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Arkansas State Board of Pharmacy

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Regulation Changes from October Meeting

The following regulation changes were adopted by the Arkansas State Board of Pharmacy after holding a public meeting during the October 2008 Board meeting.

Regulation 04 – Pharmacy

The changes clarify equipment requirements and specify that food is not to be stored in the refrigerator along with prescription medications consistent with Food and Drug Administration guidelines and Department of Health Regulations. These changes also rearrange areas of the regulation so that they are in the initial section of Regulation 4 under the section: "General Regulations Regarding Pharmacies." Regulations for the Arkansas State Board of Pharmacy underwent a major restructuring around 2000 to better organize the pharmacy regulations. During this restructuring, several sections were placed under the heading for retail pharmacy when they should have been put under "General Regulations Regarding Pharmacies" because the sections were always intended to apply to all types of pharmacies. There has also been an update for areas of the regulation to reflect previous changes in the statutes and regulations including changing from the wording "annual" to "biennial" renewal of permits consistent with the Board's biennial permits that are currently issued. The last change in Regulation 4 is to section 04-05-0001 – Hospital Pharmaceutical Services Permit. This section is being changed from nonspecific wording to wording that specifies the role of a pharmacist-in-charge and the time requirements for the pharmacist-in-charge in hospital settings. This change is being made because the language "one (1) pharmacist" was intended to mean the pharmacist-in-charge as it had been interpreted by most hospitals but was not stated specifically so. This change will correct this oversight and speak directly to the intent of the regulation.

Regulation 08 – Wholesale Distribution

The changes clarify language regarding the requirements for a wholesale distributor in Arkansas to report thefts or losses of controlled substances in a timely manner consistent with the requirements for pharmacies to report losses.

Changes also delete the term "annually" in reference to registration with the Board of Pharmacy and replace "annual license renewal" with "biennial license renewal" because all permits issued by the Board of Pharmacy are issued on a biennial basis.

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

Technician Permit Renewals

The Arkansas State Board of Pharmacy sent out pharmacy technician permit renewals in October 2008. These permit renewals are sent directly to pharmacy technicians, and it should be noted that technician permits that are not renewed expire on December 31, 2008. The Arkansas State Board of Pharmacy allows a grace period until March 31 on permits. However, there is a $20 penalty on technician permit renewal if not renewed by February 1, a $40 penalty if not renewed before March 1, and if a permit is not renewed by April 1 then the permit is void. This means that in order to get a technician permit again, an individual must apply for reinstatement and undergo a criminal background check, which includes fingerprinting and payment of reinstatement fees. While pharmacy technicians are responsible for keeping their permit 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. Past action by the Board regarding the employment of technicians without a valid permit or technicians who have allowed their permit to lapse has resulted in a $500 fine for the pharmacist-in-charge, a $1,000 fine for the pharmacy, and the technician being put on probation. We would strongly encourage you to use our Web site to renew technician permits via the Internet as it will speed up the renewal process for your technicians, and it will also reduce the turn around time for technicians to receive their new permits. This is also the only way that we can accept credit card payments for renewal of these permits.

Business Permit Renewals

The following additional permits are also in their renewal cycle at this time: charitable clinic pharmacies, institutional pharmacies, wholesale distributors, List 1 chemical distributors, hospital pharmacies, nursing home consultants, and durable medical equipment permits. Charitable clinic permits and institutional permits cannot be renewed via the Internet but all others may be renewed through our Web site. Once again, renewing these permits via the Internet will allow use of a credit card for payment and will also greatly reduce the turn around time for delivery of the new permits.

From DEA Diversion Control Q & A

Question: What changes may a pharmacist make to a prescription written for a controlled substance?

Answer: The pharmacist may add the patient's address or change the patient's address upon verification. The pharmacist may change or add the dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with and agreement of the prescribing practitioner. Such consultations and corresponding changes should be noted on the prescription as well as the patient's medical record. Pharmacists and practitioners must comply with any state/local laws, regulations, or policies prohibiting any of

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Study Fuels Concerns over Foreign Drugs Bought Online

According to study results published in the May 2008 issue of *Annals of Pharmacotherapy*, many prescription medications purchased from foreign pharmacies through Internet drug outlets differ significantly from the versions approved by the Food and Drug Administration (FDA). "These findings have implications for safety and effectiveness that should be considered by clinicians to potentially safeguard patients who choose to purchase foreign-manufactured drugs via the Internet," the study authors say.

