

November 2005



Alabama State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

New State Board of Pharmacy Member

Mike Mikell, RPh, was elected to a five-year term on the Alabama State Board of Pharmacy, effective January 1, 2006.

He replaces Lynda C. Staggs, RPh. He graduated in 1971 from Auburn University School of Pharmacy.

Mike owned Mike's Pharmacy in Millbrook, AL for 29 years (1973-2001) and after selling his store, he worked as a relief pharmacist in five independent pharmacies and 10 Winn-Dixie pharmacies. He presently is employed as a full-time relief pharmacist for Winn-Dixie.

Mike served two years on the Medicaid Drug Utilization Review Board, serving as chairman for one year. He served as member of the State Committee of Public Health from 2002-2003. After serving as Alabama Pharmacy Association (APA) district trustee from 1980-1984, Mike felt he could help pharmacy by being involved in state politics and was elected three times to the Alabama House of Representatives (1983-1994). Recently, he was elected as APA district trustee at large for the 2005-2006 term. He and his wife, Jo, live in Millbrook, AL.

Hurricanes Katrina and Rita – “A State of Emergency”

Hurricane Katrina inflicted devastation in Louisiana, Mississippi, and Alabama and caused citizens of those states to flee for safety to neighboring states or to be evacuated to relief areas away from their homes. President George W. Bush approved Governor Bob Riley's request for a Federal Disaster Declaration on August 29, 2005, and the people of Alabama coordinated efforts to provide state and federal infrastructure assistance to six counties in Alabama: Mobile, Baldwin, Washington, Clarke, Choctaw, and Sumter.

The Board of Pharmacy moved quickly to notify pharmacists that Board Rule 680-X-2-.26 EMERGENCY PRESCRIPTION REFILL was in effect for dispensing a one-time emergency refill of up to a 72-hour supply of the prescribed drug. However, as the devastation compounded and the extent of the destruction was made evident, the Board took further action by requesting Governor Riley to declare two proclamations needed to meet the pharmaceutical needs of evacuees

from these areas. The first proclamation extended the 72-hour emergency refill of maintenance medication or the continuation of chronic therapy medication, excluding Schedule II or III appearing in Title 20, Chapter 2, to a 30-day emergency supply of “all” drugs. This extension was done in coordination with the Federal Disaster Declaration and the Office of Drug Diversion, Special Assistant James C. Crawford and ended October 15, 2005. The second proclamation signed by Governor Riley allowed for out-of-state pharmacists to volunteer in Alabama for the length of the “State of Emergency” and for an expedited reciprocal process to be implemented to allow pharmacists displaced from one of the evacuated locations to work in the state of Alabama.

Information continues to transmit on a daily basis from the Department of Public Health and the Alabama Pharmaceutical Association regarding volunteer pharmacists rising to the occasion and proceeding to assist at clinics and charitable pharmacies in Mississippi, Louisiana, and Alabama. The Department of Public Health issued **Standing Prescription Orders** along with vouchers for evacuees to obtain needed medications. Louisiana and Mississippi Medicaid was made available to those who needed it in Alabama and Blue Cross Blue Shield of Alabama allowed for an early refill of current medications to people affected by this disaster.

Board of Pharmacy investigators worked with local pharmacies that needed to relocate to trailers on their sites for operation as well as with organizations offering assistance to evacuees, ie, Emergency Management Association, Red Cross, and the Federal Emergency Management Association. The Board Web site remained current with resource information including press releases to local newspapers and up-to-date instructions on emergency prescription filling and expedited reciprocation.

Alabama Prescriptive Authority Reads in Part

540-X-7-.28 Prescriptions and Medication Orders – Physicians Assistants

1. A physician assistant (PA) may prescribe a legend drug to a patient subject to both of the following conditions:

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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

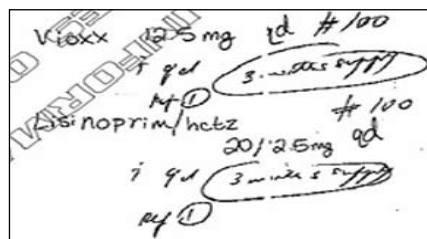
Compliance News to a particular state or jurisdiction should not be assumed (the law of such state or jurisdiction.)



