February 2007

Arkansas State Board of Pharmacy

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Board of Pharmacy Meeting Dates for 2007

The following are planned meeting dates for the Arkansas State Board of Pharmacy for 2007.

February 21-22, 2007
June 14-16, 2007*
October 9-10, 2007

* The June 2007 meeting of the Arkansas State Board of Pharmacy will be held in conjunction with the Arkansas Pharmacists Association's Annual Convention in Rogers, AR.

Board Newsletter Available Electronically

For anyone interested in looking back at a previous issue of the *Arkansas State Board of Pharmacy Newsletter* as published by the National Association of Boards of Pharmacy® (NABP®), the Arkansas State Board of Pharmacy Web site, *www.arkansas.gov/asbp,* has back issues of the *Newsletter* from August 2000 available under the heading Pharmacist Information. These *Newsletters,* as well as *Newsletters* for other states, are also available on the NABP Web site, *www.nabp.net,* under the heading Newsletters at the top of the home page. As a reminder, 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's* contents. Please contact the Board office at 501/682-0190 if you have questions regarding any of the articles in this *Newsletter*.

Controlled Substance Inventory

Board staff would like to remind pharmacists that when completing your biennial inventory of controlled substances (CS) you must include all over-the-counter solid dosage forms of ephedrine, pseudoephedrine, or phenylpropanolamine as these are classified as CS in Arkansas. This is one of the most common problems that our Board inspectors have encountered when inspecting pharmacies in Arkansas as many stores have left these products off of their inventories. The CS inventory must contain the following information:

1. The pharmacy name and address
2. Drug Enforcement Administration (DEA) number of the registrant
3. The inventory date and time the inventory is taken (this will show if the inventory was taken before opening or after close of business)
4. The drug name(s)
5. The drug strength
6. The drug form (eg, tablet, capsule, syrup, etc)
7. The number of units/volume
8. The total quantity
9. The signature of the person responsible for the inventory

A copy of this inventory must be kept on file at the pharmacy for a minimum of two years.

Change of Pharmacist-in-Charge

The Board of Pharmacy continually has questions regarding the notification and paperwork requirements for changing a pharmacist-in-charge (PIC) for an Arkansas pharmacy. Board staff often finds that pharmacists fail to realize that this requirement applies to pharmacists that act as the PIC for surgery centers as well as retail and hospital pharmacy permits.

Regulation 04-02-0005 addresses the requirements for notification of a change in PIC. An important requirement to point out that is often overlooked is that when a pharmacist ceases to be the PIC of a pharmacy, the exiting PIC is required to do the following three things:

1. The exiting PIC must notify the Board of Pharmacy within five days that he or she will no longer be the PIC of that facility.
2. The pharmacist must surrender the permit issued in his or her name for cancellation.
3. The pharmacist must provide the Board of Pharmacy with an inventory of controlled drugs for the pharmacy as the ending inventory under his or her time as PIC. If a new PIC is being identified and submitted simultaneously with the departure of the current PIC, this inventory can serve as the inventory for both the departing and incoming PIC. The Change of Pharmacist in Charge Form is the very first form located in the Forms & Instructions section of the Arkansas State Board of Pharmacy Web site.

Technician Permit Renewals

The Arkansas State Board of Pharmacy sent out pharmacy technician permit renewals in early November 2006. While these permits are sent directly to pharmacy technicians, the

Continued on page 4

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and can only be ascertained by examining

FDA Issues Nationwide Alert on Counterfeit One-Touch Blood Glucose Test Strips

In mid October 2006, United States Food and Drug Administration (FDA) alerted the public to counterfeit blood glucose test strips being sold in the US for use with various models of LifeScan, Inc, One Touch Brand Blood Glucose Monitors. The counterfeit test strips potentially could give incorrect blood glucose values; either too high or too low. At press time, no injuries have been reported to FDA.

Consumers who have the counterfeit test strips should be instructed to stop using them, replace them immediately, and contact their physicians. Consumers with questions may contact the company at 1-866/621-4855. The counterfeit test strips were distributed to pharmacies and stores nationwide – but primarily in Ohio, New York, Florida, Maryland, and Missouri – by Medical Plastic Devices, Inc, Quebec, Canada and Champion Sales, Inc, Brooklyn, NY.