The study evaluated 20 simvastatin tablets and capsules, including the US innovator product and 19 generic samples obtained from international Internet drug outlets. Tablet samples were tested according to United States Pharmacopeia (USP) guidelines where applicable, using high-performance liquid chromatography, disintegration, dissolution, weight variation, hardness, and assessment of physical characteristics.

Several international samples analyzed were not comparable to the US product in one or more aspects of quality assurance testing, and significant variability was found among foreign-made tablets themselves. Five samples failed to meet USP standards for dissolution, and two for content uniformity. Among all samples, variability was observed in hardness, weight, and physical characterization.

Testing Medication Names Prior to Marketing

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with 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: 200 Lakeside Dr, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

Medication names that look-alike and sound-alike, confusing or absent drug labeling, and non-distinct or ambiguous drug packaging significantly contributes to medication errors. This is not a new problem. These conditions have led to serious drug mix-ups and deaths. Research has identified that one of the most frequent causes of pharmacy drug dispensing errors (29%) is failure to accurately identify drugs, most prominently due to look-and sound-alike drug names (Leape et al. JAMA, July 5, 1995).

In addition, many medications are packaged in bottles with similar shapes and similar labels, making it easy to confuse one drug with another.

MedMARX data reports there are 1,470 different drugs implicated in medication errors due to brand and/or generic names that looked or sounded alike. From this data, USP has compiled a list of 3,170 pairs of names that look and/or sound alike.

FDA is also concerned about drug naming confusion and its subsequent potential error effects. On June 5-6, 2008, FDA hosted a public workshop to discuss a concept paper (*www.fda.gov/cder/drug/MedErrors/meeting_names.pdf*) about a pilot program to address look- and sound-alike brand names. The pilot, called for in the FDA Amendments Act of 2007, would allow drug companies (or outside contractors) to voluntarily evaluate proposed brand names and submit the data for review to FDA. Currently, FDA's Division of Medication Error Prevention screens drug names using its own safety testing methods, in consultation with other divisions responsible for product approval.

The concept paper outlines the types of studies that should be conducted, including simulations of real-world conditions with practicing clinicians who evaluate handwritten, electronic, and oral prescribing scenarios to detect name similarities and other potential confusion with laboratory and medical terms or abbreviations. Dosage form, strength, and frequency also should be considered, as well as the clinical environment where it will be used. Based on discussions during the June meeting and submitted comments, FDA will revise the concept paper and present testing methods to the pharmaceutical industry.

It is hoped that testing drug names prior to marketing will decrease the number of look-and sound-alike medication names. ISMP receives numerous reports of

errors and potential errors caused by look-and sound-alike medications every year. ISMP, through its wholly owned for-profit subsidiary Med-E.R.R.S., Inc®, has been reviewing drug names and packaging for pharmaceutical manufacturers for more than 10 years.

If you are a pharmacist or other health care practitioner who is interested in medication safety and error prevention, you can make a difference! Med-E.R.R.S. is looking for pharmacists from all practice settings to help test labeling, packaging, and nomenclature in the pre-marketing phase for pharmaceutical companies. The process is fun, simple, and easy and a small honorarium is paid for your participation.

For more information or to sign up, go to *www.med-errs.com* and click on "Become a Reviewer."

Coalition Looks to Pharmacies, Regulators to Reduce Diversion

A recent report by the Coalition Against Insurance Fraud looks to pharmacies and pharmacy regulators, among others, to cut down on the prevalence of prescription drug diversion, particularly of controlled substance analgesics.

The report, "Prescription for Peril: How Insurance Fraud Finances Theft and Abuse of Addictive Prescription Drugs," calls on the pharmacy profession to provide additional training on prescription drug abuse and diversion in pharmacy education curricula and continuing professional education, and to exert closer point-of-sale scrutiny of certain prescriptions and patients. For instance, the report suggests diversion could be reduced significantly if pharmacies asked for photo identification in connection with controlled substance prescriptions, similar to regulations in place for pseudoephedrine-containing products.

The coalition also recommends wider adoption of prescription monitoring programs to maintain statewide records of narcotic prescriptions, allowing closer monitoring by prescribers and dispensers. In addition, the coalition calls on lawmakers and licensing boards to "swiftly and decisively penalize the small fraction of prescribers and dispensers who facilitate drug diversion and abuse."

FDA Encourages Pharmacists to Use Patient Safety News

FDA Patient Safety News is a monthly video news program produced by FDA targeted to pharmacists and other health care professionals. The program provides the latest information on recalled and counterfeit products, important safety alerts, preventing medical errors and mitigating risks from the use of medical products, including drugs, devices, vaccines, and diagnostic products.