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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- a. The drug type, dosage, quantity prescribed, and number of refills are authorized in the job description, which is signed by the supervising physician to whom the PA is currently registered and which is approved by the Board;
- b. The drug is included in the formulary approved under the guidelines established by the Board for governing the prescription practices of PAs.
2. A PA shall not prescribe any drug, substance, or compound that is listed in Schedules I-V of the Alabama Uniform Controlled Substance Act.
3. The supervising physician and the PA shall adhere to and follow all requirements and procedures stated in written guidelines established by the Board to govern the prescribing practices of PAs.
4. A PA may not initiate a call-in prescription in the name of the supervising physician for any drug that the assistant is not authorized to prescribe unless the drug is specifically ordered for the patient by the supervising physician either in writing or by a verbal order reduced to writing and signed by the physician within the time specified in the guidelines established by the Board.
5. For any drug the PA is authorized to prescribe, a written prescription signed by the PA and entered into the patient's chart may be called in to a pharmacy.
6. Whenever a PA calls in a prescription to a pharmacy, the PA shall identify his or her supervising physician.
7. A PA may administer any legend drug the assistant is authorized to prescribe.
8. For hospitalized patients, PAs may enter verbal admission orders and verbal subsequent orders for medications from the physician. All such orders must be validated by the ordering physician within 24 hours or within the time period specified in the hospital bylaws or policies.
9. When prescribing **legend drugs** a PA shall use a prescription form that includes all of the following:
 - a. The name, medical practice site address, and telephone number of the physician supervising the PA;
 - b. The PA's name printed below or to the side of the physician's name;
 - c. The medical practice site address and telephone number of the PA, if different from the address of the supervising physician;
 - d. The PA's license number assigned by the Board;
 - e. The words "Product Selection Permitted" printed on one side of the prescription form directly underneath a signature line;

- f. The words "Dispense as written" printed on one side of the prescription form directly underneath a signature line.

Legend Drug. Any drug, medicine, chemical, or poison, bearing on the label the words, "Caution, Federal Law prohibits dispensing without prescription" or similar words indicating that the drug, medicine, chemical, or poison may be sold or dispensed only upon the prescription of a licensed medical practitioner, **except that the term legend drug shall not include any drug, substance, or compound listed in Schedules I-V of the Alabama Uniform Controlled Substance Act.**

540-X-8-.11 Prescriptions and Medication Orders – Certified Registered Nurse Practitioners

540-X-8-.25 Prescriptions and Medication Orders – Certified Nurse Midwife

1. Certified registered nurse practitioners (CRNPs) and certified nurse midwives (CNMs) engaged in collaborative practice with physicians may be granted prescriptive authority upon submission of evidence of completion of an academic course in pharmacology or evidence of integration of pharmacology theory and clinical application in the CRNP curriculum.
2. CRNPs and CNMs practicing under protocols approved in the manner prescribed by Code of Alabama 1975, §34-21-80 et seq. may prescribe legend drugs to their patients, subject to the following conditions:
 - a. The drug type, dosage, quantity prescribed, and number of refills shall be authorized in an approved protocol signed by the collaborating physician and the CRNP. This requirement may be met if written prescriptions adhere to the standard recommended dose of legend drugs as identified in the *Physicians Desk Reference* or Product Information Insert, not to exceed the recommended treatment regimen periods.
 - b. The drug shall be included in the formulary recommended by the Joint Committee and adopted by the Board of Nursing and the Board of Medical Examiners.
3. A CRNP or CNM may not initiate a call-in prescription in the name of a collaborating physician for any drug, whether legend or controlled substance, which the CRNP is not authorized to prescribe under the protocol signed by the collaborating physician and CRNP and approved under this section unless the drug is specifically ordered for the patient by the physician, either in writing or by a verbal order that has been transcribed in writing, and that has been signed by the physician within seven working days or as otherwise specified by the Board of Nursing and the Board of Medical Examiners.

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4. A written prescription for any drug that the CRNP is authorized to prescribe may be called in to a pharmacy, provided the prescription is entered into the patient's record and signed by the CRNP.
5. The CRNP and CNM in collaborative practice with prescriptive privileges shall not engage in prescribing for:
 - a. Self.
 - b. Immediate family members.
 - c. Individuals who are not patients of the practice.
 - d. The CRNP and CNM who are in collaborative practice and have prescriptive privileges may receive and sign for **samples of legend drugs** that are authorized in the approved formulary for the collaborative practice, provided the CRNP complies with all applicable state and federal laws and regulations.
6. When prescribing **legend drugs**, a CRNP and a CNM shall use a prescription form that includes all of the following:
 - a. The name, medical practice site address, and telephone number of the collaborating physician or covering physician.
 - b. The CRNP's name and a CNM's name printed below or to the side of the physician's name.
 - c. The medical practice site address and telephone number of the CRNP and the CNM if different from that of the collaborating physician.
 - d. The CRNP's and CNM's nurse license number and identifying prescriptive authority number assigned by the Board of Nursing.
 - e. The words "Product Selection Permitted" printed on one side of the prescription form directly beneath a signature line.
 - f. The words "Dispense as written" printed on one side of the prescription form directly beneath a signature line.
 - g. The date that the prescription is issued to the patient.

Legend Drug. Any drug, medicine, chemical, or poison bearing on the label the words, "Caution, federal law prohibits dispensing without prescription" or similar words indicating that such drug, medicine, chemical, or poison may be sold or dispensed only upon prescription of a licensed practitioner, except that **the term legend drug will not include any drug, substance, or compound listed in Schedules I-V of the Alabama Uniform Controlled Substance Act.**

Administrative hearings and consents can be viewed at www.albop.com.

