

November 2004



Alabama State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Tammy Rogers Appointed to the Alabama State Board of Pharmacy

Governor Bob Riley recently appointed Tammy H. Rogers to a five-year term on the Alabama State Board of Pharmacy, effective January 1, 2005. She will serve as the chain pharmacist representative rendering a valuable service to the citizens of Alabama until December 31, 2009. Clay O. Wilson, RPh, current president of the Board, will rotate off the Board on January 1, 2005. Tammy is currently a regional pharmacy operations manager with Bruno's Supermarkets, Inc, for Alabama, Florida, and Georgia. She received her bachelor of science in pharmacy degree from the University of Georgia in 1987 and serves as the District I Trustee for the Alabama Pharmacy Association. Other professional memberships include pharmacy associations in Florida and Georgia, the Pharmacy Association of Mobile County, the Escambia County Pharmacy Association, the National Association of Drug Diversion Investigators, the Board of Directors for the Escambia County Epilepsy, and the Junior League. Other distinguished Board members currently serving on the Board are Linda Staggs, RPh; Jackson Como, PharmD; Roland D. Nelson, RPh; and Rick Stephens, RPh.

Changes to Code of Alabama 1975, Title 20 Chapter 2, Alabama Uniform Controlled Substance Act, Enacted by the Legislature of Alabama

Visit the Board's Web site at www.albop.com to read the code in its entirety.

§20-2-190. Violations.

(c)

(1) On and after **August 1, 2004**, products whose sole active ingredient is pseudoephedrine in strength of 60 mg. or more per tablet cannot be offered for retail sale loose in bottles, but must be sold only in blister packages. Also, these products cannot

be offered for retail sale by self-service, but must be stored behind a counter or barrier so that it is not accessible by the public, and only accessible by a retail store employee.

- (2) On and after **August 1, 2004**, no person shall deliver in any single over-the-counter sale more than 3 packages, or any number of packages that contain a combined total of more than 9 grams of any product containing pseudoephedrine as the sole active ingredient, or in combination with other active ingredients.
- (3) This subsection does not apply to the following:
 - (a) Pediatric products labeled pursuant to federal regulations primarily intended for administration to children under 12 years of age according to label instructions.
 - (b) Products that the Alabama State Board of Pharmacy, upon application of a manufacturer, exempts because the product is formulated in such a way as to effectively prevent the conversion of the active ingredient into methamphetamine, or its salts or precursors.
- (4) This subsection shall preempt all local ordinances or regulations governing the possession by individuals or sale by a retail distributor of over-the-counter products containing pseudoephedrine.
- (5) A retailer who is the general owner or operator of an establishment where pseudoephedrine products are available for sale who violates this section shall not be penalized pursuant to this section if the retailer documents that an employee training program was conducted by or approved by the Alabama Methamphetamine Abuse Task Force pursuant to subsection (d) of this section.
- (6) A violation of subdivision (1) or (2) of this subsection shall constitute a Class C misdemeanor on a first offense and a Class A misdemeanor on subsequent offenses.

Continued on page 4



New Over-the-Counter Product Labeling

On March 24, 2004, Food and Drug Administration (FDA) passed final rulings requiring content labeling for over-the-counter (OTC) medications that contain levels of calcium, magnesium, sodium, or potassium that might be harmful to persons with certain underlying medical conditions. The final rule was effective April 23, 2004, with compliance expected by September 24, 2005. The labeling changes for oral OTC products were deemed necessary as persons with certain medical conditions such as heart disease, hypertension, kidney disease, kidney stones, or other medical conditions could worsen their condition upon consumption of these products. For example, OTC use of medications containing potassium may cause hyperkalemia in persons with compromised renal function. Under the new rules, oral OTC medications must state the exact amount of a particular ingredient in each dose if they contain:

- ◆ 5 mg or more of sodium in a single dose,
- ◆ 20 mg or more of calcium in a single dose,
- ◆ 8 mg or more of magnesium in a single dose, or
- ◆ 5 mg or more of potassium in a single dose.