The videos can be watched online or downloaded free of charge. Pharmacists can view the entire program or individual segments, and FDA encourages further use and distribution of the video or text of the program, as there are no copyright restrictions. The video and demonstrations can also be used in staff-development programs or in other teaching environments.

Pharmacists can search for video segments on topics of interest, get additional information about topics, e-mail segments to others, report problems with medical products to FDA, and sign up to be notified about each month's program. The show is also broadcast on several medical satellite networks: VHA, GE TiP-TV, HSTN, LTCN, and HNN. These networks presently reach over 4,000 hospitals and long-term care facilities across the US.

More information about the program and how to join the program mailing list is available on the FDA Web site at *www.fda.gov/psn* or by sending an e-mail to PSNews@cdrh.fda.gov.

Switch to HFA-Propelled Albuterol Inhalers Advised in Anticipation of CFC Ban

FDA recently issued a public health advisory alerting patients, caregivers, and health care professionals to switch to hydrofluoroalkane (HFA)-propelled albuterol inhalers because chlorofluorocarbon (CFC)-propelled inhalers will not be available in the United States after 2008. CFC-propelled albuterol inhalers are being phased out to comply with the Clean Air Act and an international environmental treaty, the Montreal Protocol on Substances that Deplete the Ozone Layer. Under this treaty, the US has agreed to phase out production and importation of ozone-depleting substances including CFCs. No CFC-propelled albuterol inhalers may be produced, marketed, or sold in the US after December 31. Three HFA-propelled albuterol inhalers have been approved by FDA: Proair® HFA Inhalation Aerosol, Proventil® HFA Inhalation Aerosol, and Ventolin® HFA Inhalation Aerosol. In addition, an HFA-propelled inhaler containing levalbuterol is available as Xopenex® HFA Inhalation Aerosol. More information is available on the FDA Web site at *www.fda.gov/cder/mdi/albuterol.htm*.

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these changes to controlled substance prescriptions. The majority of changes can be made only after the pharmacist contacts the prescribing practitioner. After consultation with the prescribing practitioner, the pharmacist is permitted to add or change the dosage form, drug strength, drug quantity, directions for use, and issue date. The pharmacist is permitted to make information additions that are provided by the patient or bearer, such as the patient's address; such additions should be verified.

The pharmacist is never permitted to make changes to the patient's name, controlled substance prescribed (except for generic substitution permitted by state law), or the prescriber's signature.

DEA Form 106

Federal Regulation (Section 301) of the Controlled Substances Act of 1970 (PL91-513) requires registrants to submit a report of any loss of controlled substance to the Drug Enforcement Administration (DEA).

Arkansas State Board of Pharmacy Regulation 07-04-0006 requires that any holder of a pharmacy permit that suffers a theft or loss of controlled substances shall:

(a) Notify Arkansas Department of Health Division of Pharmacy Services and Drug Control, the nearest Drug Enforcement Administration Diversion Field Office, and the Arkansas State Board of Pharmacy **immediately upon discovery** by phone or fax, and

(b) Deliver a completed DEA Form 106 to each of the agencies listed in (a) **within 7 days of the occurrence of said loss or the discovery of said loss.**

*According to 21 CFR part 1301 Sec. 1301.74 (c) "The registrant shall notify the Field Division Office of the Administration in his area, **in writing**, of any theft or significant loss of any controlled substances **within one business day of discovery of the theft or loss**." This written notice should be faxed to 501/217-6597.

A DEA Form 106 is to be used to report such loss. You should fill out an electronic DEA Form 106 through the DEA Web site at *www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html*.

The DEA Web site link above will give you the opportunity to read amended instructions on how to fill out your DEA Form 106 including instructions to print out a copy of the form once complete. After printing a copy of this form it should be signed by the company officer or pharmacist responsible for completing the form.

1. **Send the original and one extra copy to:**
   DEA Resident Office, ATTN: Diversion Investigations
   10825 Financial Parkway, Suite 200
   Little Rock, AR 72211-3557
   501/217-6500 fax 501/217-6597
2. **Send one copy to:**
   Arkansas State Board of Pharmacy
   101 East Capitol, Suite 218
   Little Rock, AR 72201
   501/682-0190 fax 501/682-0195
3. **Send one copy to:**
   Arkansas Department of Health
   Pharmacy Services and Drug Control
   4815 W Markham, Slot #H-25
   Little Rock, AR 72205-3867
   501/661-2325 fax 501/661-2769
4. **Retain one copy for your records**

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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