not been seen by the physician. By reading the [Medical Board’s] regulation, it would seem that all three of these situations would cause the prescriptions to not be valid and could therefore be a DEA issue for the prescribing physician and the pharmacist if filled. Please see the Medical Board’s interpretation for the following:

- A. Can a physician prescribe a dosage of 45 mg of phentermine for weight loss even though it exceeds the FDA-approved recommended dosage? **No.**
- B. Can a physician prescribe more than 30 days of phentermine therapy for a patient? **No.**
- C. Can a physician prescribe more than once daily dosing of phentermine? **No.**
- D. Do you have any guidance for pharmacists when given a prescription over the phone to fill or refill these medications when the patient has not been seen or weighed? **No.**

The response received from the Medical Board for all four of these questions was **No.** It is important to note that while these questions were specific to one anorexiant medication, the regulation would apply to all medications in this classification.

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 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.

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**

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 voluntary 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

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

ARKANSAS STATE BOARD OF PHARMACY
 National Association of Boards of Pharmacy Foundation, Inc
 1600 Feehanville Drive
 Mount Prospect, IL 60056