The counterfeit test strips and their characteristics are:

- One Touch Basic®/Profile®
  - Lot Numbers 272894A, 2619932, or 2606340
  - Multiple Languages – English, Greek, and Portuguese text on the outer carton
  - Limited to 50-Count One Touch (Basic/Profile) Test Strip packages
- One Touch Ultra®
  - Lot Number 2691191
  - Multiple Languages – English and French text on the outer carton
  - Limited to 50-Count One Touch Ultra Test Strip packages

LifeScan has alerted the public via a press release and has notified pharmacists, distributors, and wholesalers through a letter. In its letter, the company advises customers to contact their original source of supply for restitution. For more information, visit *www.GenuineOneTouch.com.*

New DEA Number Assignments; Updated DEA Practitioner's Manual Released

In early November 2006, Drug Enforcement Administration announced that due to the large Type A (Practitioner) registrant population, the initial alpha letter "B" has been exhausted. The Agency, therefore, has begun using the new alpha letter "F" as the initial character for all new Type A (Practitioner) registrations. For more information, visit *www.deadiversion.usdoj.gov/drugreg/reg_apps/new_reg_number110906.htm.*

Additionally, in August 2006, the Agency released the Practitioner's Manual, An Informational Outline of the Controlled Substances Act, 2006 Edition. The Manual, prepared by the Agency's Office of Diversion Control, is designed to assist practitioners (physicians, dentists, veterinarians, and other registrants authorized to prescribe, dispense, and administer controlled substances) in their understanding of the Federal Controlled Substances Act and its implementing regulations as they pertain to the practitioner's profession. The Manual can be accessed at *www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual090506.pdf.*

Optimizing Computer Systems for Medication Safety

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.

Computers that are used by pharmacists are essential professional tools that can increase staff efficiency and support effective drug utilization review and therapeutic drug monitoring. At the same time, pharmacists must not place sole reliance on this tool as a means to protect patients from drug-induced harm.

Many of today's computer order-entry systems provide vendor-defined and user-defined alerts that remind or warn staff about potential drug-related problems during order entry. The Institute for Safe Medication Practices (ISMP) often recommends these alerts as a way to inform staff about potential errors. However, pharmacists have expressed concern that the sheer number of warnings that appear on the screen during order entry can be overwhelming and slow the process. In many cases, clinically insignificant warnings are as likely to appear as those that are vital. As a result, staff may inadvertently bypass critical warnings, especially when the workload is high. This is easy to do with many systems.

In an informal survey on computer systems, we found that all too often it simply requires striking the "enter" key to bypass an alert, even those that could prevent serious or fatal errors. Also, if the system forces a response to the warning, practitioners who feel pressured to rush through order entry may select the first reason listed on the screen instead of appropriately addressing the issue. Another issue is that when pharmacists are properly alerted to a potential allergic reaction or harmful drug interaction, they may erroneously assume that the prescriber is already aware of the problem and fail to alert the prescriber directly.

When practitioners become accustomed to receiving unimportant or clinically irrelevant warnings they often ignore these "false alarms," or turn them off, at least mentally. Here are some strategies that can be used to optimize the effectiveness of alerts and minimize the possibility of overlooking the more significant ones:

- Use a tiered system for interactive warnings that allows staff to view and consider possible warnings but easily bypass less serious issues, if appropriate. Require a text entry to describe the response to more significant alerts.

- Pharmacies should assign pharmacists who enter orders the task of noting any warnings that they feel are not clinically significant. The severity level of certain alerts may need to be changed in order not to "overload" the pharmacist. However, wholesale changing of severity levels according to vendor specifications should be done with caution. Check with your vendor to fully understand how they assign severity levels before making any changes to ensure you are not missing warnings you deem to be critical.
- Make significant alerts as visible as possible. Some systems may allow large screen fonts in a contrasting color, flashing messages, sounds, or other means of distinguishing the alert.
- Maximize a system's capabilities whenever possible by incorporating serious error-prone situations that have been reported in this column as well as other publications.
- Review non-interactive pop-up messages on an ongoing basis, such as the ones we suggest for avoiding drug name mix-ups. Delete any that are no longer applicable.
- Apply auxiliary labels to drug packages and storage shelves to warn about unclear or confusing labeling and packaging, instead of using certain messages in the computer system.
- Consider printing warnings on drug labels or medication storage areas instead of building alerts into the order entry process. For example, print "Topical or External Use Only" warnings on drug labels for all drugs that can be administered safely only by this route.
- Many systems are capable of providing reports about all warnings that have been overridden. Assign a clinician or manager to review the report daily and periodically identify those warnings that are continually overridden. Share report results with staff members before changes are made to the computer system. Consider focusing on one or two common but critically important warnings to monitor the effectiveness of the computer's alert system and the response to the alert.

Revised Coumadin Labeling and Medication Guide

FDA and Bristol-Myers Squibb notified pharmacists and physicians of revisions to the labeling for Coumadin®, to include a new patient Medication Guide as well as a reorganization and highlighting of the current safety information to better inform providers and patients.

The FDA regulation 21CFR 208 requires a Medication Guide to be provided with each prescription that is dispensed for products that FDA determines pose a serious and significant public health concern.

Information about all currently approved Medication Guides is available at *www.fda.gov/cder/Offices/ODS/medication_guides.htm.*

To access the new Medication Guide, revised prescribing information and supplemental supporting documents, visit *www.fda.gov/medwatch/safety/2006/safety06.htm#Coumadin.*

FTC and FDA Act Against Internet Vendors of Fraudulent Diabetes Cures and Treatments

The Federal Trade Commission (FTC) and FDA, working with government agencies in Mexico and Canada, have launched a drive to stop deceptive Internet advertisements and sales of products misrepresented as cures or treatments for diabetes. The ongoing joint campaign has so far included approximately 180 warning letters and other advisories sent to online outlets in the three countries.

