December 2008

Kansas State Board of Pharmacy

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

Published to promote voluntary compliance of pharmacy and drug law.

Changes in Incident Reporting

On September 24, 2008, a public hearing was held on proposed changes to the Incident Report Regulation. These changes were necessary to ensure continuity between this regulation and the continuous quality improvement (CQI) statute passed by the legislature this year. A CQI law was enacted in 2008 requiring each pharmacy in Kansas to establish a CQI program no later than July 1, 2009. The purpose of the program is to assess errors in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent a recurrence of any errors.

The new provisions in the Incident Report Regulation related to incident reports will delineate what constitutes a "reportable incident for purposes of preparing the incident report." A pharmacy must report preventable medication errors involving a prescription drug and resulting in the following:

1. the patient receiving the wrong drug;
2. the patient receiving an incorrect drug strength;
3. the patient receiving an incorrect dosage form;
4. the drug being received by the wrong patient;
5. inadequate or incorrect packaging, labeling, or directions; or
6. the dispensing of a drug to a patient in a situation that results in or has the potential to result in serious harm to the patient.

The pharmacist-in-charge (PIC) shall ensure that procedures exist requiring pharmacists who become aware of a reportable incident as defined above to alert the PIC of the incident as soon as practical so that a report can be prepared. The responsibility of preparing an incident report falls on each pharmacist involved in the incident and the PIC. Any employee involved in the incident must sign the incident report. Incident reports must be maintained for a minimum of five years. The incident reports should be reviewed at least once per quarter of each calendar year and a CQI report should be generated. The CQI report takes the place of the Plan of Action Requirements. The CQI report should list those persons in attendance at the quarterly meeting, the list of incident reports reviewed, and a description of the steps taken or to be taken to prevent a recurrence of each incident that was reviewed. All reports generated by the CQI program are available for inspection by the Board of Pharmacy.

PIC Inventory

This is a reminder that each PIC who resigns as PIC shall inventory all controlled substances in the pharmacy before leaving the position. Within 72 hours after beginning to function as a PIC, the PIC shall inventory all controlled substances. A record of the inventory must be maintained for at least five years. If the outgoing PIC and the incoming PIC are available at the same time, they may take one inventory together. If there is a situation in which a PIC is not able to have access to the pharmacy in order to conduct an ending inventory, please notify the Board office or the investigator in your area to avoid disciplinary action.

Prescription Requirements for Controlled Substances

A legal prescription for controlled substances must meet certain requirements. The prescription must be dated and signed on the date when issued. The prescription must include the patient's full name and address, and the practitioner's name, address, and Drug Enforcement Administration (DEA) registration number either on the hard copy or readily associated with the prescription from information in the pharmacy's database. If the prescription is not for a controlled substance there is no legal requirement that the practitioner provide a DEA registration number.

Prescriptions for Obesity

In March 2007, the legislative pharmacists on the Kansas State House and Senate were instrumental in removing the requirement that a prescription for amphetamines or sympathomimetic amines designated in Schedule II, III, or IV adequately document the diagnosis in the practitioner's own handwriting. This change did not change the obesity statute related to amphetamine prescribing. Amphetamines shall not be dispensed or prescribed to treat obesity. The treating physician shall not dispense or prescribe more than a 30-day supply of controlled substances to treat obesity for a patient at one time. There is no restriction against faxing a Schedule III or Schedule IV in order to approve refills.

Unused Medication Act

The 2008 Legislature passed a law creating the Unused Medications Act, a voluntary program through which adult-care homes, mail-service pharmacies, and medical care facilities may donate unused medications to indigent health care clinics, federally qualified health centers, or community mental health clinic center for distribution to medically indigent Kansas residents. The Board of Pharmacy will have a public hearing on December 3, 2008, to adopt rules and regulations related to the transferring, accepting, and recall of unused medications. Each administrator or operator of an adult-care home, pharmacist-in-charge of a mail-service pharmacy, or administrator of a medical care facility shall submit notification to the Board if they intend to participate

Continued on page 4

Study Fuels Concerns over Foreign Drugs Bought Online

According to study results published in the May 2008 issue of *Annals of Pharmacotherapy*, many prescription medications purchased from foreign pharmacies through Internet drug outlets differ significantly from the versions approved by the Food and Drug Administration (FDA). "These findings have implications for safety and effectiveness that should be considered by clinicians to potentially safeguard patients who choose to purchase foreign-manufactured drugs via the Internet," the study authors say.

The study evaluated 20 simvastatin tablets and capsules, including the US innovator product and 19 generic samples obtained from international Internet drug outlets. Tablet samples were tested according to United States Pharmacopeia (USP) guidelines where applicable, using high-performance liquid chromatography, disintegration, dissolution, weight variation, hardness, and assessment of physical characteristics.

Several international samples analyzed were not comparable to the US product in one or more aspects of quality assurance testing, and significant variability was found among foreign-made tablets themselves. Five samples failed to meet USP standards for dissolution, and two for content uniformity. Among all samples, variability was observed in hardness, weight, and physical characterization.

