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Arkansas State Board of Pharmacy

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

Regulation Changes from the February Board Meeting

The Arkansas State Board of Pharmacy approved changes to the following regulation at the February 2006 Board Meeting.

Regulation 4 – Pharmacy

Amend section 04-02-0011 – **Central Fill Pharmacy** to allow a central fill pharmacy to deliver medications directly to the end user or patient when specifically outlined in a contract between the participating pharmacies and agreed upon by the patient. Previously this regulation had only allowed the central fill pharmacy to return medications to the originating community pharmacy. Under the new regulation, prescriptions for controlled substances (CS) must be delivered in accordance to Drug Enforcement Administration (DEA) regulations. The new version of the central fill regulation was enacted on March 14, 2006, and can be viewed in the “Pharmacy Lawbook” section of the Board of Pharmacy Web site at www.arkansas.gov/asbp.

Important Information for Inventory Records

Newly scheduled pseudoephedrine-, ephedrine-, and phenylpropanolamine-containing products should have been inventoried on **March 24, 2005**, as outlined in the *DEA Pharmacist’s Manual*, “When a drug not previously controlled is scheduled, the drug must be inventoried as of the effective date of scheduling.” This is also addressed in the Code of Federal Regulations 21 CFR §1304.11 Inventory Requirements.

- (c) **Biennial inventory date.** After the initial inventory is taken, the registrant shall take a new inventory of all stocks of [CS] on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.
- (d) **Inventory date for newly [CS].** On the effective date of a rule by the Administrator pursuant to §1308.45, 1308.46, or 1308.47 of this chapter adding a substance to any schedule of [CS], which substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand. Thereafter, such substance shall be included in each inventory made by the registrant pursuant to paragraph (c) of this section.

Board inspectors have repeatedly found that many Arkansas pharmacies have failed to add these products to their CS inventories or have failed to include these products in their regularly scheduled biennial inventory of CS. Inspectors have also found a number of pharmacies that have stocked and sold bottles of loose tablets of pseudoephedrine as well as packages of pseudoephedrine-containing products with more than 3 grams of pseudoephedrine in a single package size. Examples of this would be 15-count boxes of prod-

ucts containing 240 mg of pseudoephedrine or 30-count boxes of products containing 120 mg of pseudoephedrine. In Arkansas, any over-the-counter products containing pseudoephedrine, ephedrine, or phenylpropanolamine must be packaged in blister packs with no more than two doses in any single blister unless it is a liquid product.

**Arkansas State Police,
Pseudoephedrine Reporting Hotline
1-800/553-3820**

Act 162 of 2005

Entitled: AN ACT TO ALLOW DONATED PRESCRIPTION MEDICATIONS TO BE DISPENSED TO PATIENTS AT CHARITABLE CLINICS; AND FOR OTHER PURPOSES. When this legislation, sponsored by Representative Jodie Mahony, passed in February 2005, the Board of Pharmacy began the process to adopt the regulations that would both allow for and regulate the practice of dispensing donated prescription medications in charitable clinics, which was previously prohibited by Arkansas Pharmacy Regulations.

During the June 23, 2005 meeting of the Arkansas State Board of Pharmacy, changes to Regulation 4 – Pharmacy and Regulation 5 – Long-Term-Care Facilities, were presented for public hearing and accepted by the Board of Pharmacy to outline this process. Specific changes to these regulations can be seen in the August 2005 *Newsletter* and updated versions of the regulations are posted in the “Pharmacy Lawbook” section of the Board’s Web site.

The changes made to Arkansas Pharmacy Regulations 4 and 5 were then presented to the Legislative Council Subcommittee on Administrative Rules and Regulations on July 5, 2005. Both regulation changes were accepted for review and the Board of Pharmacy scheduled the effective date for these regulations for August 12, 2005, so that they would become effective on the same date as Act 162. The Board also worked with interested charitable organizations to assist them through the application process in order to have their applications completed as quickly as possible so that the organizations could appear before the Board for consideration of a Permit for Pilot Program for Donated Prescription Medications. A special meeting of the Arkansas State Board of Pharmacy was scheduled for August 16, 2005, so that any interested charitable organizations could appear regarding their permit applications to participate in this program. This special meeting was called in August 2005 so that the applicants would not have to wait an extra two months until the normally scheduled October Board meeting for consideration of their request. During the August 2005 Board meeting the following organizations appeared and had their request for a Permit for Pilot