Alabama Board of Pharmacy 2006 Meeting Dates

January 17-18	July 18-19
February 21-22	August 15-16
March 14-15	September 19-20
April 18-19	October 24-25
May 16-17	November 14-15
June 20-21	December 19-20

Optometrists' Prescriptive Authority

State law authorizes optometrists who have been certified by the State Board of Optometry to prescribe pharmaceutical agents for the treatment of the human eye and its adjacent structures. The law further allows these practitioners to prescribe controlled substances in Schedules III, IV, and V, with the exception of Schedule III agents that contain hydrocodone. Prescribing any other Schedule III drug shall be limited to a prescription, the duration of which does not exceed 96 hours. To determine if an optometrist has been certified, contact the State Board of Optometry at 205/538-9903.

August 2005 Administrative Hearings and Consent Orders

Technician Applicants

Tamara S. Crayton. Application denied. Failure to appear.

Technicians

Bo L. White #T08938, Lisa Wilson Vance #T17854, Kristin Turner Peters #T10887, Patricia Rushing Lewis #T09291, Devin Glover Guthrie #T10152. Registration revoked and all future applications for renewal denied. Failure to appear. Hearing cost \$250.

Frederica Delores Webster #T08086, Randall Blake Johnson #T10998, Rodney O'Neal Woodruff #T10163. Registration revoked and all future applications for renewal denied. Failure to appear. Administrative fine \$6,000. Hearing cost \$250.

Sherry Meadows Wells #T16823. Registration revoked and all future applications for renewal denied. Failure to appear. Administrative fine \$600. Hearing cost \$250.

Brandi Whitlock Weldon #T10535. Registration on probation for one (1) year. Administrative cost \$100.

Jeffrey B. Straub #T02007. Registration suspended five (5) years. Suspension may revert to probation after one (1) year pending conditions are met. Administrative fine \$1,200. Hearing cost \$250.

Cynthia Bennet Parvin #T14068. Registration suspended. Suspension may revert to probation for a period of five (5) years pending conditions are met. Administrative fine \$300. Hearing cost \$250.

Lucretia Marie Knight #T09585. Registration suspended. Suspension may revert to probation for a period of three (3) years pending conditions are met. Administrative fine \$600. Hearing cost \$250.

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Shelley Fleming Fomby #T02964. Violated Code of Alabama (1975), §41-22-12 (e). Action – Probation one (1) year. Administrative fine \$200. Hearing costs \$250.

Jatin D. Patel #T11848. Probation granted. Action – Hearing cost \$250.

Georgia Gore Blalock #T13528. Registration revoked and all future applications for renewal denied. Failure to appear. Action – Administrative fine \$6,000. Hearing costs \$250.

Pamela Crowe Luckie #T08923. Registration revoked and all future applications for renewal denied. Failure to appear. Action – Administrative fine \$600. Hearing costs \$250.

Nathan Rocky Perkins #T13010. Registration revoked and all future applications for renewal denied. Failure to appear. Action – Administrative fine \$200. Hearing costs \$250.

Jana Brown Mastroni #T12949. Registration revoked and all future applications for renewal denied. Failure to appear. Action – Administrative fine \$1,800. Hearing costs \$250.

Eric Keane Johnson #T13758. Violation of Code of Alabama (1975), §34-23-132(3). Failure to appear. Action – Administrative fine \$250. Hearing costs \$250.

Pharmacists

Mitchell Douglas Ames #10351, Scott Lee Miller #12235, and Season Dionne Scott #44850. License suspended for a period of five (5) years with immediate reversion to probation pending conditions are met. Administrative fine \$2,500.

Aneshia G. Taylor #14610. Violated Code of Alabama (1975), §34-23-33 (2)(7) by dispensing a drug or drug preparation bearing upon the package the words “caution:

federal law prohibits dispensing without a prescription,” or similar wording which causes such drugs to be classified as “legend drugs” in violation of Code of Alabama (1975), §34-23-70 (1). Action – Letter of Reprimand. Hearing costs \$250.

Michael Fred McGuire #8048. Violated Code of Alabama (1975), §34-23-35 (5), §34-23-33 (6)(13)(12), Code of Alabama (1975), §20-2-54(a)(4). Action – License suspended for a period of five (5) years. Administrative fine \$2,500. Hearing costs \$250.

Richard Eric Patterson #12217. Violated Code of Alabama (1975), §34-23-33(6)(7) in connection with practicing pharmacy and working as a pharmacist during 2005 without first having renewed his certificate of licensure with the Board. Action – Administrative fine \$500.

Retail Medical Oxygen Suppliers

McVay’s Home Care Rental and Sales. Violated Code of Alabama (1975), §41-22-12 (f) by engaging in activities as a retail medical oxygen supplier without having a renewed permit. Action – Consent order fine \$1,000.

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