

Missouri Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

PO Box 625, Jefferson City, MO 65102

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Regulation Update

Rules have been amended that will change certain aspects of the continuing education (CE) requirements for licensure. CE credits must be earned from the time a renewal cycle begins and until the cycle ends as prescribed by the Missouri Board of Pharmacy. The Board has determined that the cycle began September 1 and ends on a biennial cycle on August 31. This means that for the next renewal period, CE credits must have been earned between September 1, 2004, and August 31, 2006. In addition, if a pharmacist is audited by the Board at any time after the renewal period has ended and is found to be deficient in the number of hours or documentation of CE credits as required by law, a CE delinquent fee payment will be required. The fee is currently set at \$500. The Board may initiate disciplinary action as well against any pharmacist who has renewed a license under false pretenses or cannot produce the required documentation when audited. **See 4CSR 220-2.100 Continuing Pharmacy Education and 4CSR 220-4.010 General Fees.**

Awards

Tom Glenski, chief inspector, was chosen as the 2005 recipient of the National Association of Boards of Pharmacy® (NABP®) Distinguished Service Award for inspectors. He received the award at the NABP Annual Meeting in May 2005.

During 2005, Frank Van Fleet, inspector, and Don Walker, drug distributor coordinator, received service awards from the Board for five years of employment during 2005. Congratulations to these employees for their well deserved awards.

Compounding Notes From the Board

Innovations of products used by pharmacies to compound drug products or assist in compounding processes continue to be marketed. The Board has addressed some of these innovations by noting the following. Compounding kits that contain the ingredients needed to compound certain products are now available. The use of these kits is considered compounding and compliance with 4 CSR 220-2.400 is required. These kits are not considered “commercially available” in reference to 4 CSR 220-2.400 (9) listed above.

Overfills

Inspectors continue to report to the Board office the observation of pharmacy staff returning “will-call” drugs back to stock by pouring them back into an original stock container. This practice is illegal in that once a drug has been transferred out of a manufacturer stock container, it should not be returned since the drug has undergone manipulations outside of its original container. Mixing lot numbers can also occur, which is inappropriate.

Licensing Action Report

Pharmacists

- Daryl G. Daniels, #43088**, Winchester, MO – August 5, 2005. Revoked effective August 5, 2005, cannot reapply for five (5) years. Pled guilty to felony burglary in the second degree. Section 338.065.1, RSMo 2000.
- Daniel B. Drewry, #41934**, Springfield, MO – July 20, 2005. Probation for three (3) years from July 20, 2005. Loss of controlled substances (CS) from place of employment, failure to maintain security to deter theft of CS by personnel. Section 338.055.2(5), (13), and (15), RSMo Supp. 2002.
- Harry K. George, #26531**, Cape Girardeau, MO – July 28, 2005. Probation for three (3) years from July 28, 2005. Pharmacist-in-Charge (PIC) allowed technician to work with expired registration, losses of CS, made no provisions to deter theft after having knowledge of CS shortages, audit discrepancies,

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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

Compliance News

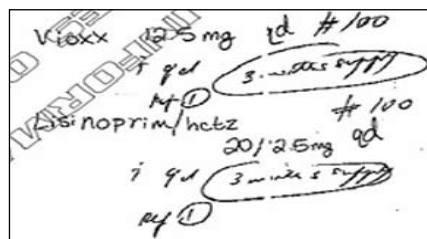
Compliance News to a particular state or jurisdiction should not be assumed to be the law of such state or jurisdiction.)



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 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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recordkeeping. Section 338.055.2(5), (6), (10), (13), and (15), RSMo Supp 2002.

Chad S. Herlyn, #43689, Kansas City, MO – August 3, 2005. Probation for two (2) years from August 3, 2005. PIC failed to require pharmacy technicians to provide a copy of registration information prior to employment, assisted and enabled technicians who were not registered with the Board to be actively employed in the pharmacy. Section 338.055.2(6), (10), (13), and (15), RSMo Supp. 2002.

Gary V. Mantese, #29599, St Louis, MO – May 17, 2005. Three (3) years suspension, followed by five (5) years probation. Arrested for possession of drug paraphernalia, tested positive for cocaine, impaired pharmacist. Section 338.055.2(13), (15), (17), RSMo Supp. 2002.

Richard H. Mullen, #27080, Leawood, KS – July 20, 2005. Probation for one (1) year from July 20, 2005. Dispensing errors. Section 338.055.2(5), (13), and (15), RSMo Supp. 2002.

Chalen E. Reed, #2005021435, Horton, KS – July 12, 2005. Restricted license issued on Probation for four (4) years from July 12, 2005. Use and addiction to benzodiazepines, impairment, practiced as a pharmacist prior to licensure. Section 338.055.1 and .2(1) and (6), RSMo Supp. 2003.

Pharmacies

Broadway Prescription Shop, #5857, Cape Girardeau, MO – July 28, 2005. Probation for three (3) years from July 28, 2005. PIC allowed technician to work with expired registration, losses of CS, made no provisions to deter theft after having knowledge of CS shortages, audit discrepancies, recordkeeping. Section 338.055.2(5), (6), (10), (13), and (15), RSMo Supp 2002.

McKenzie's Prescription Center, #3394, Moberly, MO – August 19, 2005. Probation for five (5) years effective August 19, 2005. Refilled legend drugs more frequently than authorized; dispensed legend drugs without a valid prescription on file or in quantities other than prescribed without authorization; Schedule IV CS dispensed more frequently than authorized, without a valid prescription on file, or in quantities other than prescribed without authorization; changes were made in

prescriptions without a clear audit trail of prescriber contact; Medicaid was billed for more frequent refills than authorized by means of fraudulent documentation. Section 338.055.2(4), (5), (6), (13), and (15) RSMo.

Terrace Pharmacy, #2002011019, Ogden, UT – August 25, 2005. Voluntary surrender of pharmacy permit effective August 25, 2005. Dispensed prescriptions based on online questionnaires whereby no examination had been conducted by the prescribers, and the prescribers were not licensed in Missouri. Section 338.055.2(5), (13), and (15), RSMo 2000.

Walgreens, #4190, Creve Cuoer, MO – August 24, 2005. Censure of pharmacy permit. Failure to provide adequate security to ensure confidentiality of patient records. Section 338.055.2(5), (6), (13), and (15); and Section 338.285, RSMo Supp. 2002.

Drug Distributors

Medline Industries, Inc, #2002031660, Kansas City, MO – August 3, 2005. Probation for five (5) years from August 3, 2005. Failure to maintain a facility where temperature is controlled and humidity is maintained, failure to timely notify the Board of changes in location of facility, failure to establish and maintain a policy and procedure manual, failure to display a valid license, failure to renew license and operation without a license, opening for business at a new location prior to inspection and approval. Section 338.353.1 and 338.055.2 (6), (12), and (15), RSMo Supp. 2002.

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The *Missouri Board of Pharmacy News* is published by the Missouri 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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