September 2005

Kansas State Board of Pharmacy

Landon State Office Bldg
900 Jackson, Room 560
Topeka, KS 66612
www.accesskansas.org/pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

New Board Members

Governor Kathleen Sebelius has appointed two new board members. The new appointments replace two members who have served admirably but whose three-year terms have expired.

Dr Shirley T. Arck, PharmD, has been appointed to succeed Jeff Thompson RPh. Dr Arck is the director of pharmacy at Kansas State University Veterinary Medical Teaching Hospital in Manhattan, KS. Dr Arck received a bachelor of science in pharmacy from the University of Kansas (KU) in 1981 and a doctor of pharmacy from KU in 2003. She is certified in pain management and certified to administer adult immunizations. Her term expires in 2008.

Michael Coast, RPh, has been appointed to replace Frank Whitchurch, RPh. Mike is the pharmacist-in-charge (PIC) at Clark Pharmacy, Inc, in Cimarron, KS. Mike is also a consultant to numerous area hospitals, nursing homes, and hospices. He received a bachelor of science in accounting from Saint Mary of the Plains College in Dodge City, KS in 1992 and a bachelor of science in pharmacy from KU in 1995. Mike is a certified geriatric pharmacist. His term expires in 2008.

The Kansas State Board of Pharmacy staff welcomes the new members and wishes them great success and accomplishments in their tenure.

Disciplinary Actions

(Note: At the June 2005 Board meeting the Board discussed the reporting of disciplinary actions in the *Newsletter*. Numerous pharmacists requested that names of pharmacists be omitted from the *Newsletter*. Therefore, the Board agreed to this change.)

John Nicholas Patterson, #14-564 – Pharmacy Technician – Roeland Park. Drug Diversion; Registration Revoked.

Toby R. Linebaugh, #14-1216 – Pharmacy Technician – Wichita. Drug Diversion; Registration Revoked.

Heather L. Meyer, #14-453 – Pharmacy Technician – Lawrence. Drug Diversion; Registration Revoked.

Sherri Pearce, #14-655 – Pharmacy Technician – Pratt. Drug Diversion; Registration Revoked.

Pharmacy Case 05-27

Emergency Agency Order – Providing controlled drugs without a prescription.

Pharmacy Case 05-60

Emergency Agency Order – Failure to comply with previous agency order.

Increased Violations

The investigative staff has noticed an increase in the number of cases in which a pharmacy has been without a designated PIC for a period of time. K.A.R. 68-2-5 requires each pharmacist to notify the Board in writing within five days of ceasing to serve as the PIC. Pursuant to K.A.R. 68-1-2a(b) each pharmacy that operates for more than 30 days without a designated PIC shall be deemed in violation.

Likewise, the staff had noted numerous occasions where pharmacy technicians were not registered with the Board. All technicians must be registered with the Board prior to working or training in the pharmacy. Pharmacy technician renewals were mailed out the end of August. They were mailed to the technician's home address so if you have moved you need to make sure that the Board has a current address. Technicians **do not** have to take the test again for renewal of their registration.

Pharmacy technicians may not take new prescriptions via the telephone from the practitioner or the practitioner's agent. The Board of Pharmacy may initiate proceedings against pharmacy technicians who perform such tasks or functions resulting in errors that otherwise violate rules and regulations. In addition, a violation of the rules and regulations may result in a supervising pharmacist being held responsible. Technicians are reminded to identify themselves as a "pharmacy technician" in all telephone conversations while on duty in the pharmacy as well as wear name badges with the appropriate designation.

It is important to note that a pharmacy may not be entered or staffed unless a pharmacist is present at all times. This restriction has become more important since the implementation of

Continued on page 4

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.

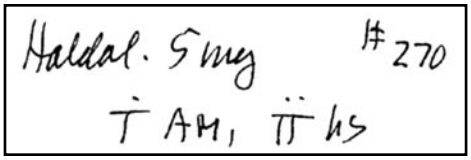
Problem: Numbers containing decimal points are a major source of error and, when misplaced, can lead to misinterpretation of prescriptions. Decimal points can be easily overlooked, especially on prescriptions that have been faxed, prepared on lined order sheets, or written or typed on carbon and no-carbon-required (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.

Continued from page 1

federal privacy laws concerning medical records. It is the joint responsibility of the PIC and the permit holder to be aware of these rules and to strive for compliance with them.

Turn in Pharmaceutical Pill Pushers Confidentially

The Drug Enforcement Administration (DEA) has launched a toll-free international hotline to report the illegal sale and abuse of pharmaceutical drugs. People will now be able to provide anonymous telephone tips about the diversion of prescription drugs into the illegal market by individuals and suspicious Internet pharmacies. In addition, such information can be reported online through the DEA Web site.

According to DEA Administrator Karen P. Tandy, "For the first time – with one simple call – people in the United States and Mexico have an anonymous, safe, and free way to bring information about suspected illegal pharmaceutical distribution to DEA. This information will greatly assist us in bringing drug dealers to justice and preventing the tragedies that come from prescription drug abuse.

"DEA is particularly interested in hearing from families whose loved one has overdosed or died as a result of obtaining pharmaceuticals over the Internet. Tips including the Web site addresses will help put these pill pushers out of business," Tandy stated. Anonymous reports will be taken at 1-877/RxAbuse (1-877/792-2873) or can be made online at www.dea.gov by clicking on a link and filling out an electronic form. The hotline will be staffed by bilingual operators around the clock, 365 days per year.

Frequently Asked Questions

Question: *Can a physician write a prescription for a Schedule II drug (ie morphine 10 mg/mL, 10 mL vial) for "office use"?*

Answer: No. It is not the authorized method for any practitioner to obtain drugs for office use. A physician's office must use a DEA Form 222 to transfer a Schedule II drug from one DEA registrant to another, just as is the case between pharmacies. Schedule III, IV, and V drugs can simply be sold and transferred by invoice. The invoice would require the DEA number of the person you are selling to along with their address. Your DEA number and address should also be on the invoice.

Question: *What reports must be filed if a practitioner/physician experiences a theft or significant loss of controlled substances?*

Answer: All thefts or any significant losses must be reported to the DEA immediately upon discovery of the theft. Notification must be accomplished by completing and filing a DEA Form 106, *Report of Loss or Theft.* Notification to the Board of Pharmacy is not mandatory. The form may be found on the Internet at www.DEAdiversion.usdoj.gov or may be obtained on the Board of Pharmacy's Web site at www.accesskansas.org/pharmacy under Forms and Applications.

Regulation Update

The compounding regulations are still being formalized regarding United States Pharmacopeia (USP) General Chapter 797 Pharmaceutical Compounding – Sterile Preparations. The regulations have been drafted but are still in the process of review by the Department of Administration and the Attorney General's Office. Once this process has been accomplished the Board will have a final public hearing on the proposed regulations. Check the Board Web site under "News from the Board" for a draft of all regulations being considered.

The *Kansas State Board of Pharmacy News* is published by the Kansas 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.

Debra L. Billingsley, JD - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Larissa Doucette - Editorial Manager

KANSAS STATE BOARD OF PHARMACY

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

Presorted Standard
U.S. Postage
PAID
Chicago, Illinois
Permit No. 5744