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Arkansas State Board of Pharmacy

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Disciplinary Actions from October Board Meeting

During the October 2005 Arkansas State Board of Pharmacy meeting, several disciplinary hearings were held regarding adequate control and accountability for controlled substances (CS) in retail pharmacies. The following action was taken as a result of these hearings.

PD License #6770 and Pharmacy Permit #AR-17724 – Charged with failure to provide for adequate accountability and security of CS resulting in shortages and overages of CS in the drug inventory. Charged with failure to immediately notify the Board and other agencies and to submit Drug Enforcement Administration (DEA) 106 reports within seven days of a discovered shortage. The Board ordered the pharmacy to have an order for a new software system within 45 days, hire an outside auditor to survey the pharmacy and give recommendations for a plan of corrective action, give quarterly audit reports to the Board for two years on CS, put the store permit on probation for five years, and fined the store $5,000. The pharmacist's license was put on probation for five years.

PD License #6927 and Pharmacy Permit #AR-19374 – Charged with failure to provide for adequate accountability and security of CS resulting in shortages of CS in the drug inventory. Charged with dispensing CS without the authorization of a practitioner. The Board suspended the pharmacist's license for a minimum of one year and ordered the pharmacist to get a substance abuse evaluation. Furthermore, as of October 31, 2005, the pharmacy's permit is revoked.

PD License #6936 – Charged with delivering CS without the order of a practitioner in the ordinary course of professional treatment and when the practitioner does not have a DEA [Drug Enforcement Administration] permit. Charged with deliveries of legend drugs to pharmacy technicians without the authorization of a practitioner. The Board suspended the pharmacist's license until satisfactory completion of a substance abuse evaluation, ordered PD 6936 to retake the Arkansas Pharmacy Law Test, assessed a fine of $5,000, and put the pharmacist's license on probation for a period of five years.

Pharmacy Permit #AR-13170 – Charged with failure to operate the pharmacy according to law in violation of Arkansas Code Annotated §17-92-407(c). The Board fined the pharmacy permit $5,000 and ordered them to follow a plan of corrective action.

PD License #5144 & PD License # 8421 – Charged with deliveries of misbranded drugs, unprofessional conduct, consumption of alcoholic beverages, and posing a risk to the public health and safety as a result of use of alcoholic beverages in the workplace. The Board suspended the pharmacists' licenses pending satisfactory completion of substance abuse evaluations and appearance at the next or subsequent Board meeting. Furthermore, the Board will impose a two-year probation once the suspension is lifted. The Board also fined the pharmacists $2,500 each, required them to retake the Arkansas Pharmacy Law test, and required whatever store that employs either pharmacist in the future to have quarterly audits reported to the Board.

Generic Substitution

To address the growing number of inquiries regarding the Board's interpretation of generic equivalence, the following regulation speaks specifically to this practice. It is important to point out that unrated drug products are not substitutable unless the substitution is authorized by the prescriber. Examples of unrated drug products include medications such as Nalex®-A, Chlorex-A, Coldex-A, Rhinacon-A, and Blanex-A tablets. Although these products may be linked by your software as substitutes for each other since they contain the same ingredients in the same strengths, they are not rated products and therefore they may not be substituted or interchanged unless authorized by the prescriber.

07-00-0006 – Generic Substitution

The Arkansas State Board of Pharmacy recognizes Federal Food and Drug Administration's (FDA) Approved Drug Products with Therapeutic Equivalence Evaluations "Orange Book" as the basis for the determination of generic equivalency within the limitations stipulated in that publication. If FDA approves a drug product as bioequivalent and publishes that product with an "A" (AA, AB, AN, AO, AP, and AT) rating in the "Orange Book," an Arkansas pharmacist, or any pharmacist dispensing drugs to patients in Arkansas, may substitute that product consistent with law. Conversely, if the drug product is "B" rated, is changed from an "A" rating to a "B" rating, or is not rated, the pharmacist may not substitute without the consent of the prescribing practitioner. When a pharmacist substitutes a bioequivalent drug product for the drug prescribed, the patient shall be notified of the substitution by a pharmacist involved in the dispensing process. (June 21, 2001)

