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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

New Board Member Appointed by Governor Huckabee

It is our pleasure to announce that our office has received official notice from Governor Mike Huckabee that Benji Post, PD of Pine Bluff, AR, has been appointed to the Arkansas State Board of Pharmacy for a six-year term that commenced on June 30, 2005. Join us as we welcome Dr Post and congratulate him on his appointment. We look forward to working with him as we continue our mission to promote, preserve, and protect the public health, safety, and welfare by and through the effective regulation of the many aspects of the drug delivery system.

Dr Post is replacing Dr Larry Autry of DeQueen, AR, who has finished his term on the Board. Dr. Autry has served on the Board for eight years. His experience, leadership, and expertise will be missed by all of us and we wish him the best in his future endeavors.

We are also pleased to announce that Ross Holiman, BS, HEd of Little Rock, AR, has been reappointed to the Board for a second term. Mr Holiman has served on the Board since 1999 and we are glad to see that he will be continuing his service with us.

Regulation Changes from the June Board Meeting

The Arkansas State Board of Pharmacy approved changes to the following regulations at the June 2005 Board Meeting.

Regulation 4: Pharmacy

Amend section 04-00-0004 – **Re-use of Drugs Prohibited** to read: The reuse of returned portions of a prescription drug for human consumption is prohibited whether dispensed by order of a prescription or otherwise, except to allow patients in nursing facilities to donate unused medications to charitable clinic pharmacies as provided by Ark. Code Ann. §17-92-1101 *et seq* and Board Regulations 04-03-0004 and 04-07-0006.

The addition of subsection 04-03-0004 provides for charitable clinics to obtain a permit to participate in the pilot program to accept and dispense donated prescription medications by completing an application with supporting documentation to be presented to the Board for approval. The permit will expire on June 30, 2007, unless provided hereafter by legislation or Board regulation.

The addition of subsection 04-05-0004 defines standards for remote or off-site order entry that can be used by hospital pharmacies and outlines procedures to be submitted for Board approval of the request to use this process.

The addition of subsection 04-07-0006 defines and outlines the process that must be used by the nursing facility to donate and the charitable clinic to obtain and dispense the donated prescription medications.

Regulation 5: Long-Term-Care Facilities

Amend section 05-00-0003: to define the responsibilities of the nursing home consultant pharmacist in charge for the processing of unused prescription medications that will be either destroyed or donated in accordance with regulation 04-07-0006.

Amend subsection 05-00-0004: to clarify language regarding content changes for emergency kits used in long-term-care facilities. Under previous regulation, the annual review of each emergency kit needed to be reviewed by the executive director of the Board of Pharmacy even if it was within the emergency kit guidelines. With this regulation change, only exceptions to the approved guidelines for emergency kits will have to be approved by the Board of Pharmacy.

Regulation 8: Wholesale Distribution

The amendment to subsection 08-00-0008 exempts wholesalers that only carry medical gas from the requirement of equipping facilities with monitored alarm systems.

This is a brief summary of the changes to each Regulation. These changes will officially be part of Arkansas Pharmacy Regulations on August 12, 2005. The complete regulation can be obtained from our Web site at www.arkansas.gov/asbp in the "Pharmacy Lawbook" section. Please contact the Board Office at 501/682-0190 if you have any questions regarding these changes.

Duplication of Commercially Available Products

The Arkansas State Board of Pharmacy has had numerous questions regarding the practice of duplicating commercially available products. The Board has continually educated pharmacists that Arkansas Pharmacy Laws and Regulations do not allow for the practice of duplicating commercially available products. Arkansas Pharmacy Regulation **07-02: Compounding** sets forth very specific guidelines regarding the duplication of commercially available products:

07-02-0001 – Standards for Compounding and Dispensing Sterile Products

The purpose of this regulation is to provide standards in the conduct, practices, and operations of a pharmacy preparing and dispensing products requiring sterility, such as injectables, ophthalmics, and inhalants.

