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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

Continued on page 4

Public Hearing Garners Recommendations on Use of Medication Guides

Participants in a public hearing held in June 2007 by the Food and Drug Administration (FDA) Center for Drug Evaluation and Research suggested ways to improve the FDA Medication Guide program. The program provides for the distribution of FDA-approved written patient information for certain medications that pose serious and significant public health concerns.

FDA officials heard testimony from a member of Congress and 40 individuals representing academia, consumers and consumer groups, the pharmaceutical industry, health care professional groups, practicing physicians, pharmacists, and pharmacy organizations.

Participants acknowledged the importance of patients receiving appropriate risk information in the form of Medication Guides to make informed decisions about certain prescribed medications. Some said the current program is too cumbersome and lacks a standard distribution system. Participants urged FDA to increase awareness of Medication Guides, make them easier to read and understand, move toward facilitating electronic distribution, and consider combining the information contained in Medication Guides with other information such as in Consumer Medication Information.

The public hearing is summarized on the FDA Web site at *www.fda.gov/cder/meeting/medication_guides_200706.htm.*

Reporting Makes a Difference

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing 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 recommendations for prevention of reported errors that you can put into practice today, subscribe to ***ISMP Medication Safety Alert!® Community/Ambulatory Edition*** *by visiting www.ismp.org. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

In both Institute of Medicine (IOM) reports, *To Err is Human: Building a Safer Health System,* and *Identifying and Preventing Medication Errors,* the importance of error reporting is highlighted. The reports suggest that greater effort is needed to identify medication errors in most care settings, both to measure the extent and scope of errors and to assess the impact of prevention strategies. Although no single recommendation or activity offers a full solution to medical error, error prevention experts agree that successful error reduction strategies depend heavily on responsible detection and open reporting of errors.

According to the IOM report, reporting programs, whether voluntary or mandatory, must satisfy two primary purposes:

1. to hold providers accountable for performance and patient safety; and
2. to provide information that leads to new knowledge and improved patient safety.

Reports to voluntary systems typically come from front-line practitioners or others similarly close to the error, who can best describe the specific conditions that led to that error. Better error descriptions make possible more effective analysis of the system-based causes of errors. This first-hand reporting and the improved analysis it affords has been used by error prevention experts to create a "road map" for improvement that easily and realistically can be extrapolated and implemented at the broadest variety of health care organizations. These practical recommendations for safe practice have been established, published, and widely disseminated throughout the health care community.

Further, voluntary reporting programs have learned that many errors are caused by factors outside the health care practice site and beyond the direct control of a health care practitioner. Thus, safe practice recommendations have been communicated to medical device manufacturers, pharmaceutical companies, automation technology companies, health care reimbursement systems, and others less directly involved in patient care, but nonetheless influential in the safe provision of care.

The success of current voluntary reporting systems also stems from the trust and respect that has typically developed between reporters and recipients who use the information to improve patient safety across the nation. Reporting is perceived to have immense value when those who report an error or potentially hazardous situation can readily see that the information is swiftly acted upon and used confidentially and proactively to develop and publish safe practice recommendations that can prevent errors.

The USP-ISMP Medication Errors Reporting Program (MERP) operated by the United States Pharmacopeia (USP) in cooperation with ISMP is a confidential national voluntary reporting program that provides expert analysis of the system causes of medication errors and disseminates recommendations for prevention. Regulatory agencies and manufacturers are notified of needed changes in products when safety is of concern.

Without reporting, such events may go unrecognized and thus important epidemiological and preventive information would be unavailable. Errors, near-errors, or hazardous conditions may be reported to the program. These include, but are not limited to, administering the wrong drug, strength, or dose of medications; confusion over look-alike/sound-alike drugs; incorrect route of administration; calculation or preparation errors; misuse of medical equipment; and errors in prescribing, transcribing, dispensing, and monitoring of medications.

Providing causative information on actual or potential errors, or near misses to USP and ISMP, which is automatically shared with FDA and the involved manufacturers, has resulted in drug name changes. For example:

- Losec® (error reports indicating mistaken as Lasix®) to Prilosec®,
- Levoxine (error reports indicating mistaken as Lanoxin®) to Levoxyl®,
- Reminyl® (error reports indicating mistaken as Amaryl®) to Razadyne™ (and unfortunately new error reports show Razadyne being mistaken as Rozerem™)

♦ 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 "intrinsically 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.*

Continued from page 1

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

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