The rules also require warnings to alert consumers on sodium-, calcium-, magnesium-, or potassium-restricted diets to consult their physician before using oral products that contain maximum daily doses of:

- ◆ more than 140 mg sodium,
- ◆ more than 3.2 grams calcium,
- ◆ more than 600 mg magnesium, or
- ◆ more than 975 mg potassium.

Currently the new label requirements do not include mouth rinses, fluoride toothpastes, or mouth washes. Detailed information on the rulings can be found in the Federal Register at www.fda.gov/OHRMS/DOCKETS/98fr/04-6479.htm and www.fda.gov/OHRMS/DOCKETS/98fr/04-6480.htm.

FDA Requests Antidepressant Manufacturers to Strengthen Warnings

On March 22, 2004, FDA issued a public health advisory that cautions physicians, their patients, and families and caregivers to closely monitor adults and children with depression. Results of antidepressant studies in children since June 2003 appeared to suggest an increased risk of suicidal thoughts and actions in those children taking certain antidepressants. FDA has initiated a review of these reports, but it is not clear whether or not antidepressants contribute to suicidal thinking and behavior.

As a result of the studies, FDA is asking manufacturers to change the labels of 10 drugs to include stronger cautions and warnings to monitor patients for worsening depression and the emergence of suicidal ideation. The drugs affected include bupropion (Wellbutrin®), citalopram (Celexa™), escitalopram (Lexapro™), fluvoxamine (Luvox® – not FDA approved for treatment of depression in the US), fluoxetine (Prozac®), mirtazapine (Remeron®), nefazodone (Serzone®), paroxetine (Paxil®), venlafaxine (Effexor®), and sertraline (Zoloft®). It should be noted that

Prozac is the only drug approved for use in children with major depressive disorder. Prozac, Zoloft, and Luvox are approved for pediatric patients with obsessive-compulsive disorder.

Patients taking these antidepressants should be monitored for behaviors associated with the drugs such as anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia, hypomania, and mania. Physicians are urged to closely monitor patients with bipolar disorder as monotherapy with antidepressants is believed to have the potential to induce manic episodes in such patients. A causal relationship has not been established between physical symptoms and suicidal ideation; however, medications may need to be discontinued when the symptoms are severe, abrupt in onset, or were not part of the presenting symptoms. Further information can be found on CDER's Web site: www.fda.gov/cder/drug/antidepressants/default.htm.

Let Past Experience with Chloral Hydrate Syrup Guide its Safe Use



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, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Chloral hydrate can be used safely to sedate pediatric patients for diagnostic procedures such as endoscopic procedures, CT scans, or MRIs. However, in several error reports over the years we have seen the sad stories of fatalities that have occurred after excessive doses of the drug were dispensed in error. Typically, deaths have occurred in cases where the order was not clear or when untrained individuals, both staff and parents, were involved without adequate supervision or the knowledge that they were administering an overdose. In some cases, to save time, chloral hydrate has been prescribed for use at home prior to travel to the practice site. In one instance, a 500 mg/5 mL concentration was dispensed instead of 250 mg/5 mL, which also is available. Unfortunately, the dose was prescribed by volume (teaspoonful), which made detection of the twofold overdose impossible. In another incidence, 120 mL of syrup was incorrectly dispensed instead of the prescribed 12 mL. The label instructed the mother to give her child the entire bottle, which she did. Without trained personnel and emergency equipment present to treat these accidental overdoses, the children in both cases died.

Compliance News

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



Recently the tragedy happened again. A prescription was written for a 17-month-old child; the pharmacist read the directions as “30 cc before office visit” and instructed the mother to give

her child that amount. In truth, the physician wanted the child to receive 500 mg 30 minutes before the office visit. The double hash-mark symbol (“), which the physician intended to mean minutes, was misread as cc. Actually, a double hash mark stands for seconds; a single hash mark (') is used for minutes. Neither symbol should be used in medicine, however, because not everyone understands their meaning.

