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Arkansas State Board of Pharmacy

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Disciplinary Actions from October Board Meeting

During the October 2006 Arkansas State Board of Pharmacy meeting, a disciplinary hearing was held regarding the operation of a pharmacy without having a pharmacist present. The following action was taken as a result of this hearing.

PD License #7818, Pharmacy Technician #PT88001, and Pharmacy Permit #AR19514 – Charged with violations of Regulation 03-00-0005(a), allowing a pharmacy technician to dispense prescription-only drugs when the pharmacist was not present. The Board ordered the pharmacist to pay a monetary penalty of two thousand dollars ($2,000), ordered the pharmacy technician to pay a monetary penalty of five hundred dollars ($500), and ordered the pharmacy permit to pay a monetary penalty of five thousand dollars ($5,000). The Board also placed all three permits on probation for a period of two years.

Regulation Changes from the October Board Meeting

The Arkansas State Board of Pharmacy approved changes to the following regulation at the October 2006 Board meeting.

Regulation 01 – General Operations

Amend section 01-00-0005 – Certificates of Licensure – Expiration, to clarify the dates of expiration of permits issued by the Arkansas State Board of Pharmacy to reflect changes that are now in effect in related statutes and regulations.

Amend section 01-00-0006 – Board of Pharmacy Meeting Requirements, to clarify the normal time for designated meetings of the Arkansas State Board of Pharmacy.

Amend section 01-00-0007 – Fees Charged by the Board of Pharmacy, to update the fees for intern registration and to clarify the expiration of certain business permits due to nonrenewal.

Regulation 02 – Pharmacists

Amend section 02-01-0003 – Definitions, to remove the definition "limited supervision" from this regulation. This change will remove the ability for a graduate intern to work within "phone contact" of a licensed pharmacist and will mean the graduate intern must be supervised by a preceptor while working.

Amend section 02-01-0004 – Requirements for Internship Training, to update requirements for foreign pharmacy graduates to train as interns in Arkansas to match the National Association of Boards of Pharmacy® (NABP®) Foreign Pharmacy Graduate Examination Committee™ (FPGEC®) Certification program requirements. Additions have also been made to this regulation to specify that only hours worked under the direct supervision of the intern's assigned preceptor will count for practical experience. Changes to this section also include the deletion of the word "limited" from the supervision requirements for graduate interns.

Amend section 02-01-0005 – Rules Applying to Preceptors Who Train Interns, to require one year of licensure to be certified as a preceptor and to amend the requirement so that a pharmacist does not have to be employed full time to serve as a preceptor. Language in this section was also changed to require attendance of at least one professional meeting during each licensure biennium instead of each year for preceptors and alternate preceptors. It is important to note once again that interns will only receive hours of credit for practical experience for hours worked under their assigned preceptor.

Amend section 02-01-0007 – Accredited Pharmacy Degree Program, to update language to state doctor of pharmacy for accredited pharmacy degree programs as that is the current national standard for the Accreditation Council for Pharmacy Education.

Amend section 02-02-0001 – Requisites for Examination, to update language regarding FPGEC Certification from NABP.

Regulation 08-01 Medical Equipment, Legend Devices, and/or Medical Gas

Amend section 08-01-0002 – Licensure Required, to outline the minimum required information for licensure under this regulation. Language has also been added to define the minimum qualifications for licensure for this type of permit.

*These regulation changes took effect November 13, 2006. The updated regulations may be viewed in their entirety in the Pharmacy Lawbook section of our Web site at www.arkansas.gov/asbp.

Technician Permit Renewals

The Arkansas State Board of Pharmacy sent out pharmacy technician permit renewals in early November 2006. 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, 2006. The Arkansas State Board of Pharmacy allows a grace period until March 31 on permits; however, there is a $20 penalty on technician permit renewals if not renewed by February 1, a $40 penalty if not 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 permits 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

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FDA Launches Consumer Educational Program on the Safe Use of OTCs

The United States Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, in cooperation with the National Council on Patient Information and Education and Maryland's Montgomery County Public Schools, has launched "Medicines in My Home," an interactive educational program aimed at informing middle school students about the safe and effective use of over-the-counter (OTC) medicines. Key concepts students will learn from the program are:

- the Drug Facts label tells you what a medicine treats, if it is right for you and your problem, and how to use the medicine;
- read the label and follow the directions carefully and correctly;
- two medicines with the same active ingredient should not be used at the same time; and
- measure medicines correctly with measuring tools made for medicines.

The program emphasizes that medicines should be used only with permission from an adult and that if there are questions about medicine use, ask a pharmacist or doctor. Materials are provided to encourage students to share what they learn with their families so that all family members can learn to use OTC medicines more safely. Program information can be found at www.fda.gov/medsinmyhome.