The joint diabetes initiative to stop commercial sale of fraudulent therapies originated with a Web surf for "hidden traps" by the International Consumer Protection and Enforcement Network, an organization of law enforcement authorities, members of the Mexico, United States, and Canada Health Fraud Working Group (MUCH), and the attorneys general offices of Alaska, Michigan, Ohio, Virginia, and Wisconsin. MUCH, which consists of regulatory officials from health, consumer, and competition protection agencies in the three North American countries, had previously conducted a campaign against fraudulent weight-loss products. Using the results of the Internet sweep, FTC sent warning letters for deceptive ads to 84 domestic and seven Canadian Web sites targeting US consumers, and referred an additional 21 sites to foreign governments. About a quarter of the firms have already changed their claims or removed their pages from the Internet, and several others are in contact with FTC.

FTC also announced a new consumer education campaign to teach consumers how to avoid phony diabetes cures. The materials encourage consumers to "Be smart, be skeptical!" and will be available in English, Spanish, and French. One component is a "teaser" Web site available at *http://wemarket4u.net/glucobate/index.html.* At first glance, the site appears to be advertising a cure for diabetes called Glucobate, but when consumers click for more information on ordering the product, it reveals information about avoiding ads for phony cure-alls in the future. The new education materials, including a bookmark and consumer alert, were introduced to coincide for Diabetes Awareness Month in November.

FDA Implements Strategy for Phony Dietary Supplement Claims

FDA has developed a strategy to focus its enforcement efforts in the area of dietary supplements. The strategy was designed to address illegal dietary supplement ingredients and ensure integrity and truthful labeling of dietary supplements. One emphasis is on claims aimed at patients with serious diseases such as cancer and diabetes. Over an approximate 12-month time frame, the Agency has sent more than 100 warning letters and other advisories to Internet firms and has seized products at one firm. In addition, the Agency maintains special Web sites, in English and Spanish, which amplify the Agency's counsel to consumers to check with their doctor, nurse or pharmacist before trying any new health care product. These materials cover a broad range of subjects of special interest to patients with diabetes (*www.fda.gov/diabetes/; www.fda.gov/diabetes/pills.html; www.fda.gov/opacom/lowlit/diabetes.html; www.fda.gov/opacom/lowlit/sdiabetes.html*), as well as more general health care information.

Continued from page 1

Board has had a number of technicians who have called saying that they have not received any renewal notices. In most cases, this has been due to a change of address of which the Arkansas State Board of Pharmacy has not been notified. This is a violation of pharmacy technician registration requirements and may be subject to disciplinary action.

Please review Regulation 03-00-0002 – Pharmacy Technicians – Registration Required

(e) If there is a change of mailing address for the pharmacy technician, the pharmacy technician shall immediately notify the Board of Pharmacy, in writing, of the new address.

Furthermore, it should be noted that technician permits that were not renewed expired on December 31, 2006. As of January 2, 2007, Board records show that 2,887 technicians had not renewed their permits for the 2007-2008 biennium. 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 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, 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 registrations current, it is the responsibility of the 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 action by the Board regarding the employment of technicians without valid permits or technicians who have allowed their permits to lapse has resulted in a $500 fine for the PIC, a $1,000 fine for the pharmacy, and the technician being put on probation. The Board encourages pharmacists to check and make sure that technicians working under your supervision have their renewed permits displayed in the pharmacy, and if any of your technicians have failed to renew by this point the Board suggests that they do so as soon as possible. The quickest way to renew a technician permit is by utilizing the option to renew online at *www.arkansas.gov/asbp* by clicking on the link License Maintenance and Online Renewals. When a permit is renewed online it is automatically entered into our system, which greatly reduces the processing time for the renewal.

DEA Phone Numbers

The Little Rock office of DEA has changed phone numbers recently. Its new telephone number is 501/217-6500, and its new fax number is 501/217-6597.

Just the Facts

When pulling the distribution list of pharmacists for this *Newsletter,* we took note that there are a total of 4,050 pharmacists currently licensed with the Arkansas State Board of Pharmacy with 2,821 currently residing in the state of Arkansas. For those of you thinking about your own pharmacist license number, the Board just issued license number PD10435. Listed by the license numbers, here are a couple of interesting facts: license numbers first exceeded PD05000 in 1961, PD06000 was issued in 1975, PD07000 was issued in 1983, PD08000 was issued in 1993, PD09000 was issued in 2000, and the Arkansas State Board of Pharmacy exceeded the 10,000 mark in 2004.

Arkansas Pharmacy Support Group Help Line
870/636-0923

The *Arkansas State Board of Pharmacy News* is published by the Arkansas State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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