Errors also happen in diagnostic areas where technical support personnel often administer oral conscious sedation even though they are not properly trained. In some cases, an ambiguous physician order such as “give chloral hydrate 5 cc prn sedation” or “. . . prn agitation,” rather than a specific milligram amount and maximum dose, has led to events where multiple doses of chloral hydrate were dispensed from the supply available to personnel. By the time the child fell asleep, the amount administered was a massive overdose leading to respiratory arrest.

Please consider reviewing your process for dispensing oral liquids used for conscious sedation in children, whether to a medical facility or to a family member. We suggest that the following precautions, in addition to package insert recommendations, be employed. Advise physicians that the drug should not be prescribed by volume (eg, “5 mL,” “one teaspoonful,” etc). There are two available concentrations of this drug. Instead, the specific milligram dose should be expressed. The prescription should state that it is for pre-procedure sedation. In hospital situations or when pharmacies dispense to health care facilities, prescriptions are best dispensed for each patient in labeled, unit-dose, oral syringes; providing the product in bulk packages as floor stock is less safe. We believe it is safest for pharmacists to *not* dispense prescriptions for patient use in the home when it is for pre-procedure sedation. Should the caregiver receive such a prescription, he or she should be advised that they are safest for the dose to be administered where the procedure will be performed. Official labeling for Versed® Syrup, another drug used for conscious sedation in children, notes that the syrup is intended for use only in monitored settings, never the home. Also, as noted in the product’s boxed warning, only health care professionals trained in conscious sedation procedures and authorized to administer conscious sedation drugs should do so. Careful monitoring by direct visual observation is necessary and age-/size- appropriate resuscitation equipment must be readily available. The American Academy of Pediatrics agrees; the Academy’s current “Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures” (*Pediatrics* 2002; 110:836-838)

recommend that children should not receive sedative or anxiolytic medications without supervision by skilled medical personnel. These medications should be administered by, or in the presence of, individuals skilled in airway management and cardiopulmonary resuscitation and administered in a health care facility where appropriate monitoring, including continuous pulse oximetry, can be instituted.

One final argument for administering children’s sedation on site is to ensure proper timing in case of unpredictable schedule delays.

NABP Releases Updated NAPLEX Blueprint

NABP has released the updated blueprint for the North American Pharmacist Licensure Examination™ (NAPLEX®). The blueprint is available for viewing on NABP’s Web site, www.nabp.net, as of September 2004. Examinations based on the updated blueprint will be administered beginning spring 2005.

Changes to the NAPLEX blueprint include the addition of competency statements addressing dietary supplements and pharmacotherapeutic equivalency as well as integration of the skill of communicating with patients and other health care providers in the entire examination blueprint instead of focusing it within a single competency area as with the current NAPLEX. The examination continues to consist of three major areas that are divided into several competency and subcompetency statements.

The updated blueprint and competency statements require a new passing standard. However, the NAPLEX continues to be a computer-adaptive examination that requires a scaled score of 75 or greater to pass. Calculation of the score is the same as in the past: the score is calculated by first determining the candidate’s ability level on the NAPLEX and then comparing this to the predetermined minimum acceptable ability level established for the NAPLEX. The new passing standard will go into effect along with the updated blueprint in spring 2005.

For more information about the NAPLEX, contact the Customer Service Department by calling 847/698-6227 or visit the Association’s Web site at www.nabp.net.

December 2004 FPGEE Date and Location Announced

On December 4, 2004, 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 Mateo, CA. Candidates who have been accepted to sit for the December 4, 2004 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.

(d)

- (1) The Alabama Methamphetamine Abuse Task Force is created to develop education and training programs that will curb the abuse of methamphetamine precursors used to make methamphetamine, and curb the use of methamphetamine in the State of Alabama.