Testing Medication Names Prior to Marketing

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with 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, and publishes its recommendations. To read about the recommendations for prevention of reported errors that you can put into practice today, subscribe to ***ISMP Medication Safety Alert!®*** ***Community/Ambulatory Edition*** *by visiting www.ismp.org. 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: 200 Lakeside Dr, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

Medication names that look-alike and sound-alike, confusing or absent drug labeling, and non-distinct or ambiguous drug packaging significantly contributes to medication errors. This is not a new problem. These conditions have led to serious drug mix-ups and deaths. Research has identified that one of the most frequent causes of pharmacy drug dispensing errors (29%) is failure to accurately identify drugs, most prominently due to look-and sound-alike drug names (Leape et al. JAMA, July 5, 1995).

In addition, many medications are packaged in bottles with similar shapes and similar labels, making it easy to confuse one drug with another.

MedMARX data reports there are 1,470 different drugs implicated in medication errors due to brand and/or generic names that looked or sounded alike. From this data, USP has compiled a list of 3,170 pairs of names that look and/or sound alike.

FDA is also concerned about drug naming confusion and its subsequent potential error effects. On June 5-6, 2008, FDA hosted a public workshop to discuss a concept paper (*www.fda.gov/cder/drug/MedErrors/meeting_names.pdf*) about a pilot program to address look- and sound-alike brand names. The pilot, called for in the FDA Amendments Act of 2007, would allow drug companies (or outside contractors) to voluntarily evaluate proposed brand names and submit the data for review to FDA. Currently, FDA's Division of Medication Error Prevention screens drug names using its own safety testing methods, in consultation with other divisions responsible for product approval.

The concept paper outlines the types of studies that should be conducted, including simulations of real-world conditions with practicing clinicians who evaluate handwritten, electronic, and oral prescribing scenarios to detect name similarities and other potential confusion with laboratory and medical terms or abbreviations. Dosage form, strength, and frequency also should be considered, as well as the clinical environment where it will be used. Based on discussions during the June meeting and submitted comments, FDA will revise the concept paper and present testing methods to the pharmaceutical industry.

It is hoped that testing drug names prior to marketing will decrease the number of look-and sound-alike medication names. ISMP receives numerous reports of

errors and potential errors caused by look-and sound-alike medications every year. ISMP, through its wholly owned for-profit subsidiary Med-E.R.R.S., Inc®, has been reviewing drug names and packaging for pharmaceutical manufacturers for more than 10 years.

If you are a pharmacist or other health care practitioner who is interested in medication safety and error prevention, you can make a difference! Med-E.R.R.S. is looking for pharmacists from all practice settings to help test labeling, packaging, and nomenclature in the pre-marketing phase for pharmaceutical companies. The process is fun, simple, and easy and a small honorarium is paid for your participation.

For more information or to sign up, go to *www.med-errs.com* and click on "Become a Reviewer."

Coalition Looks to Pharmacies, Regulators to Reduce Diversion

A recent report by the Coalition Against Insurance Fraud looks to pharmacies and pharmacy regulators, among others, to cut down on the prevalence of prescription drug diversion, particularly of controlled substance analgesics.

The report, "Prescription for Peril: How Insurance Fraud Finances Theft and Abuse of Addictive Prescription Drugs," calls on the pharmacy profession to provide additional training on prescription drug abuse and diversion in pharmacy education curricula and continuing professional education, and to exert closer point-of-sale scrutiny of certain prescriptions and patients. For instance, the report suggests diversion could be reduced significantly if pharmacies asked for photo identification in connection with controlled substance prescriptions, similar to regulations in place for pseudoephedrine-containing products.

The coalition also recommends wider adoption of prescription monitoring programs to maintain statewide records of narcotic prescriptions, allowing closer monitoring by prescribers and dispensers. In addition, the coalition calls on lawmakers and licensing boards to "swiftly and decisively penalize the small fraction of prescribers and dispensers who facilitate drug diversion and abuse."

FDA Encourages Pharmacists to Use Patient Safety News

FDA Patient Safety News is a monthly video news program produced by FDA targeted to pharmacists and other health care professionals. The program provides the latest information on recalled and counterfeit products, important safety alerts, preventing medical errors and mitigating risks from the use of medical products, including drugs, devices, vaccines, and diagnostic products.

The videos can be watched online or downloaded free of charge. Pharmacists can view the entire program or individual segments, and FDA encourages further use and distribution of the video or text of the program, as there are no copyright restrictions. The video and demonstrations can also be used in staff-development programs or in other teaching environments.

Pharmacists can search for video segments on topics of interest, get additional information about topics, e-mail segments to others, report problems with medical products to FDA, and sign up to be notified about each month's program. The show is also broadcast on several medical satellite networks: VHA, GE TiP-TV, HSTN, LTCN, and HNN. These networks presently reach over 4,000 hospitals and long-term care facilities across the US.

