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Arkansas State Board of Pharmacy

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New Assistant Director on Staff

The Arkansas State Board of Pharmacy is pleased to announce that John Clay Kirtley, PharmD, has been named assistant director of the Board. John comes to the Board from University of Arkansas for Medical Sciences (UAMS) College of Pharmacy, where he worked with community clinical clerkship rotations. He is originally from Camden, AR, and completed his pre-pharmacy coursework at Ouachita Baptist University in Arkadelphia. John is a 2002 PharmD graduate of UAMS and has also worked as a community pharmacist. As a student he served as the national student president and as a member of the Board of Trustees for the American Pharmacists Association. He and his wife, Melanie, who is also a pharmacist, live in Little Rock with their beautiful daughter, Allison Grace, and their Labrador, Daisy.

Arkansas State Board of Pharmacy Computer Conversion

The Board recently installed new computer licensing software and we are in Phase I of the conversion process. This conversion has helped us identify many deficiencies that we had in our old computer system and in our office procedures – some of which we were aware of and some of which we were not. The new system is up and running and, as we process pharmacy technician and business renewals, we are adding and correcting data such as mailing and e-mail addresses, phone numbers, places of employment, facility ownership, and other information. Please bear with us while we make these changes. Phase II will begin in the spring and will provide for online license verification and for other improved processes.

You may notice that we have made some minor changes to the look of permits, letters, and notices. We have also changed the numeric lead-in to license/registration numbers so that they all have the same basic format. For example, hospital pharmacy permits are now in the format HP012345, instead of H-12345. The numbers have not changed but we eliminated leading dashes, spaces, and zeros.

Technician Permit Renewals

The Board sent out pharmacy technician permit renewals in early December 2004. While these permits are sent directly to pharmacy technicians, the Board has had a number of technicians who have called saying that they have not received a renewal notice. In most cases this has been due to a change of address that the Board did not receive. This is a violation of pharmacy technician registration requirements and may be subject to disciplinary action. Furthermore, it should be noted that technician permits that were not renewed expired on December 31, 2004. The Board 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 receive a technician permit, 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 license current, it is the responsibility of the pharmacist-in-charge (PIC) 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 actions by the Board regarding the employment of technicians without a valid license or technicians who have allowed their license to lapse has resulted in a $1,000 fine for the PIC, a $500 fine for the pharmacy, and the technician being put on probation. Regulation 03-00-0002 may be viewed in its entirety on our Web site at www.arkansas.gov/asbp.

Change of Employment Status

Not only is a change of employment status required for pharmacy support staff, but also for pharmacists. Both the pharmacist and employer should notify the Arkansas State Board of Pharmacy of any employment status changes. This applies to numerous pharmacy employment settings including retail/community pharmacy, charitable clinic pharmacy, hospital pharmacy, nuclear pharmacy, and nursing home consulting. The following regulation addresses this issue:

02-00-0001 CHANGES IN EMPLOYMENT Whenever any licensed pharmacist shall change his [or her] place of employment for any reason, it shall be the duty of the former and current employer and said licensed pharmacist to notify the Arkansas State Board of Pharmacy in writing of such change within five days after such change of employment. Notification must be made by letter, fax or email and must contain the new place of employment of the licensed pharmacist, his [or her] license number, and his [or her] renewal number. (October 9, 1980, amended October 14, 1981)

The Effects of the Flu Vaccine Shortage

In early October 2004, Chiron Corporation, one of two major pharmaceutical manufacturers of influenza vaccine, informed the Centers for Disease Control and Prevention (CDC) that it would be unable to distribute its estimated 48 million doses of Fluvirin® in time for the 2004-05 flu season. The United Kingdom's Medicines and Healthcare products Regulatory Agency temporarily suspended Chiron's license for its Liverpool facility that was scheduled to produce Fluvirin for distribution throughout the United States.

During the 2003-04 flu season, approximately 87 million doses of influenza vaccine were administered. Before Chiron's announcement, it was expected that 100 million doses would be available during this season, with Aventis, the other major influenza vaccine (Fluzone®) producer, contributing 54 million doses. Aventis has indicated that it will be able to produce an additional 2.6 million doses of influenza vaccine by January 2005.

