December 2005

Kansas State Board of Pharmacy

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www.kansas.gov/pharmacy/

Published to promote voluntary compliance of pharmacy and drug law.

Disciplinary Actions

Case No. 04-60 – License revoked until Respondent provides written verification from mental health professional that Respondent is safe to practice.

Case No. 05-25 – Stipulation entered requiring five-year contract with Committee on Impaired Pharmacy Practice (CIPP).

Case No. 05-37 – License revoked and a total fine of $15,000 assessed based on a failure to maintain records, failure to fill in strict conformity, and engaging in behavior that demonstrates a manifest incapacity or incompetence to practice pharmacy.

Case No. 04-58 – Licensee assessed a fine in the amount of $10,000 for filling prescriptions on multiple occasions without a prescription or verification from physician. Licensee ordered to take the pharmacist-in-charge (PIC) examination and pass with an 85% rate or more.

Case No. 05-38 – Stipulation entered requiring five-year contract with CIPP.

Case No. 05-34 – Licensee fined $1,200 for dispensing promethazine with codeine over the counter. Licensee fined $500 for failing to see that pharmacy technicians employed at pharmacy were registered with the Board.

Case No. 05-29 – Licensee fined $500 for failing to see that pharmacy technicians employed at pharmacy were registered with the Board.

Case No. 05-32 – Licensee fined $500 for failure to counsel patient, which would have caught an error in the filling.

Incident Reports

K.A.R. 68-7-12 (d) requires every community pharmacy to document **any** prescription-dispensing error with an incident report. Errors to be documented shall include, but not be limited to, incorrect medication, dosage form, directions, miscounts, patient, or prescriber. **Any** other incident that could result in a consumer complaint should also be included on the incident report.

The incident report shall be maintained in the pharmacy, kept easily retrievable, and made available to a pharmacy inspector upon request. When investigating an incident, the first item requested by an inspector is this report.

The Kansas State Board of Pharmacy has disciplined numerous pharmacists for failure to complete this report. The PIC is responsible for making sure these reports are completed.

Prescriptions Written by ARNPs or PAs

Advanced registered nurse practioners (ARNPs) and physician assistants (PAs) may write prescriptions authorized by a drug prescription protocol. Every written prescription shall contain the name, address, and telephone number of the responsible physician and the name, address, and telephone number of the ARNP or PA. It must be signed by the PA or ARNP, with the letters "ARNP" or "PA" following the signature. It shall also contain the Drug Enforcement Administration number of the PA or ARNP if a controlled substance is prescribed. PAs also have to indicate whether or not the prescription is a direct order of the responsible physician, pursuant to protocol, or because of an emergency situation. A Kansas pharmacy may fill a prescription from an out-of-state PA or ARNP, but the prescription must meet Kansas law. There has been some confusion over whether or not the laws were changed this year regarding PAs and ARNPs and they were not.

K.A.R. 68-7-14 requires the label of each prescription medication to be typed or machine printed and **must** include the name of the prescribing practitioner. In addition to the name of the practitioner, the label shall include the name of the PA or ARNP.

Restrictions on Dispensing Amphetamines or Sympathomimetic Amine Controlled Substances

The Board of Healing Arts requires a physician who prescribes amphetamines or sympathomimetic amine controlled substances to write in their own handwriting the purpose for which the drug is given. Therefore, prescriptions for amphetamines or sympathomimetic amines may not be faxed. This law

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DEA Amends Rule for Reports of Theft or Significant Loss of Controlled Substances

Drug Enforcement Administration's (DEA) amended regulations regarding reports by registrants of theft or significant loss of controlled substances became effective September 12, 2005. Changes were made to the regulations, found in Title 21 of the Code of Federal Regulations, Part 1300 to 1399, due to confusion as to what constitutes a significant loss and when and how initial notice of a theft or loss should be provided to DEA. Specifically, DEA made changes in order to clarify the exact meaning of the phrases "upon discovery" and "significant loss."

Regarding the timing of initial theft or loss reports, DEA inserted the word "immediately" before the phrase "upon discovery." While DEA Form 106 is not immediately necessary if the registrant needs time to investigate the facts surrounding a theft or significant loss, he or she should provide, in writing, initial notification of the event. This notification may be a short statement provided by fax. DEA notes that faxing is not the only method a registrant may use, but that the notification should be in writing. If the investigation of a theft or significant loss lasts longer than two months, registrants should provide updates to DEA.

To help registrants determine whether or not a loss is "significant," DEA has added to the rule a list of factors to be considered. DEA recognizes that no single objective standard can be applied to all registrants – what constitutes a significant loss for one registrant may be construed as comparatively insignificant for another. If a registrant is in doubt as to whether or not the loss is significant, DEA advises the registrant to err on the side of caution in alerting the appropriate law enforcement authorities.

