

Kentucky Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.



Season's Greetings



2006 Pharmacist Renewals

Pharmacist licenses expire on February 28, 2006. The Kentucky Board of Pharmacy is pleased to announce that for the first time a pharmacist may renew and pay his or her license online. A letter with details of the online renewal and payment process will be mailed out the first week of January 2006. Renewal applications will not be mailed out; however, a renewal application may be printed from the Board's Web site at www.pharmacy.ky.gov.

DEA Clarification

Submitted by N. Katie Busroe, RPh, Pharmacy and Drug Inspector

As of September 12, 2005, Drug Enforcement Administration (DEA) has amended its regulations regarding the reporting of theft or loss of controlled substances (CS). Title 21 of the Code of Federal Regulations, Section 1301.74(b) stated "the registrant shall notify the Field Division Office of the Administration in his area of the theft or **significant loss** of any [CS] **upon discovery** of such loss or theft. The registrant shall also complete DEA Form 106 regarding such loss or theft." The new ruling will help to clarify the phrases "upon discovery" and "significant loss."

DEA has inserted the word "immediately" before the phrase "upon discovery." The submission of DEA Form 106 itself is not immediately necessary if the registrant needs time to investigate the facts surrounding the theft or significant loss. In that instance, DEA recommends that the initial notification be a short statement provided to DEA Field Office in writing within one business day of the discovery of a theft or loss. DEA Form 106 shall be submitted once the investigation is finalized, but if the investigation continues beyond 60 days, updates should be provided to DEA.

DEA suggests several factors that registrants should consider to determine if a loss of CS is significant. These include:

1. The actual quantity of CS lost in relation to the type of business;
2. The specific CS lost;

3. Whether or not the loss of the CS can be associated with access to those CS by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the CS;
4. A pattern of losses over a specific time period, whether or not the losses appear to be random, and the results of efforts taken to resolve the losses;
5. Whether or not the specific CS are likely candidates for diversion; and
6. Local trends and other indicators of the diversion potential of the missing CS.

DEA recognizes that there is no single objective standard that can be applied to all registrants as to what constitutes a significant loss. DEA also encourages registrants to use additional factors beyond these suggestions in the evaluation of whether or not a loss is significant. DEA states that "individual registrants should examine both their business activities and the external environment in which those business activities are conducted to determine whether or not unexplained losses of [CS] are significant. When in doubt, registrants should err on the side of caution in alerting the appropriate law enforcement authorities, including DEA, of thefts and losses of [CS]." **All** in-transit losses must be reported to DEA.

DEA Form 106, Theft or Loss of a Controlled Substance, is now available for online submission at www.DEAdiversion.usdoj.gov under "Diversion Programs, Application & on-line forms>Theft or Loss of Controlled Substances." Per KRS 218A.200 (9), a copy of the detailed list of lost or stolen CS (DEA Form 106) shall be forwarded to the Drug Enforcement and Professional Practices Branch of the Office of Inspector General at the Cabinet for Health and Family Services. It is strongly suggested that a copy also be forwarded to the Kentucky Board of Pharmacy.

KASPER Reporting Close or Change of Ownership of Pharmacy

Submitted by Dave Sallengs, Branch Manager, Office of Drug Enforcement and Professional Practices Branch

Kentucky pharmacies either closing or changing ownership are required to notify the Kentucky Board of Pharmacy pursuant to 210 KAR 2:106. Complete compliance with data reporting requirements to the Kentucky All Schedule Prescription Electronic Reporting (KASPER) program, mandated in KRS

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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.

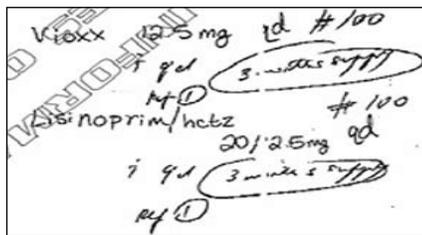
Problem: Most health care practitioners would agree that fax machines have facilitated communication of prescriptions. But there are inherent problems associated with this technology. In fact, an article in the *Journal of Managed Care Pharmacy* found that prescriptions received by fax required a greater 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 mis-



interpreted 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 pos-

sible, 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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218A.202, should also be documented in the notification.

To ensure that there are no gaps in data reported to the KASPER system, you may call the Drug Enforcement and Professional Practices Branch at 502/564-7985. Please be prepared to give your pharmacy DEA number and the date you plan to either close or change ownership. After verification by the Drug Enforcement and Professional Practices Branch, a letter certifying compliance will be sent to your pharmacy. A copy of the certification letter must be attached to the Board notification.

Gaps in KASPER data reporting could result in Board action and/or criminal charges being filed by the Drug Enforcement and Professional Practices Branch against the pharmacist-in-charge. Noncompliance with the data reporting requirement is a Class A misdemeanor.

Board Passes Motion Regarding Duragesic Patches

Submitted by Benjamin M. King, PharmD Candidate

Over the past several weeks many pharmacists in the state have raised questions about Medicaid preferring brand name Duragesic® patches over generic. The majority of concerns were about KRS 217.830, which requires each pharmacy to post a sign stating that the pharmacy is “required to dispense the lowest priced generic drug in stock.”

Due to rebates from Duragesic manufacturer Janssen, LP, it is more cost effective for Medicaid to have Duragesic on the formulary than either of the available generics. Claims submitted for Duragesic patches require prior authorization, which, when approved, require a \$2 co-pay from the patient. Claims submitted for generic other fentanyl patches also requires prior authorization, which, when approved, require a \$3 co-pay from the patient.

At the October 5, 2005 meeting, the Board of Pharmacy unanimously passed a motion stating that since Duragesic is lower in price than other fentanyl patches for the purchaser and KRS 217.822 dictates and allows the dispensing of the brand name, a pharmacist could and should dispense the Duragesic patch in accordance with Medicaid Policy.

Protocols and Standing Orders

Submitted by Benjamin M. King, PharmD Candidate

Protocols and standing orders have long been standard procedure in institutional pharmacy. What regulations give institutions the authority to dictate such orders? Let us take a closer look at those regulations.

201 KAR 2:074 Section 4(1) states that institutional pharmacies “shall be responsible for the procurement, distribution and control of all drugs and parenteral solutions use” The policies and procedures governing these functions “shall be developed by the pharmacist with input from other involved hospital or other organized health care facility staff . . . and committees” such as the Pharmacy and Therapeutics Committee.

Section 4(9) is similar in regards to administration of drugs. This section states that “drugs shall be administered only upon order of a licensed practitioner” and that “the institutional pharmacy shall participate in the establishment of policies and procedures regarding the administration of medication.” These specific procedures “shall be developed in cooperation with appropriate hospital or other health care facility personnel”

The Kentucky Administrative Regulations listed above provide institutions the ability to implement protocols and standing orders as long as those procedures are approved by the Pharmacy and Therapeutics Committee or other committee as the institution sees fit.

The Board appreciates Paul Sinclair, RPh, director of pharmacy services at St Elizabeth Medical Center, for his involvement with this clarification.

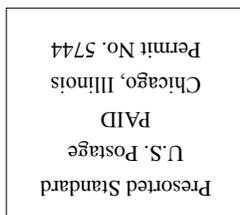
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