680-X-2-27 Private Consultation Areas for Pharmacies

- (1) Since the implementation of patient consultation requirements as a result of OBRA '90 guidelines, it has become evident that the current setup in pharmacies is not conducive to proper communication with patients by pharmacist. Research shows that private consultation areas will facilitate proper consultation with patients by pharmacists and the resultant patient outcomes will be enhanced. Therefore, in order to protect the health of the public and enhance their medication outcomes, private consultation areas must be furnished by pharmacy owners.
- (2) The size of the consultation area must be large enough to accommodate the participants and must be entirely devoted to enhancing patient outcomes and not a storage room for merchandise or other non-related items. The area must be accessible by the patient from **outside of the pharmacy area** without having to traverse a stock room or pharmacy area and must have the capability of being private to both sounds and viewing by unauthorized parties. The area must be away from checkout areas and flows of traffic that would present a barrier to patient communication.
- (3) All new pharmacies that open after January 1, 1997, must be in compliance before a permit is issued. All pharmacies that are relocated after January 1, 1997, shall be in compliance. All existing pharmacies must be in compliance on or before **January 1, 2005**.

Pharmacist Certificate of Licensure §34-23-52

Reads in part. . . .

- (a) All certificates of licensure shall expire on December 31 of even-numbered years. Every licensed pharmacist in order to continue to be licensed shall pay a biennial renewal fee to be determined by the Board, but the fee shall not be less than twenty-five dollars (\$25) nor more than one hundred fifty dollars (\$150) to the secretary of the Board, the fee being due on October 31 and **delinquent after December 31 of even-numbered years** except, that holders of life certificate to practice pharmacy previously issued shall not be required to pay a renewal fee. **(The controlled substance license will continue a YEARLY RENEWAL until at such time it is rolled**

into the biennial even-numbered year renewal.)

The payment of the renewal fee shall entitle the registrants to renewal of their certificates at the discretion of the Board. If any pharmacist shall fail to pay a renewal fee on or before the due date (**December 31 of even-numbered years**), the holder of the certificate may be reinstated as a licensed pharmacist only upon payment of a penalty of ten dollars (\$10) for each lapsed month and all lapsed fees, provided the lapsed time of registration shall not exceed five years, in which case reinstatement may be had only upon satisfactory examination by the Board.

- (b) In addition to any fee requirements, each pharmacist is required to complete 15 hours of continuing education per calendar year, of which three hours shall be live presentation.

Technician Registration Changes §34-23-131

Reads in part. . . .

- (c) A pharmacy technician shall register and pay a fee as determined by the Board before performing any pharmacy functions. The Board shall develop rules and regulations relating to the registration of all pharmacy technicians. The registration of a pharmacy technician shall be **renewable biennially in odd numbered years** upon payment of the required fee.
- (d) In addition to any other registration requirements, a pharmacy technician shall complete three hours of continuing education annually, of which one hour shall be live presentation.

Administrative Hearings – July 2004 Through August 2004

Manufacturer/Wholesaler/Distributor: **Calvin Scott & Company, Inc** #192285. Engaging in activities without renewing permit. Action – \$500 fine.

Manufacturer/Wholesaler/Distributor: **AmerisourceBergen – Atlanta Distribution Center**. Florida violations. Action – \$2,000 fine.

Manufacturer/Wholesaler/Distributor name: **Quick Aid** #192982. Engaging in activities as a manufacturer/wholesaler/distributor without renewing permit. Action – \$500 fine.

Manufacturer/Wholesaler/Distributor name: **Schering-Plough Animal Health Corporation**. Violations of United States District Court. Action – Permit issued. \$1,000 fine.

Pharmacy's name: **Barnes Health Center** #112091. Dispensing of controlled substances (CS) III-V without a prescription. Action – Probation five (5) years, \$4,000 fine.

Pharmacy's name: **Leighton Pharmacy** #106070. Inaccurate records of prescription medications. Action – Probation one (1) year, \$1,200 fine.



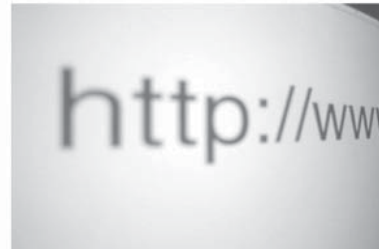
The Old Way.