Regarding "in-transit losses of controlled substance," DEA intends that all in-transit losses be reported, not just significant losses; therefore, the text is being amended to reflect this.

Changes to the regulations were reported in the August 12, 2005 edition of the *Federal Register*.

FDA Releases Update on Combating Counterfeit Drugs

Food and Drug Administration (FDA) recently released "Combating Counterfeit Drugs: A Report of the Food and Drug Administration Annual Update (Update)." This Update follows up on the agency's initial February 18, 2004 report addressing counterfeit drugs. Since the 2004 report, which identified measures that can be taken to better protect Americans from counterfeit drugs, FDA has worked with manufacturers, wholesale distributors, pharmacies, consumer groups, technology specialists, standard setting bodies, State and Federal agencies, international governmental entities, and others to advance the measures outlined in the 2004 report such as the development and implementation of electronic product codes and radio frequency identification. In its 2005 Update, FDA notes that significant progress is being made in securing drug products and packaging, securing the movement of the product, enhancing regulatory oversight, increasing penalties for counterfeiters, heightened vigilance and awareness of counterfeits, and increasing international collaboration. However, more work needs to be done to further secure the United States' drug supply.

In 2004, FDA's Office of Criminal Investigations initiated 58 counterfeit drug cases, a significant increase over the 30 cases in 2003; however, the agency notes that this is likely due to increased vigilance. FDA also states that most of the suspect counterfeits discovered in 2004 were found in smaller quantities than those found in 2003.

The Update reviews steps taken and future actions required for track-and-trace technology, authentication technology, regulatory oversight and enforcement (electronic pedigree), state efforts, secure business practices, heightened vigilance and awareness, counterfeit alert network, and education. The full Update can be accessed at www.fda.gov/oc/initiatives/counterfeit/update2005.html.

"Fax noise" = Medication Errors in the making

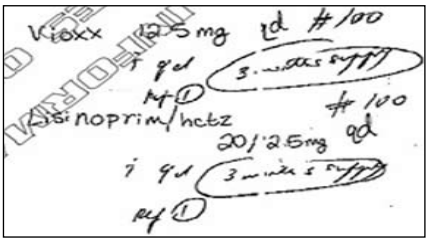
This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other 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, Suite 810, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Problem: Most health care practitioners would agree that fax machines have facilitated communication of prescriptions. But there are inherent problems associated with this technology. In fact, an article in the *Journal of Managed Care Pharmacy* found that prescriptions received by fax required a greater number of clarification calls than those received by other methods of communication.[1] ISMP received a report from a long-term care facility about a patient who had been

receiving **Neurontin**® (gabapentin) 600 mg TID [three times a day]. However, an order had been faxed to the pharmacy to change the Neurontin dose to "**300 mg** 1 tab QID [four times a day]." The change was made and the new dose was sent to the facility. Later, when the pharmacist received the original order from the long-term care facility and compared it with the faxed copy, he realized that the physician had actually requested a change to "**800 mg** 1 tab QID." The left side of the order had been cut off during the fax transmission, making the "8" look like a "3." Fortunately, since the pharmacist had been sent the original order for comparison, he quickly realized the mistake. Unfortunately, not all pharmacies receive the original prescription for comparison purposes.

In another report received by ISMP, a faxed prescription was received at a pharmacy for what appeared to be **Monopril**® (fosinopril) **10 mg** #90 one tablet daily. Despite the fact that the fax machine created a definite vertical streak that ran between the drug name and the strength, the pharmacist felt confident in her interpretation of the prescription. Unfortunately, it was later discovered that the prescription was actually for **40 mg**. The streak had run through the "4" in 40 mg, making it look like 10 mg instead.

The following prescription (see image below) was faxed to a mail-order pharmacy. Look at the bottom order for "Lisinopril/hctz." (Note: ISMP does not condone the use of the abbreviation "hctz.") The pharmacist interpreted this order as "20/25 mg." But what the prescriber had actually written was "20/12.5 mg." A subtle vertical gap in the faxed copy (which can be seen "breaking" the circles around "3 months supply") had obliterated the "1" in 12.5. In addition, the pharmacist reading the order had misinterpreted the decimal point as one of many stray marks on the faxed prescription.