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FDA Cautions Consumers About Filling US Prescriptions Abroad

Food and Drug Administration (FDA) issued a warning to health care professionals and consumers that filling their prescriptions abroad may have adverse health consequences due to the confusion with drug brand names that could inadvertently lead consumers to take the wrong medication for their condition. In an investigation, FDA has found that many foreign medications, although marketed under the same or similar-sounding brand names as those in the United States, contain different active ingredients than in the US. Taking a different active ingredient could potentially harm the user.

FDA found 105 US brand names that have foreign counterparts that look or sound so similar that consumers who fill such prescriptions abroad may receive a drug with the wrong active ingredient. For example, in the United Kingdom, Amyben[®], a brand name for a drug product containing amiodarone, used to treat abnormal heart rhythms, could be mistaken for Ambien[®], a US brand name for a sedative. Using Amyben instead of Ambien could have a serious adverse outcome. For more information on this topic visit www.fda.gov/oc/opacom/reports/confusingnames.html.

Safety Can Not be Sacrificed For Speed



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, then publishes its recommendations. 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.

Problem: Typically, pharmacies have developed well-established methods for monitoring the accuracy of the dispensing process. But today, pharmacy work is increasingly stressful and these checks and balances can easily be strained beyond capacity. With an increasing number of prescriptions and a shortage of qualified pharmacists, conditions are ripe for potentially unsafe working conditions – long hours without breaks; multitasking between answering phones, overseeing other pharmacy staff, dispensing prescriptions, and counseling patients; and ever-increasing time spent attending to insurance issues. Inevitably, these conditions can increase the chance for dispensing errors.

One pharmacy knows this all too well after a five-year-old boy died as a result of an order entry and medication compounding error that was not caught by the usual verification process. In this case, imipramine was dispensed in a concentration five times greater than prescribed. Imipramine is a tricyclic antidepressant used to treat adults, but it is also used to treat childhood enuresis.

An extemporaneous solution was to be prepared at this pharmacy that specialized in compounded prescriptions since a liquid formulation was not commercially available. A pharmacy technician incorrectly entered the concentration of the prescribed solution into the computer as **50 mg/mL** instead of **50 mg/5 mL**, along with the prescribed directions to give 2 tsp at bedtime. He then proceeded to prepare the solution using the incorrect concentration on the label rather than the concentration indicated on the prescription. When the compound was completed, the technician placed it in a holding area to await a pharmacist's verification. At this time, one of the two pharmacists on duty was at lunch and the high workload of the pharmacy made it difficult for the pharmacist to check the prescription right away. When the child's mother returned to pick up the prescription, the cash register clerk retrieved the prescription from the holding area without telling a pharmacist, and gave it to the mother, unaware that it had not yet been checked. At bedtime, the mother administered 2 tsp of the drug (500 mg instead of the intended 100 mg) to the child. When she went to wake him the next morning, the child was dead. An autopsy confirmed imipramine poisoning.

There are many factors that contributed to this error including inaccurate order entry and issues related to high workload. However, a critical breakdown in safety processes occurred when the cash register clerk took the prescription from the pharmacy holding area (to prevent the mother from waiting any longer for the prescription), thereby circumventing the usual pharmacist verification process.

While this error underscores a growing problem in health care, the problem was clearly evident to this pharmacy owner – even a year before the error occurred. When interviewed for an article that appeared in a national publication, he vented his frustrations about the scant attention paid in our society to pharmacist workload difficulties faced in today's health care environment. On the day of the interview, 49 prescriptions were in the process of being prepared and about a dozen patients were standing in line or wandering around the store waiting for prescriptions. Yet this was a slow day. The owner also said that, while managed care had reduced profits considerably over the past several years, prescription volume had increased 50% (at the time of the error, the pharmacy was dispensing about 10,000 prescriptions per month versus 7,000 per month during the prior year, without an increase in staff) and medication regimens and drug interactions were more complex. To overcome these barriers, the owner added private consultation areas for patient counseling; installed a \$175,000 robot that accurately dispenses the 200 most common drugs; and diversified sales to offset full-time pharmacists' salaries. But these efforts could not have prevented this tragic fatal error that circumvented the normal safety processes.