Shortly after this announcement CDC convened its Advisory Committee on Immunization Practices to issue recommendations to prioritize the existing supply of influenza vaccine. In summary, the CDC recommends that the following priority groups be given available doses first due to their increased risk of complications from influenza infection:

- Persons aged 65 years or older;
- Children six to 23 months of age;
- Residents of long-term care facilities and nursing homes;
- Persons two to 64 years of age with chronic medical conditions;
- Health care workers involved in direct patient care;
- Household contacts and out-of-home caregivers of children less than six months of age;
- Children and teenagers between the ages of six months and 18 years who are receiving aspirin therapy; and
- Pregnant women.

Although not appropriate for everyone, FluMist® (MedImmune), the intranasal influenza vaccine, may be a good alternative for healthy persons between the ages of five and 49. Unlike Fluvirin and Fluzone injectables, which are inactivated influenza vaccines, FluMist is a live attenuated virus, which, if administered to at-risk groups, particularly those with compromised immune systems, may in rare instances actually cause disease.

Other alternatives include antiviral medications, which may be used to prevent and treat influenza infection. The antiviral agents rimantadine, Tamiflu® (oseltamivir), and amantadine are Food and Drug Administration (FDA) approved for treatment and prophylaxis of influenza. Relenza® (zanamivir) is only approved for influenza treatment. To help minimize resistance, CDC currently encourages the use of amantadine or rimantadine for influenza prevention while using the other antivirals oseltamivir or zanamivir for treatment.

Although vaccination and other pharmacologic interventions are extremely beneficial, health care professionals should educate patients on practical measures that can be taken to prevent the spread of influenza. These include:

- Washing your hands frequently to avoid the spread of viruses and bacteria;
- Avoiding contact with people who may be sick;
- Cleaning telephones, door knobs, and other environmental surfaces with disinfecting agents to help prevent the spread of viruses and bacteria;
- Covering your mouth and nose when coughing or sneezing;
- Staying home from work and/or school when you are sick and limiting/eliminating contact with those who have compromised immune systems.

In late August 2004, US Department of Health and Human Services (HHS) Secretary Tommy G. Thompson released preliminary plans for a National Pandemic Influenza Preparedness Plan that details a national strategy to prepare for and respond to an influenza pandemic and provides action steps that should be taken at the national, state, and local levels during a pandemic. At press time, the draft plan was located at www.hhs.gov/nvpo/pandemicplan. Pharmacists have become increasingly active in efforts to increase the public access to immunizations; according to National Association of Board's of Pharmacy® (NABP®) 2003-2004 *Survey of Pharmacy Law*, more than half of the states allow pharmacists to administer immunizations.

Because of the influenza vaccine shortage, many have expressed concerns about the possibility of counterfeit influenza vaccines. Pharmacies and health care institutions should only secure product from reputable resources and immediately report any suspect product. Also, many pharmacies have reported that the price of influenza injectable vaccines from some distributors has more than doubled since the shortage. In mid-October 2004, HHS Secretary Thompson urged the state attorneys general to prosecute those who were price gouging the cost of influenza vaccines.

For more information visit these Web sites:

FDA Flu Information – www.fda.gov/oc/opacom/hottopics/flu.html.

CDC Influenza Information (including vaccination information and Antiviral Medication Usage Guidelines) – www.cdc.gov/flu.

FDA Urges Consumer Education About Counterfeit Drugs

In an interim report, FDA's Anti-Counterfeiting Task Force stressed the importance of increasing awareness and education of stakeholders including the public concerning counterfeit drugs. The report called for increasing efforts of FDA and other government agencies to educate consumers and health care professionals on how to reduce the risk of obtaining counterfeit drugs before the event occurs; educating consumers and health care professionals on how to identify counterfeit drugs; and improving and coordinating FDA and industry messages and efforts to address and contain a counterfeit event. At press time, FDA had available on its Web site (www.fda.gov/cder/consumerinfo/counterfeit_all_resources.htm) public service announcements that can be printed for consumers as well as educational articles to inform the public.