More information about the program and how to join the program mailing list is available on the FDA Web site at *www.fda.gov/psn* or by sending an e-mail to PSNews@cdrh.fda.gov.

Switch to HFA-Propelled Albuterol Inhalers Advised in Anticipation of CFC Ban

FDA recently issued a public health advisory alerting patients, caregivers, and health care professionals to switch to hydrofluoroalkane (HFA)-propelled albuterol inhalers because chlorofluorocarbon (CFC)-propelled inhalers will not be available in the United States after 2008. CFC-propelled albuterol inhalers are being phased out to comply with the Clean Air Act and an international environmental treaty, the Montreal Protocol on Substances that Deplete the Ozone Layer. Under this treaty, the US has agreed to phase out production and importation of ozone-depleting substances including CFCs. No CFC-propelled albuterol inhalers may be produced, marketed, or sold in the US after December 31. Three HFA-propelled albuterol inhalers have been approved by FDA: Proair® HFA Inhalation Aerosol, Proventil® HFA Inhalation Aerosol, and Ventolin® HFA Inhalation Aerosol. In addition, an HFA-propelled inhaler containing levalbuterol is available as Xopenex® HFA Inhalation Aerosol. More information is available on the FDA Web site at *www.fda.gov/cder/mdi/albuterol.htm*.

Continued from page 1

in the unused medications program. Forms have been developed and will be available on the Board's Web site at *www.kansas.gov/pharmacy* under the link for Forms and Applications. As the transfer occurs the entity donating the drug shall determine the quality and suitability of each medication by a pharmacist's verification that the unused medication can be identified, is in the manufacturer's sealed container, a pharmacy unit-dose package, or a hermetically sealed tamper-evident package from the pharmacy. It shall not have passed its beyond-use date, cannot be a controlled substance, shall not be adulterated, and shall not be a medication that can be dispensed only to a patient or resident registered with the drug manufacturer.

The identifying name of the patient shall be removed in order to protect confidentiality. There shall be a consultation with the qualifying center or clinic to determine whether the center or clinic is willing to accept the unused medication and to ensure that the center or clinic has a consulting pharmacist and is registered with the Board of Pharmacy to accept unused medications.

The donating entity shall also complete a manifest on a form supplied by the Board of Pharmacy. The manifest copy shall be included with the donated medications. The donating entity shall also maintain a copy of the manifest that was signed and returned by the qualifying center or clinic for at least five years.

The qualifying center or clinic that elects to participate in the unused medication program shall submit written notification to the Board of Pharmacy on forms supplied by the Board of Pharmacy and available on the Board's Web site. The center or clinic shall maintain all medication in a storage unit with controlled access. After acceptance of the medication, the center or clinic shall determine the quality and suitability of each unused medication by verification of a pharmacist or practitioner that the medication can be identified, is not a medication that can be dispensed only to a patient or resident registered with the drug manufacturer, that the name of the patient has been removed to protect confidentiality, and that each medication has been checked against the manifest to resolve any discrepancies with the donating entity. The manifest must be completed and signed and returned to the donating entity. Each center or clinic shall maintain a copy of the signed manifest for at least five years.

If an unused medication is recalled and the qualifying center or clinic does not have the lot number on the label to differentiate between the recalled medications and the nonrecalled medications, all of the medication shall be destroyed. If the donating entity has transferred medication that is subsequently recalled and the donating entity has been notified of the recall, the donating entity shall be responsible for notifying the qualifying center or clinic. Each qualifying center or clinic in possession of any unused medication that is expired, adulterated, or recalled shall make a manifest for and destroy the medication. Following the destruction of the unused medications, the manifest shall be signed by the consulting pharmacist and a witness to verify the destruction. Each drug destruction manifest shall be maintained for at least five years.

Board Newsletter

The Board of Pharmacy is pleased to announce that it will be providing the quarterly *Newsletter* via e-mail in 2009. The costs associated with printing have risen, so it will be most cost effective to provide the *Newsletter* electronically. To find the most current issue of the *Newsletter*, as well as past issues, visit the Kansas State Board of Pharmacy Web site at *http://www.kansas.gov/pharmacy/* or visit the National Association of Boards of Pharmacy® (NABP®) Web site at *www.nabp.net*.

Beginning December 15, 2008, anyone wishing to subscribe or unsubscribe to an e-mail alert that will indicate to them when a new issue of the *e-Newsletter* is available may do so by sending an e-mail to KansasBOPNewsletter@nabp.net with the word "Subscribe" in both the subject line and body of the e-mail. A link to subscribe or unsubscribe will also be available on both the Board of Pharmacy Web site and the NABP Web site.

Anyone wishing to subscribe directly through the Board must provide the Board with a current e-mail address so that we can provide you with continued *Newsletter* service.

Once again, the December 2008 Kansas State Board of Pharmacy *Newsletter* will be the final printed version for circulation.

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 - Communications Manager

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

KANSAS STATE BOARD OF PHARMACY

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