HHS Warns Public of Heroin and Fentanyl Deadly Combo

In efforts to warn the public and health care professional communities regarding a recent rash of drug-related deaths due to an illicit street drug combination consisting of the prescription medication fentanyl and either heroin or cocaine, the Department of Health and Human Services (HHS) released a fact sheet containing specific information with the goal of saving lives.

A letter from H. Westley Clark, director of HHS Center for Substance Abuse Treatment, to health care professionals warned that in "just one week, an estimated 33 individuals in the Detroit, MI area are reported to have died after using this fatal mix of drugs; the same drug combination may have been responsible for more than 100 deaths in the same region last September [2005]." Philadelphia, PA; Chicago, IL; St Louis, MO; and Camden, NJ have also recently experienced similar clusters of drug-related deaths.

Fentanyl, an injectable Schedule II prescription opioid analgesic, is roughly 50 to 80 times more potent than morphine but can also be produced in clandestine laboratories in powder form and then mixed with or substituted for heroin. Fentanyl-related overdoses can result in sudden death through respiratory arrest, cardiac arrest, severe respiratory depression, cardiovascular collapse, or severe anaphylactic reaction. In some cases, heroin or cocaine users are aware they are purchasing this dangerous combination of drugs and in other cases, they are not. Because the potency of street-sold heroin or cocaine is amplified markedly by fentanyl and because the inclusion of fentanyl may not be disclosed, any use, even a reduced dose, can result in overdose or death. The fact sheet advises that suspected overdoses should be treated rapidly with a naloxone injection, 0.4 to 2 mg intravenously, subcutaneously, or intramuscularly every two to three minutes, which should rapidly reverse symptoms related to a narcotic overdose; if there is no response after 10 minutes, then a different diagnosis should be considered.

For additional information, contact Kenneth Hoffman at the Substance Abuse and Mental Health Services Administration at 240/276-2701 or via e-mail at Kenneth.Hoffman@samhsa.hhs.gov.

Pharmacy Technicians and Medication Error Prevention

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.

In an October 2005 article in the *American Journal of Health-System Pharmacists*, the results of a random nationwide survey of more than 800 pharmacy technicians' views about their medication errors was published (Desselle SP. Certified pharmacy technicians' views of their medication preparation errors and educational needs. *Am J Health-Syst Pharm.* October 1, 2005; 62:1992-97). Most of the technicians worked in community pharmacies, but more than a quarter (27%) were employed in hospitals.

As one might expect in both settings, interruptions and inadequate staffing were among the most frequent factors perceived to contribute to technician medication preparation errors. Inadequate staffing was perceived as especially problematic in chain pharmacies, while inadequate supervision by pharmacists was cited as a factor more frequently by hospital technicians. It also may come as no surprise that the pharmacists' most frequently cited response to an error that was caught during the checking process was to make the technician aware of the error and require him or her to correct it. However, only about 17% of the technicians reported that the pharmacist had used the error as an opportunity to provide instructions on how to avoid the same or similar errors in the future.

While many of these respondents attributed this responsibility to the organization as a whole, not necessarily the individual pharmacist who detects an error, it appears technicians may not be receiving guidance about system and process changes that can help avert errors. After an

error is corrected, the checking pharmacist should find time that same day (or the next day, if necessary) to review the error with the technician and suggest ways to avoid it, including safer behavioral choices if applicable. Later, during pharmacy staff meetings or other forms of intradepartmental communication, errors, their causes, and ways to prevent them should be shared with all staff in a way that does not embarrass those who were possibly involved in the errors.

One or Both Nostrils?

Submitted by ISMP

Although many nasal sprays are intended for administration in each nostril for a single dose, there are notable exceptions. For example, some medications are meant to be delivered via the nasal passage but **not** sprayed into each nostril. Calcitonin salmon (**Fortical®, Micalcin®**) is a prime example. Patients should administer a single spray (200 international units) into one nostril daily, using alternate nostrils each day. Other examples in metered-dose or unit-dose nasal spray containers include butorphanol, desmopressin (**DDAVP®**), sumatriptan (**Imitrex®**), and zolmitriptan (**Zomig®**).

Some pharmacy and/or physician electronic prescribing systems have been preprogrammed to print directions that default to "spray in each nostril" when nasal sprays are selected. For the previously mentioned drugs, this would result in the administration of a double dose of medication. One health care facility recently reported that about 50 patients, who had been prescribed medications intended to be given into one nostril, had prescription container labels that instructed the patients to administer the spray into both nostrils. Some physicians might anticipate patients' confusion and write the prescription for "half" doses in each nostril. Even if instructed to use the spray in one nostril, patients who administer other nasal medications in both nostrils may spray these medications into both nostrils without thinking.

Explicit verbal directions and written instructions that emphasize administration via one nostril only are critical to avoid an overdose.