One recent high-profile case concerned Viagra® (sildenafil citrate) that was dispensed from two pharmacies located in California. The counterfeit product closely resembled genuine Viagra tablets with respect to size, shape, color, and imprinting; however, the counterfeit drugs had subtle differences in tablet edging, film coating, imprinting font, and packaging. At press time, FDA, along with Pfizer, Inc, the legitimate manufacturer of Viagra, was analyzing the counterfeit product to determine its true composition and whether or not it posed any health risks; fortunately, no injuries had been reported. For comparative photos of the counterfeit drug and genuine Viagra, refer to Pfizer's "Dear Pharmacist" letter posted on the company's Web site at www.pfizer.com as well as FDA's distributed a press release that is now available at www.fda.gov.

Exactly one month after the counterfeit Viagra product was discovered, FDA expressed concern regarding counterfeit versions of the prescription drugs Zocor® (simvastatin) and carisoprodol, which were imported from Mexico by US citizens. Tests of these products revealed that the counterfeit Zocor, reportedly purchased at Mexican border-town pharmacies and sold under the name Zocor 40/mg (lot number K9784, expiration date November 2004, and lot number K9901, expiration date December 2006), did not contain any active ingredient. Likewise, the counterfeit carisoprodol 350/mg (lot number 68348A) test results indicated that the products differed significantly in potency when compared to the authentic product. FDA continues to investigate this matter and is working with Mexican authorities to ensure that further sale and importation of these products are halted. For more information on counterfeit Zocor, visit www.fda.gov/bbs/topics/ANSWERS/2004/ANS01303.html.

Diabetes or Alzheimer's Disease?

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.

Several reports of mix-ups have been reported in which the antidiabetic agent **AMARYL®** (glimepiride) had been dispensed to geriatric patients instead of the Alzheimer's Disease medication **REMINYL®** (galantamine). Each drug is available in a 4 mg tablet, although other tablet strengths are also available for each.

In one case, a 78-year-old woman with a history of Alzheimer's disease was admitted to the hospital with hypoglycemia (blood glucose on admission 27 mg/dL). A review of the medications she was taking at home revealed that her pharmacist dispensed Amaryl 4 mg, which she took twice daily instead of Reminyl 4 mg BID. In another case, an 89-year-old female received Amaryl instead of Reminyl for three days, eventually requiring hospitalization for treatment of severe hypoglycemia. A third patient received Amaryl instead of Reminyl while in the hospital, leading to severe hypoglycemia. All patients recovered with treatment. These events have been linked to poor prescriber handwriting and sound-alike, look-alike names. It is possible that prescriptions for Amaryl are more commonly encountered than those for Reminyl. Thus, confirmation bias (seeing that which is most familiar, while overlooking any disconfirming evidence) may lead pharmacists or nurses into "automatically" believing a Reminyl prescription is for Amaryl.

Obviously, accidental administration of Amaryl poses great danger to any patient, especially an older patient, who may be more sensitive to its hypoglycemic effects. Practitioners should be alerted to the potential for confusion between Amaryl and Reminyl. Prescribers should be reminded to indicate the medication's purpose on prescriptions. Consider building alerts about potential confusion into computer order entry systems and/or adding reminder labels to pharmacy containers. Patients (or caregivers) should be educated about all of their medications so they are familiar with each product's name, purpose, and expected appearance. Most importantly, at all times pharmacists and nurses should confirm that patients are diabetic before dispensing or administering any antidiabetic medication, including Amaryl. FDA, Aventis (Amaryl), and Janssen Pharmaceutica Products LP (Reminyl) are aware of these reports and will be taking action to help reduce the potential for errors.

Medication Safety Videos Available Free

FDA's Center for Devices and Radiological Health has been producing a monthly series of patient safety videos available via the Internet. ISMP and FDA's Division of Medication Errors and Technical Support, Office of Drug Safety, has been cooperating in this effort. Access www.ismp.org/Pages/FDAVideos.htm for videos related to medication errors. See www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/viewbroadcasts.cfm for a complete list of all broadcasts.

2005 Survey of Pharmacy Law Now Available

NABP's *2005 Survey of Pharmacy Law* CD-ROM is now available. Eight new questions were added to this year's *Survey;* topics include the formatting requirements of prescription pads, laws/regulations on the disposal of medications, and whether or not pharmacists are allowed to dispense emergency contraception without a prescription.