Safe Practice Recommendations: The environment and demands placed on health professionals significantly affect their ability to provide safe health care services. While technology such as robots can help, overstressed professionals cannot consistently perform at the maximum level of safety. Therefore, it is important that the public and health care leadership understand this problem so they can be more open to tradeoffs, such as working



with one patient at a time and incurring longer turnaround times, which are necessary to enhance patient safety. With a shortage of qualified professionals, we need to demand more rapid adoption of computerized prescribing to reduce time spent with prescription transcription. We should identify the biggest distractions that occur in our workplaces and eliminate or reduce the source by batching common interruptions and reorganizing work areas. Staff members need to be properly trained to understand safety procedures that are in place and know the limits of their specific duties. Fail-safe processes to ensure an independent double check before dispensing medications and performing other critical processes are a must. The pharmacy where this error occurred now requires two pharmacists to check every prescription. Unfortunately, this level of vigilance is typical after a patient has been harmed from an error. In other pharmacies, especially where there is only one pharmacist on duty, technicians may be involved in the double-check process.

A few other strategies can be used to prevent similar errors:

- ◆ Have one person perform order entry and a different person prepare the prescription, if possible, to add an independent validation of the order entry process.
- ◆ Do not prepare prescriptions using only the computer-generated label, as order entry may have been incorrect.
- ◆ Ensure that the original prescription, computer-generated label, prepared product, and manufacturer's product(s) remain together throughout the preparation process.
- ◆ Verify dispensing accuracy by comparing the original prescription with the labeled patient product and the manufacturer's product(s) used.

NIH Develops Community Drug Alert Bulletin

The National Institute on Drug Abuse, as part of the National Institutes of Health (NIH), has developed a new Community Drug Alert Bulletin that addresses the latest scientific research on the non-medical use of prescription drugs of abuse and addiction.

This bulletin is geared toward parents, teachers, counselors, school nurses, and health professionals who are associated with those at risk from prescription drug abuse for non-medical purposes. It summarizes the growing problem in the US and the trend of non-medical use of prescription drugs. For more information on this bulletin visit www.nida.nih.gov/PrescripAlert/index.html.

Implementation of the Anabolic Steroid Control Act of 2004

According to the December 16, 2005 *Federal Register*, effective January 20, 2005, the Anabolic Steroid Control Act of 2004 amended the Controlled Substances Act (CSA) and replaced the existing definition of "anabolic steroid" with a new definition. This new definition changed the basis for all future administrative scheduling actions relating to the control of the anabolic steroids as Schedule III controlled substances (CS) by eliminating the requirement to prove muscle growth. Also, the Act lists 59 substances as being anabolic steroids; these substances and their salts, esters, and ethers are Schedule III CS. The Act also revised the language of the CSA requiring exclusion of certain over-the-counter products from regulation as CS.

According to the House Report, the purpose of the Act is "to prevent the abuse of steroids by professional athletes. It will also address the widespread use of steroids and steroid precursors by college, high school, and even middle school students."

The changes to the definition include the following:

- ◆ Correction of the listing of steroid names resulting from the passage of the Anabolic Steroid Control Act of 1990.
- ◆ Replacement of the list of 23 steroids with a list of 59 steroids, including both intrinsically active steroids as well as steroid metabolic precursors.
- ◆ Automatic scheduling of the salts, esters, and ethers of Schedule III anabolic steroids without the need to prove that these salts, esters, or ethers promote muscle growth.
- ◆ Removal of the automatic scheduling of isomers of steroids listed as Schedule III anabolic steroids.
- ◆ Addition of dehydroepiandrosterone to the list of excluded substances.

FDA Unveils New Package Insert Format

On January 18, 2006, FDA unveiled a major revision to the format of prescription drug information, commonly called the package insert, which will give health care professionals clear and concise prescribing information. This new format was developed in order to manage the risks of medication use and reduce medical errors; the new package insert will provide the most up-to-date information in an easy-to-read format. This new format will also make prescription information more accessible for use with electronic prescribing tools and other electronic information resources.