Safe Practice Recommendations: "Fax noise" (the random marks and streaks on faxes) is an inherent problem with this form of communication, which may be more common in old or poorly maintained fax machines. Usually, fax noise is just an inconvenience. In the case of prescriptions, however, there is a very real chance that a patient could be harmed by misinterpretations caused by fax noise. To manage this risk, safeguards should be instilled into the fax process. Such safeguards include a careful review of all prescriptions received by fax for fax noise. If the transmission has fax noise in the area of the order, the prescriber should be contacted to confirm the prescription. Whenever possible, compare the faxed order against the original prescription. Prescribers should consider giving a copy of the prescription to the patient to present at the pharmacy for verification. To prevent confusion or duplication of the prescription at a different pharmacy, the copy could be stamped with a statement such as "Verification Copy ONLY" to indicate that the prescription was already faxed to a particular pharmacy. Maintenance should be regularly scheduled for fax machines on both the sending and receiving end. If maintenance fails to improve fax quality, the machine should be replaced.

1. Feifer RA et al. Mail-order prescriptions requiring clarification contact with the prescriber: prevalence, reasons, and implications. *JMCP* 2003;9:346-352.

December 2005 FPGEE Date and Locations Announced

On December 3, 2005, NABP will again administer a paper-and-pencil Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®). The examination is being offered at three United States locations: Northlake (Chicago area), IL; New York, NY; and San Francisco, CA. Candidates who have been accepted to sit for the December 3, 2005 administration were mailed their admission tickets in early fall.

To prepare for the December examination, candidates may take the Pre-FPGEE®, a Web-based practice examination for the FPGEE. The practice examination is accessible at www.nabp.net and www.pre-fpgee.com.

For more information on the FPGEE, visit NABP's Web site at www.nabp.net.

2006 Survey of Pharmacy Law

NABP's *2006 Survey of Pharmacy Law* CD-ROM will be available in late November 2005. New topics include the number of wholesale drug distributors and laws and/or regulations concerning the sales of over-the-counter pseudoephedrine, and information concerning emergency contraception.

The *Survey* consists of four sections: organizational law, licensing law, drug law, and census data. Most charts specify terms that can be used when conducting searches on NABP's NABPLAW® Online state pharmacy law and rules database. 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 money order to NABP. The CD-ROM is provided free of charge to all final-year pharmacy students through a grant from AstraZeneca Pharmaceuticals. 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.

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can be found in the Useful Information section of the *Kansas Pharmacy and Related Laws* book on pages 352-353 or K.S.A. 65-2837a. There are no restrictions on the amount that can be dispensed. The only Kansas regulation that restricts the amount of a drug prescribed is Board of Healing Arts Regulation KAR 100-23-1 regarding the treatment of obesity. If the physician is writing a prescription for the treatment of obesity, he or she shall not prescribe more than a 30-day supply. This information can be found in the Useful Information section of the *Kansas Pharmacy and Related Laws* book on page 316.

Medical Care Facility Labels

A medical care facility can provide a patient with their medication upon discharge from the hospital per physician order. This is to remind everyone that there have been problems with patients being discharged with medications that are not labeled in accordance with K.A.R. 68-7-14. Multi-dose type medications such as insulin, eye drops, inhalers, and ointments are not always properly labeled. These medications should be labeled with the name, address, and telephone number of the hospital; the name of the prescriber and the ARNP or PA, if applicable; the full name of the patient; the identification number assigned to the interim supply; and the date the medication was supplied. The regulation also states that the label should provide adequate directions for use; the beyond use date; the brand name or corresponding generic name; the name of the manufacturer or distributor; the strength of the drug; the contents in terms of weight, measure, or numerical count; and the necessary auxiliary labels and storage instructions. The Board discussed this at its September 2005 Board meeting and wanted to remind everyone to properly label **all** medications that are sent home with the patient.

Upcoming Board of Pharmacy Meetings

The Board of Pharmacy is inviting everyone to mark their calendar for the following meetings:

March 7-8, 2006, Kansas University (KU) School of Pharmacy – Lawrence, KS

June 6-7, 2006 – Topeka, KS

Board meetings are open to the public and pharmacists are encouraged to attend. While the meetings have a formal structure, they do provide a public comment period. If you would like to be placed on the meeting agenda distribution list, please contact Karen Hollon at 785/296-6504.

2005 Kansas Pharmacy and Related Laws

The *Kansas Pharmacy and Related Laws* book now includes a searchable CD-ROM version. (CD not sold separately.) Available through Kansas Pharmacists Association (KPhA) at www.kansaspharmacy.org.

Tripartite Meets

In order to sustain the range of programs and services provided to pharmacists in Kansas, the State Board of Pharmacy has been meeting regularly with the KU School of Pharmacy and the KPhA. This group addresses a full range of topics relating to pharmacy education, continuing education, professional functions of practitioners, and societal needs and manpower issues. Dean Ken Audus and Executive Director John Kiefhaber have developed a "team concept" in working with the Board in order to analyze important concerns affecting the protection of the public health in Kansas. The Board of Pharmacy would like to publicly thank KU and the KPhA for working in a cooperative manner with the Board in order to meet the challenges facing the profession while continuing to pursue their individual mission statements.

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.

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