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Arkansas State Board of Pharmacy

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License/Permit Renewals

Pharmacist and pharmacy renewals have been sent out for Arkansas licensed pharmacists. As with years past, part of the renewal process will be for pharmacists to report their continuing education (CE) for the last two years. Specific instructions will be included in the renewal letter that will be sent to your mailing address of record. **Once again, the best way to renew your license will be through the Internet as this allows our staff to turn around your renewal much faster.** Additionally, this is the only way to use a credit card when renewing your permit and will allow you to print a confirmation of the renewal directly from your computer. As a reminder, the CE requirements for Arkansas include a total of 30 hours of CE credit with 12 of the hours being live drug therapy or patient-care oriented CE. Specific questions regarding CE should be directed to Arkansas State Board of Pharmacy staff. Only CE attained during the 2006-2007 biennium will count towards this requirement. Please remember that Board regulations require pharmacists to retain certificates of participation for proof of CE for a period of four years.

Regulation Changes from October Meeting Regulation 2 – Pharmacists

The changes update requirements for intern training and requisites for examination as a pharmacist in Arkansas, which will require oversight by the pharmacist-in-charge for the facility instead of just the preceptor or staff pharmacist when tracking hours of experience for student pharmacists.

Regulation 4 – Pharmacy

The changes modify equipment specifications for various pharmacies to only require equipment necessary for the specific scope of practice for the respective pharmacy. Changes to Regulation 4 also add an additional section of institutional pharmaceutical services permits that specifically addresses correctional facilities that obtain medications on a patient-specific basis from retail pharmacies.

Regulation 5 – Long-Term-Care Facilities

The changes clarify language regarding the requirements for consultant pharmacists to notify the Board of Pharmacy of changes in their employment status in consulting for nursing homes. These changes also remove the bed limit for consulting

and add breathing medications and corticosteroids to the approved classes of medications for emergency kits in nursing homes.

These summaries briefly explain the overall changes to the regulations, which can be viewed in their entirety on the Board Web site in the Pharmacy Lawbook section at www.arkansas.gov/asbp.

Regulation 07-00-0009 – Proper Practitioner-Patient Relationship

The following regulation was adopted on an emergency basis on October 31, 2007, and reads as follows:

In accordance with Ark. Code Ann. §17-92-1004(c) and Ark. Code Ann. §17-92-1003(15), an in-person physical exam of the patient performed by a practitioner, physician, doctor or other prescribing health professional (“a practitioner”) prior to the issuance of any prescription is required in order to establish a valid or proper relationship between a patient and a practitioner, unless the prescribing practitioner is consulting at the specific request of another practitioner who maintains an ongoing relationship with the patient, has performed an in-person physical exam of the patient, and has agreed to supervise the patient’s ongoing care and use of prescribed medications. (10/31/2007)

Promethazine with Codeine Syrup No. 1 Diversion/Theft Drug for Pharmacies in Arkansas?

While this may seem funny, odd, outlandish, or impossible, the Board has seen dozens of issues for pharmacy break-ins, forged prescriptions, and prescription drug diversion involving promethazine with codeine cough syrup. There have been several pharmacy break-ins and burglaries where a traditional smash-and-grab approach has been used, and the only medication taken from the pharmacy has been a bottle or two of this product. Even more alarming is the fact that the Board has heard two cases where technicians have diverted over 350 pints of promethazine with codeine cough syrup out of two pharmacies. If you have not heard of this phenomenon then you might Google the terms “Sizzurp” or “Purple Drank” to see that this is a product of hip-hop culture and has been featured in rap music in the South originating in the Houston, TX area. No matter the reason or the source, you might check

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◆ and the most recent, Omacor® (error reports indicating mistaken as Amicar®) to Lovaza.

To those who report medication errors, keep up the great work. The actions resulting in the name changes listed above, alone, demonstrate the tremendous impact you make when you report your experiences to USP-ISMP MERP. Many other error reports have resulted in manufacture label and stock bottle changes. For more information on reporting incidents, visit www.ismp.org and click on "Report Errors."

FDA Finds Consumers Still Buying Potentially Risky Medications via Internet

FDA continues to warn the American public about the dangers of buying medications over the Internet.

New data collected by FDA show that consumers who are trying to save money on prescription drugs need not take chances by buying prescription drugs from foreign Internet sites because low-cost generic versions are available in the United States. These findings also indicate that some consumers are likely buying foreign drugs online to avoid having to obtain a prescription from their doctors or health care professionals, as many Web sites do not require a prescription.

FDA urges consumers to obtain prescriptions from their doctors or other health care professionals before using prescription drugs, stating that the use of prescription medications without a prescription is an "inherently unsafe practice." FDA also encourages consumers to review www.fda.gov for information on buying medications online before making such purchases.

FDA cites the following potential risk factors associated with buying medications from unregulated Internet sellers:

- ◆ inadequate labeling for safe use;
- ◆ inappropriate packaging and, therefore, uncertain product integrity;
- ◆ possible previous withdrawal from the US market for safety or efficacy reasons;
- ◆ drug-specific risks requiring initial screening and/or periodic patient monitoring;
- ◆ potential harm or abuse, such as with the use of controlled substances; and
- ◆ potential drug-drug interactions.