The New Way.



The Old Way.



The New Way.

Log on to the Alabama Board of Pharmacy's Web site to manage all of your licensing needs.

<http://www.albop.com/>



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Pharmacy's name: **Barnes Health Center** #112091. Dispensing CS III-V without a prescription. Action – Probation five (5) years, \$4,000 fine.

Pharmacy's name: **Jerry's Pharmacy** #105633. Inaccurate records of prescription medications. Action – Probation two (2) years, \$1,750 fine.

Pharmacy's name: **Propst Discount Drugs, Inc.** #108215. Allowing a technician to work without a current technician registration. Administrative penalty \$500.

Pharmacist name: **Rodney Logan** #8045. Dispensing CS Schedule III, IV, and "legend drugs" without a prescription. Action – Probation one (1) year, \$1,400 fine.

Pharmacist name: **Arthur Thompson Delashment**. Mississippi and Tennessee probation. Reciprocity denied.

Pharmacist name: **Daniel L. Entrekin**. West Virginia violation. Action – Licensure granted with probation for one (1) year, \$250 fine.

Pharmacist name: **Jerry Donald Rogers** #7797. Dispensing CS and "legend drugs" without a prescription. Action – Probation two (2) years, \$1,750 fine.

Pharmacist name: **Paul David Connolly** #9865. Felony conviction. Action – Probation one (1) year, \$1,750 fine.

Pharmacist name: **Tracey Lee Lawson** #14519. Dispensed "legend drug" without proper authorization. Action – Reprimand and \$250 fine.

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Pharmacist names: **Mark Alan Chastain** #12268. **Jeanna Gullege Bulman** #12932. Allowing a technician to work without a current technician registration. Administrative penalty \$250.

Technician name: **Mary Denise Green**, applicant for Tech. Obtained registration by fraudulent means. Action – Probation two (2) years, \$250 fine.

Technician name: **Brian Gregory Foster**, applicant for Tech. Obtained registration by fraudulent means. Action – Probation (3) years, \$250 fine.

Technician names: **Anthony C. Morris** #T12701, **Robin Rena Winters** #T04676, **Heather Kay Sibley** #T13068, **Phillip Darryl Luker** #T12226, **Laura Ann Russ** #T00480, **Leona Phillips Brunson** #T08302. Registrations revoked.

Technician name: **Cassandra S. Jones**, applicant for Tech. Obtained registration by fraudulent means. Action – Registration granted. Probation one (1) year.

Technician name: **Kevin W. Woodard** #T11747. Theft of property, possession of a CS. Action – reprimand.

Technician name: **Tyna D. Spivery** #T11401. Obtained registration by fraudulent means. Action – Probation one (1) year, \$750 fine.

Technician name: **Amanda Michelle Walker** #T15129. Performing pharmacy functions and working as a technician without timely renewing and possessing a current technician registration. Administrative penalty \$125.

Retail Medical Oxygen Suppliers: **Covenant Laboratories** #900298. **Apria Healthcare, Inc** #900239. Engaging in activities without renewing permit. Action – \$500 fine.

Do You Know a Pharmacist or Technician Who Needs Help?

Call the Committee on Rehabilitating Impaired Pharmacists help line at the voice mail of Steve Moore at 205/975-8548. All calls are confidential.

Quality Improvement Note

Develop a systems approach to PATIENT SAFETY making it difficult to make mistakes and easy to do things correctly, for. . . .

Pharmacists are human

And

To err

Is

inevitable.

challenge yourself and your staff

To Find

Solutions that

Address a

Framework and

Environment

Toward creating a “culture of safety.”

White JP, Ketring SP. *Developing a Systemwide Approach to Patient Safety: The First Year*. Oklahoma City, OK: INTEGRIS Health; 2002.

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The *Alabama State Board of Pharmacy News* is published by the Alabama 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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