Compounding a drug product that is commercially available in the marketplace or that is essentially a copy of a commercially available Food and Drug Administration (FDA)-approved drug product is generally prohibited. However, in special circumstances a pharmacist may compound an appropriate quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available based on documentation provided by the

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New Board Will Oversee Management of Drug Safety Monitoring

Food and Drug Administration (FDA) has unveiled a program that aims to improve oversight of drug safety monitoring and to bolster openness in agency product review and decision making. Included is the creation of an independent Drug Safety Oversight Board, made up of medical experts from FDA and other government agencies. Also planned are Web postings of emerging drug data and risk information as well as written materials that provide targeted drug safety information to the public. For more information, see www.fda.gov/oc/factsheets/drugsafety.html.

ACPE Changes Provider Criteria Regarding Drug and Device Manufacturers

In early 2005, the Accreditation Council for Pharmacy Education (ACPE) ceased accepting applications from pharmaceutical and biomedical device manufacturers seeking accreditation as providers of continuing education (CE). Effective July 1, 2005, the organization will no longer recognize pharmaceutical and biomedical device manufacturers as accredited providers. In addition, any CE issued by a pharmaceutical or device manufacturer after June 30, 2005, is not valid. These changes were approved by the ACPE Board of Directors at its January 2005 meeting after the organization determined that manufacturers could not meet both ACPE's requirements and the recommended restrictions as stated in a Compliance Program Guidance for Pharmaceutical Manufacturers published by the Office of the Inspector General of the United States (OIG).

In 2003, OIG stated that manufacturers could be subjected to liability under federal statutory provisions if they maintain any influence over CE subject matter or presenters, or provide funding for attendees or other incentives with respect to CE attendance. Strict compliance with OIG's guidelines would relegate manufacturers to solely providing educational grants to CE providers in order to be free of liability. Meanwhile, ACPE's Criteria for Quality require that the CE provider control the content speakers or authors of a CE program, putting ACPE's requirements in opposition to OIG's guidelines; hence, ACPE, out of responsibility to health regulatory boards, the profession, and the public, must now accredit only those providers who are in compliance with the ACPE criteria and the OIG guidelines.

In accordance with ACPE's new policies, organizations with a commercial interest and any proprietary entity producing health care goods or services, with the exception of nonprofit or government organizations and non-health care-related companies, will not be eligible for ACPE accreditation status.

For more information, contact ACPE Executive Director Peter Vlasses at 312/664-3575, or via e-mail at pvlasses@acpe-accredit.org.

Let's Get to the 'Point': Prescription Misinterpretations Due to Decimal Points

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.

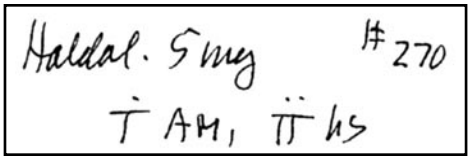
Problem: Numbers containing decimal points are a major source of error and, when misplaced, can lead to misinterpretation of prescriptions. Decimal points can be easily overlooked, especially on prescriptions that have been faxed, prepared on lined order sheets, or written or typed on carbon and no-carbon-required (NCR) forms (often used in hospitals and long-term care facilities). If a decimal point is missed, an overdose may occur. The importance of proper decimal point placement and prominence cannot be overstated.

For one, a decimal point should always be preceded by a whole number and never be left "naked." Decimal expressions of numbers less than one should always be preceded by a zero (0) to enhance the visibility of the decimal. For example, without a leading zero, a prescription for "Haldol® .5 mg" (see image shown on next page) was misinterpreted and dispensed as "Haldol 5 mg." We have received similar reports with Risperdal® (risperidone) in which "Risperdal .5 mg" was prescribed (instead of Risperdal 0.5 mg), but the patient received several 5 mg doses because the decimal point was overlooked.

In addition, a whole number should never be followed with a decimal point and a zero. These "trailing zeros" (eg, "3.0") are a frequent cause of 10-fold overdoses and should never be used. For example, when prescriptions have been written for "Coumadin® 1.0 mg," patients have received 10 mg in error. Similarly, a prescription for "Synthroid® 25.0 mcg" could be misread as "Synthroid 250 mcg."