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 check or money order to NABP. The CD-ROM is provided free of charge to all final-year pharmacy students through a grant from GlaxoSmithKline. 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.

NABP Headquarters Moves to New Location

NABP has moved its Headquarters to 1600 Feehanville Drive, Mount Prospect, IL 60056. The new phone number is 847/391-4406 and the new fax number is 847/391-4502. All printed communications can be sent to the Feehanville Drive address. If you have any questions concerning the Association's new Headquarters, please contact the Customer Service Department at custserv@nabp.net or call 847/391-4406.

Register Now for NABP's 101st Annual Meeting

Register now for NABP's 101st Annual Meeting, May 21-24, 2005, at the Sheraton New Orleans Hotel, New Orleans, LA, so you can take advantage of the chance to earn up to five hours of continuing education (CE).

This year, CE sessions will focus on topics that fall under the Meeting's theme, "A Medley for Patient Safety: Accreditation, Self Assessment, Quality Care." Other events include the Educational Presentation Area and Poster Session, the President's Welcome Reception, NABP's annual business sessions, and the Annual Awards Dinner. In addition, you and your spouse or guest will have the opportunity to participate in a special recreational tour and the annual Fun Run/Walk.

For more information visit NABP's Web site at www.nabp.net, or contact NABP at 847/391-4406 or custserv@nabp.net.

Changes Pharmacists Can Make to a Schedule II Prescription

The majority of changes to a Schedule II prescription can be made only after the pharmacist contacts the prescribing practitioner. The pharmacist is permitted to change the patient's address, drug strength, drug quantity, drug dosage form, and directions for use. The pharmacist may add information such as the patient's address. The pharmacist is never permitted to make changes to the patient's name, controlled substance prescribed (except to substitute a generic drug), or the prescriber's signature. After consulting with the prescriber, the pharmacist must document any changes made including the time and date and his/her signature. Documentation on the prescription is the pharmacist's account of the changes made. These changes should match what appears in the patient's chart at the prescriber's practice site if the dosage form or the directions for use are changed.

The following letter was recently sent to the Arkansas State Board of Pharmacy from the Arkansas Department of Environmental Quality (ADEQ) as a response to issues that had arisen regarding the destruction of expired medications.

Disposal of Expired Drugs by physicians, clinics, hospitals, and pharmacies

The practice by druggists, hospitals, and clinics of flushing expired drugs is not a desirable or legal means of disposal for these materials, because it tends to put them directly into the ecosystem where they sometimes have unfortunate consequences. To dispose of expired drugs in this manner could harm the environment and put the business at risk of enforcement action by ADEQ or EPA [Environmental Protection Agency].

Expired drugs are "solid waste" (see APC&E [Arkansas Pollution Control and Ecology Commission] Reg. No. 23, Section 261.2) and therefore must be managed as such. The process for this is to:

- First, determine if your solid waste is a "hazardous waste" (see APC&E Reg. No. 23, Section 261.3)
- If the business generates "hazardous wastes," and if the business doesn't have an EPA ID number, it may be required to obtain one and provide periodic waste generation and disposal reports to the ADEQ. (see APC&E Reg. No. 23, Section 262.12)
- Regulated hazardous wastes are subject to special waste management requirements and may only be disposed of at [a] permitted hazardous waste disposal facility and shipped using a permitted hazardous waste transporter. (See APC&E Reg. No. 23, multiple sections)
- Should the wastes not be hazardous wastes, they are then considered industrial solid wastes and can go to a permitted Class I or Class IV landfill for disposal if the landfill operator agrees to accept these wastes.

It is a violation of Federal Regulations (40 CFR 403.5) for a business to discharge pollutants to a publicly owned treatment works (POTW) discharges [sic] that might harm the treatment system or violate discharge limits.

It is a violation of State regulations (APC&E Reg. No. 6 Section 6.106) for any business to discharge industrial wastewater into the environment without first having obtained a permit from ADEQ.

All APC&E Regulations are available for printing, downloading, or viewing at our website (www.adeq.state.ar.us) and EPA regulations are available at the EPA website (www.epa.gov).

Ron Alexander
ADEQ Business Assistance Program
12/03/04

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