FDA/ISMP National Campaign to Help Eliminate Ambiguous Medical Abbreviations

FDA and the ISMP have launched a national education campaign that focuses on eliminating the use of potentially harmful abbreviations by health care professionals, medical students, medical writers, and the pharmaceutical industry. The campaign addresses the use of error-prone abbreviations in all forms of medical communication, including written medication orders, computer-generated labels, medication administration records, pharmacy or prescriber computer order entry screens, and commercial medication labeling, packaging, and advertising. For more information visit www.fda.gov/cder/drug/MedErrors.

DEA Provides Retail Training Materials

Drug Enforcement Administration (DEA) recently announced the availability of training materials regarding self-certification training for regulated retail sellers of non-prescription drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine as required by the Combat Methamphetamine Epidemic Act of 2005 (Title VII of Public Law 109-177).

Two sets of training materials have been developed: one for regulated persons who are mobile retail vendors, and one for regulated persons who are not mobile retail vendors. Both sets of training materials may be found on the Diversion Control Program Web site, www.deadiversion.usdoj.gov, under "Combat Methamphetamine Epidemic Act of 2005."

DEA notes that regulated sellers must use the content of these training materials in the training of their employees who sell scheduled listed chemical products. A regulated seller may utilize additional content in its training program, but DEA's posted material must be included.

DEA is continuing to work to promulgate regulations to implement the Combat Methamphetamine Epidemic Act of 2005.

FDA Announces Release of Guidance on Useful Written Consumer Medication Information

In the July 18, 2006 *Federal Register,* FDA announced the availability of a guidance entitled "Useful Written Consumer Medication Information (CMI)." This guidance is intended to assist individuals or organizations (eg, pharmacies, private vendors, health care associations) in developing useful written consumer medication information to comply with Public Law 104-180. CMI is written information about prescription drugs developed by organizations or individuals, other than a drug's manufacturer, that is intended for distribution to consumers at the time of dispensing. Since neither FDA nor the drug's manufacturer reviews or approves CMI, FDA recommends that the developers of written medication information use the factors discussed in this guidance to help ensure that their CMI is useful to consumers.

This guidance can be accessed at www.fda.gov/cder/guidance/7139fnl.htm.

2007 Survey of Pharmacy Law Available Soon

NABP's 2007 *Survey of Pharmacy Law* CD-ROM will be available in early December 2006. New topics include whether or not licensure for wholesale distributors of non-prescription drugs is required and the recognition of Verified-Accredited Wholesale Distributors® accreditation.

The *Survey* consists of four sections: organizational law, licensing law, drug law, and census data. The *Survey* can be obtained for $20 from NABP by downloading the publication order form from www.nabp.net and mailing in the form and a money order to NABP. The CD-ROM is provided free of charge to all final-year pharmacy students through a grant from AstraZeneca Pharmaceuticals. If you do not have Web access or would like more information on the *Survey,* please contact NABP at 847/391-4406 or via e-mail at custserv@nabp.net.

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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.

Internet Pharmacy

The Board of Pharmacy has received a steady stream of calls regarding contracts offered to community pharmacies throughout Arkansas requesting that pharmacies act as fulfillment centers for "mail order pharmacies," "Internet pharmacies," or "specialty pharmacies." These requests often offer up front money, guaranteed prescription counts, and minimum profit levels for a community pharmacy and will usually say something to the effect that they either have "too much business" or that they are trying to expand their business model. These contracts are usually based upon nonvalid patient prescriber relationships, which result in illegal prescriptions. Once again the saying "if it sounds too good to be true" comes to mind. If you have been approached with a contract similar to these then please contact the Board office to notify us that these companies are soliciting business with you.

Combat Methamphetamine Act of 2005

As a reminder to all of our Arkansas licensed pharmacists, if your employer sells pseudoephedrine-containing products, in addition to state-based requirements for the sale of these products, the Combat Methamphetamine Act of 2005 has been in full effect since September 30, 2006. The federal requirements in this act require that logbooks have the following notice for buyers to read when giving information for their purchases: "Notice to Purchasers: Warning: Section 1001 of Title 18, United States Code, states that whoever, with respect to the logbook, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or makes any materially false, fictitious, or fraudulent statement or representation, or makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, shall be fined not more than $250,000 if an individual or $500,000 if an organization, imprisoned not more than five years, or both."

Product Substitution

The Board has had questions regarding the decrease in availability of chlorofluorocarbon (CFC) albuterol inhalers and the switching of patients from CFC to hydrofluoroalkane (HFA) albuterol inhalers. It is important to note that CFC albuterol prescriptions cannot be automatically switched to HFA albuterol prescriptions as these products are not equivalently rated. Furthermore, at the current time, the HFA albuterol inhalers are not A-rated products and may not be substituted either. Changing from CFC to HFA or changing between HFA albuterol products at this time will require physician approval and the creation of a new prescription.

Arkansas Pharmacy Support Group Help Line
870/636-0923

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