Revised for the first time in more than 25 years, the new format requires that the prescription information for new and recently approved products meet specific graphical requirements and includes the reorganization of critical information so physicians can find the information they need quickly. Some of the more important changes include:

- ◆ A new section called *Highlights* to provide immediate access to the most important prescribing information about benefits and risks.
- ◆ A table of contents for easy reference to detailed safety and efficacy information.
- ◆ The date of initial product approval, making it easier to determine how long a product has been on the market.
- ◆ A toll-free number and Internet reporting information for suspected adverse events to encourage more widespread reporting of suspected side effects.

This new format will be integrated into FDA's other e-Health initiatives and standards-settings through a variety of ongoing initiatives at FDA. For more information please visit www.fda.gov/cder/regulatory/physLabel/default.htm.

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Program for Donated Prescription Medications approved pending a signed contract with a nursing home for the donation of medications and inspection of the charity clinic facility by Board staff:

- ◆ River City Medical Clinic, North Little Rock, AR
- ◆ Westside Free Medical Clinic, Little Rock, AR
- ◆ Conway County Christian Clinic, Morrilton, AR
- ◆ Interfaith Clinic, El Dorado, AR
- ◆ Mountain Home Christian Clinic, Mountain Home, AR

The Board also developed and provided copies of medication donation consent forms, contracts for the nursing home and charity clinic donation agreement, medication donation manifest forms, waiver forms for patients receiving donated medications, and copies of newly adopted regulations pertaining to the permit to all applicants and interested parties.

Since the August meeting, Interfaith Clinic in El Dorado, AR, has submitted a signed contract with a nursing home for the donation of unused medication. Upon submission of this document to the Board, Interfaith Clinic was inspected by Board Staff and was issued the first Permit for Pilot Program for Donated Prescription Medications on November 22, 2005. Currently, Interfaith Clinic in El Dorado, AR, is the only charity clinic that has applied for this pilot program permit and completed the application process through the step of securing a contract with a nursing home to accept donated prescription medications. Interfaith Clinic has just started the process of gathering donated medications to be dispensed to the indigent patients served in the clinic with the first collection of medication occurring in March 2006 with a reported value of over \$9,000. These donated medications are being used to stock the charitable clinic pharmacy and are already being distributed to patients. Additional information about the impact of this program should be available in the months to come as they continue operating under their permit. Please contact the Board office if you are interested in obtaining information regarding this program or would like copies of sample forms such as:

- * Nursing Facility and Charitable Clinic Pharmacy Agreement for Donation of Unused Prescription Medication Contract
- * Medication Donation Manifest Form
- * Authorization for Donation of Unused Prescription Medication Form
- * Arkansas Donated Medication Pilot Program Patient Release Form

Reciprocating Pharmacists

The following pharmacists were approved to receive an Arkansas Pharmacist license by reciprocity at the February 2006 Board Meeting:

Tom Bader	April Kirk
Rodney Blackburn	Andrea Knybel

Melanie Brooks
 Guy Decker
 Michael Draeger
 Leslie Duncan
 Robert Dunn
 Lanier Evans
 John Flynn
 Anna Garcia
 Sarah Goeders
 James Hinchey
 Tommy Holbrook
 Brad Hopkins
 Allan Jeffy

Michelle Macumber
 Larry Melton
 Cassandra Morris
 George Melton
 Michael Moti
 Brian Richard
 Marvin Robinson
 Elizabeth Rodgers
 Alfred Romay
 Catherine Sharp
 Jo-Ann Sorokunov
 Charles Stachowiak
 Ingrid Thomas
 Nathan Vo

**Arkansas Pharmacy Support Group
 Help Line – 870/636-0923**

If you think you have a problem, you are probably right. Without help, alcohol and drug problems always get worse – **never better!**

Notice About This Newsletter

The Arkansas State Board of Pharmacy has designated this *Newsletter* as an official method to notify pharmacists licensed by the Board about information, regulation changes, 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* contents. Please contact the Board office at 501/682-0190 if you have questions regarding any of the articles in this *Newsletter*.

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National Association of Boards of Pharmacy Foundation, Inc
 1600 Beehanville Drive
 Mount Prospect, IL 60056
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