Dangerous use of decimals can also be problematic if they appear in electronic order entry systems or on computer-generated labels. A newly admitted hospital patient told her physician that she took Phenobarbital® 400 mg PO three times daily. Subsequently, the physician wrote an order for

the drug in the dose relayed by the patient. A nurse saw the prescription vial and verified that this was the correct dose. However, prior to dispensing, a hospital pharmacist investigated the unusually high dose. When he checked the prescription vial, he found that it was labeled as "phenobarbital 32.400MG tablet." The label indicated that 30 tablets were dispensed with instructions to take one tablet three times daily. The hospital pharmacist contacted the outpatient pharmacy and suggested that the computer expressions including trailing zeros be changed to avoid serious medication errors. The pharmacy management agreed that trailing zeros appearing on labels might pose a risk and made the change immediately.



Safe Practice Recommendations

In order to avoid misinterpretations due to decimal point placement, pharmacists should consider the following:

- Always include a leading zero for dosage strengths or concentrations less than one.
- Never follow a whole number with a decimal point and a zero (trailing zero).
- Educate staff about the dangers involved with expressing doses using trailing zeros and naked decimal points.
- Eliminate dangerous decimal dose expressions from pharmacy and prescriber electronic order entry screens, computer-generated labels, preprinted prescriptions, etc.
- Avoid using decimals whenever a satisfactory alternative exists. For example, use 500 mg in place of 0.5 gram, 125 mcg instead of 0.125 mg, or 2 ½ mg instead of 2.5 mg.
- Identify drugs with known 10-fold differences in dosage strength (eg, Cytomel® 5 mcg and 50 mcg, Coumadin 1 mg and 10 mg, levothyroxine 25 mcg and 250 mcg) and place reminders in electronic order entry systems and on pharmacy shelves to alert practitioners to double-check the dosage strength.
- When sending and receiving prescriptions via fax, health care practitioners should keep in mind that decimal points can be easily missed due to "fax noise." Whenever possible, encourage prescribers to give original prescriptions (with an indication that it has been faxed) to their patients to take to the pharmacy for verification. Pharmacists should carefully review faxed prescriptions and clarify prescriptions that contain fax noise.
- Eliminate the lines on the back copy of NCR forms so that a person receiving can clearly see decimal points or other marks that were made on the top copy.
- Notify prescribers of the potential for error if misinterpretations due to decimal point usage are discovered.

DEA Issues Final Rules for Electronic Orders for Controlled Substances

On April 1, 2005, Drug Enforcement Administration (DEA) issued final rules regarding electronic orders for controlled substances. DEA revised its regulations to provide an electronic equivalent to the DEA official order form (Form 222), which is legally required for all distributions involving Schedule I and II controlled substances. The regulations will allow, but not require, registrants to order Schedule I and II substances electronically and maintain the records of these orders electronically. The regulations will reduce paperwork and transaction times for DEA registrants who handle, sell, or purchase Schedule I or II controlled substances. The effective date of the final rules was May 31, 2005.

The final rules were issued via the *Federal Register* on April 1, 2005, and may be downloaded from the following Web site address: www.access.gpo.gov/su_docs/fedreg/a050401c.html.

FDA Publishes Final Rule on Chlorofluorocarbons in Metered Dose Inhalers

FDA announced that albuterol metered-dose inhalers (MDI) using chlorofluorocarbon propellants must no longer be produced, marketed, or sold in the US after December 31, 2008.

The Health and Human Services (HHS) is encouraged that the manufacturers of three environmentally friendly albuterol inhalers are implementing programs to help assure access to these albuterol MDI for patients for whom price could be a significant barrier to access to this important medicine. These programs include MDI giveaways, coupons for reducing the price paid, and patient assistance programs based on financial need.

In a final rule, published March 31, 2005, in the *Federal Register*, HHS stated that sufficient supplies of two approved, environmentally friendly albuterol inhalers will exist by December 31, 2008, to allow the phasing out of similar, less environmentally friendly versions.