Arkansas State Police, Pseudo Reporting Hotline, 1-800/553-3820

The Arkansas State Board of Pharmacy has received numerous phone calls from pharmacists expressing concerns regarding the lack of a centralized mechanism to anonymously report suspicious activity by individuals attempting to purchase pseudoephedrine and ephedrine products. Certain individuals appear to be shopping at several stores, known as "smurfing," in an attempt to circumvent the "nine (9) gram within 30 day" limit. Additionally, they may be confrontational or appear impaired at the time of purchase. To address this situation, Senator Percy Malone met with

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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

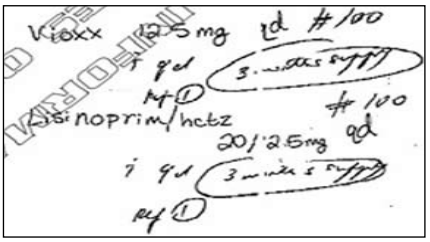
This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other 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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Colonel Steve Dozier, state police director, and Captain Cleve Barfield, commander of the Arkansas State Police Criminal Investigation Division. Senator Malone, Colonel Dozier, and Captain Barfield formalized a mechanism for pharmacists to anonymously report suspicious purchases or aberrant behavior by these individuals. They stressed that pharmacists should be non-confrontational in these situations and should adhere only to the "nine (9) gram within 30 day" limit for their store. The toll-free number to anonymously report suspicious activity is 1-800/553-3820. This number serves as the Arkansas State Police Drug Information Hotline.

Amended Instructions for Reporting Controlled Substances Loss for DEA Registrants

Federal Regulation (Section 301) of the Controlled Substances Act of 1970 (PL91-513) requires registrants to submit a report of any loss of CS to DEA.

Arkansas State Board of Pharmacy Regulation 07-04-0006 requires that any holder of a pharmacy permit that suffers a theft or loss of CS shall:

a. Notify the Arkansas Department of Health, Division of Pharmacy Services and Drug Control; the nearest DEA Diversion Field Office; and the Arkansas State Board of Pharmacy **immediately upon discovery by phone or fax**, and
b. Deliver a completed DEA Form-106 to each of the agencies listed **within seven days** of the occurrence of said loss or the discovery of said loss.

* **New Requirement**. According to 21 CFR part 1301 Sec. 1301.74 (c), The registrant shall notify the Field Division Office of the Administration in his area, **in writing**, of any theft or significant loss of any CS **within one business day of discovery of the theft or loss**.

This written notice should be faxed to the Little Rock DEA Office at 501/312-8652.

Scanning Prescriptions

During a special August meeting of the Arkansas State Board of Pharmacy, the Board discussed prescription scanning technology and specifically addressed the subject of who could scan prescriptions into the computer database in pharmacies where this technology is being utilized. After discussing the practice of allowing non-licensed personnel (pharmacy clerks) to scan prescriptions into the computer system, the Board decided to allow only licensed or registered personnel (pharmacists, interns, and pharmacy technicians) to scan prescriptions into the computer and not allow clerks to perform this function.

Electronic Prescriptions Received Via Fax

During the October Meeting, Emdeon Corp, formerly WebMD, made a presentation to the Board highlighting electronic prescribing and security measures incorporated into the process of electronic prescribing to ensure valid electronic signatures for prescriptions. A topic of concern during this discussion was the fact that most pharmacies are not currently set up to receive electronic prescriptions directly to a computer in the pharmacy. Because of this, processing companies that transmit the electronic prescriptions to pharmacies must transmit the prescription to the fax machine in the pharmacy much like a computer generated request for refill authorizations, which a computer faxes to a prescriber. At the end of this discussion, the Board decided that electronic prescriptions that are submitted by prescribers electronically and received in a pharmacy on a fax machine are considered electronic prescriptions and do not require a handwritten signature. If there are any questions about the legitimacy of the prescription, it should be treated like a phoned-in prescription and the pharmacist must verify it with the prescriber. It is important to note that this process is only for **non**-controlled medications. Currently, the process for CS is being determined by DEA; therefore, electronically produced prescriptions for CS must be printed out and signed by the prescriber before being faxed to the pharmacy or given to the patient.

Pharmacist License Renewals

Pharmacist and Pharmacy renewals have been sent out along with instructions on how to renew online. Renewing online will help Board staff to complete your renewal much more quickly and will greatly decrease the amount of time needed to process, print, and deliver permits. Renewing online is quick, easy, and does not cost anything extra. You will report your continuing education as part of this process and will not have to mail in a separate form for this. When renewing online, be sure to print a copy of the confirmation to keep with your records.

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.

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