Recent examinations of a sample of drugs shipped to US consumers found several drugs are associated with higher risks if used without the supervision of a doctor or health care professional. For example: the use of warfarin requires close monitoring to prevent stroke or death; amoxicillin and other antibiotics should not be used for self-treatment because of the risk of antibiotic-resistant infections; levothyroxine use requires close monitoring to ensure effective treatment; and clopidogrel may pose increased risk of cardiac events, such as heart attack, if used in suboptimal doses, which might be found in imported tablets.

Improper labeling also presents a risk to consumers. For example, alendronate sodium labeling should warn patients of significant side effects with improper use. In addition, imported eye drop preparations may have been manufactured under unsterile conditions, presenting a risk of contamination that may result in serious infections.

In light of these and other risks associated with medications purchased over the Internet, FDA stresses the importance of obtaining only FDA-approved drugs along with health care provider monitoring.

Death in Canada Tied to Counterfeit Drugs Bought via Internet

Canada's first confirmed death from counterfeit drugs purchased over the Internet reinforces long-stated concerns of the Canadian Pharmacists Association (CPhA), the association states in a recent press release.

A British Columbia coroner's report concludes that pills bought from a fake online pharmacy are to blame for the March death of a Vancouver Island woman. These drugs were later determined to be contaminated with extremely high quantities of metal.

CPhA is calling on Canadian pharmacists to be especially vigilant and discuss these issues with patients when necessary.

Since 1999, NABP, through its Verified Internet Pharmacy Practice Sites™ program, has warned of the dangers of purchasing potentially counterfeit drugs from illegitimate online pharmacies.

FDA Sets Standards for Dietary Supplements

FDA recently issued a final rule requiring current good manufacturing practices (CGMP) for dietary supplements. The rule is intended to ensure that dietary supplements are produced in a quality manner, free of contaminants and impurities, and accurately labeled.

The regulations establish the CGMP needed to ensure quality throughout the manufacturing, packaging, labeling, and storing of dietary supplements. The final rule includes requirements for establishing quality control procedures, designing and constructing manufacturing plants, and testing ingredients and finished products, as well as requirements for record keeping and handling consumer product complaints.

Manufacturers also are required to evaluate the identity, purity, strength, and composition of their dietary supplements. If dietary supplements contain contaminants or lack the dietary ingredient they are represented to contain, FDA would consider those products to be adulterated or misbranded.

FDA also issued an interim final rule that would allow manufacturers to request an exemption to the CGMP requirement for 100% identity testing of specific dietary ingredients used in the processing of dietary supplements. To be eligible for an exemption, the manufacturer must provide sufficient documentation that less frequent testing would still ensure the identity of the dietary ingredients. FDA is soliciting comments from the public on the interim final rule until September 24, 2007. Comments may be addressed to the Division of Dockets Management Branch at www.fda.gov/dockets/ecomments.

The final CGMP and the interim final rule became effective on August 24, 2007. The rule has a three-year phase-in for small businesses. Companies with more than 500 employees have until June 2008, companies with fewer than 500 employees have until June 2009, and companies with fewer than 20 employees have until June 2010 to comply with the regulations.

The FDA Web site provides background information at www.cfsan.fda.gov/~dms/dscgmps7.html and a fact sheet at www.cfsan.fda.gov/~dms/dscgmps6.html.

More information is available on the FDA Unapproved Drugs Web site at www.fda.gov/cder/drug/unapproved_drugs/default.htm.

your wholesaler invoices to see how much of this product has been ordered by your pharmacy compared to how much has been legitimately dispensed this year. While most pharmacists keep a close watch on benzodiazepines and opioids, not very many think about diversion or theft of the syrups.

Emergency Drug Services

Board staff has noticed several pharmacies that have indicated they are not providing emergency or after hours services but have failed to post notices of this fact to the public. If a pharmacy is not offering to provide emergency drug services, notice should be posted in the pharmacy where it can be seen by the public, both when the pharmacy is open and when it is closed. Please review the following regulation regarding emergency services:

Regulation 04-00-0006 Emergency Pharmacy Services

Any pharmacy providing prescription drugs to one or more patients in a nursing home or other institution shall provide emergency prescription services for those patients and shall provide information to the nursing home or institution indicating how the pharmacists can be reached after pharmacy hours.

All pharmacies (other than hospital and institutional) who do not provide emergency drug services for non-institutionalized patients shall post a sign at least 8½" by 11" with letters of at least one (1) inch stating "This pharmacy will not provide emergency prescription drugs when the pharmacy is closed." (6/25/83)

Iodine

Drug Enforcement Administration has increased regulation on iodine and some retail pharmacies have started to require customers to sign a log and show proof of identification for it because it is used in the manufacture of methamphetamine. This is not a requirement for the state, but some pharmacies are doing this to help prevent illegitimate sales.

Tramadol

Tramadol is in Schedule IV as of July 31, and should have been added to your controlled substance (CS) inventory. As a reminder, solid dosage forms of **over-the-counter pseudoephedrine** are also CS in Arkansas (Schedule V). Both of these should already be on your current CS inventory, but more importantly, do not forget to include these in your future CS inventory counts.

Transferring Prescriptions

Board inspectors have been asked during routine inspections about the appropriate protocol for legally transferring prescriptions from one pharmacy to another when the computer systems are not part of a centralized database. We would like to emphasize that this process is to be communicated verbally from one pharmacist to another and should not be processed via facsimile. For further guidance please review the following regulation on the Arkansas Web site:

07-00-0002 – Prescription Transfers

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.

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