FDA Develops PSAs to Educate Consumers About Purchasing Medications Online

FDA recently released two public service announcement (PSA) brochures, which educate consumers about the advantages and disadvantages of purchasing medication online. The brochures also advise consumers to ensure a Web site is a US-licensed pharmacy by contacting their state board of pharmacy. Consumers may want to refer to the list of Verified Internet Pharmacy Practice Sites™ (VIPPS®) on www.nabp.net to find out if a Web site has been checked to make sure it it has met state and federal rules. Consumers also will know if an online pharmacy is VIPPS-accredited when they notice the VIPPS Seal on that particular Web site.

For more information on these PSAs visit www.fda.gov/cder/consumerinfo/Buy_meds_online_all_resources.htm.

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prescribing physician of a patient specific medical need (eg, the physician requests an alternate product due to hypersensitivity to excipients or preservative in the FDA-approved product, or the physician requests an effective alternate dosage form) or if the drug product is not commercially available. The unavailability of such a drug product must be documented prior to compounding. The recommended methodology for documenting unavailability is to print the screen of wholesalers showing back-ordered, discontinued, or out-of-stock items. This or similar documentation must be available when requested by the Board.

Immunization Administration (Injectable and Inhalation)

This is a good time of the year for all pharmacists with the Authority to Administer to review the section of the law that allows for the practice of giving immunizations. Additionally, this is a good time to remind pharmacists that inhaled immunizations such as FluMist™ fall under the same criteria as injectable immunizations and require the pharmacist to hold an immunization certification that is current. The Authority to Administer is discussed in Board Regulation 09-00-0002 and ACA §17-92-101 (16) and ACA §17-92-101 (22) (B). Here are a few things to remember:

- The administration of medications shall not include the administration of medications to any person under the age of eighteen (18).
- The administration of medications shall be limited to the following classifications of medications: immunizations, vaccines, allergy medications, vitamins, minerals, ant-ihyperglycemics, and antinausea medications.
- An Authority to Administer for immunizations and vaccinations may be a general protocol.
- An Authority to Administer, once granted, is valid for a time period not to exceed one (1) year.

Only persons who have met all of the requirements set forth in the statute and Board **Regulation 09-00-0002 (b) Authority for pharmacists to administer medications/immunizations** may administer immunizations and vaccines, regardless of the route of administration (injectable or inhalation). These requirements include but are not limited to the following: The pharmacist must possess a Certification for the Authority to Administer Medications/Immunizations issued by the Board to be qualified to accept an Authority to Administer and must maintain a current certification in Cardiaopulmonary Resuscitation (CPR) or Basic Cardiac Life Support (BCLS).

Please contact the Board office at 501/682-0190 if you have any questions about vaccinations, immunizations, or the Authority to Administer.

Employment Change Notification

Throughout the year, the Board Office finds numerous examples of pharmacists who fail to notify the Board of changes in their employment when they change jobs. This is a requirement of every pharmacist licensed with the Arkansas State Board of Pharmacy and is clearly stated in **Regulation 02-00-0001 Changes in Employment.**

Whenever any licensed pharmacist shall change his 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 e-mail and must contain the new place of employment of the licensed pharmacist, his license number, and his renewal number.

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's* contents. Please contact the Board Office at 501/682-0190 if you have questions regarding any of the articles in this *Newsletter*.

Correction

In the first paragraph of the article "Surrender of Unwanted Controlled Substances" on page 4 of the May 2005 *Newsletter* there was a misprint. The *Newsletter* text read "In addition, discontinued or unwanted controlled substances must be submitted each time there is a **charge in the licensed person responsible (pharmacist-in-charge)** for the controlled substances at the facility." The text was supposed to read, "In addition, discontinued or unwanted controlled substances must be submitted each time there is a **change in the licensed person responsible (pharmacist-in-charge)** for the controlled substances at the facility." NABP apologizes for any confusion in this matter.

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.

John Kirtley, PharmD - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Larissa Doucette - Editorial Manager

ARKANSAS STATE BOARD OF PHARMACY

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

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