October 2004

Louisiana Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

5615 Corporate Blvd, Suite 8E, Baton Rouge, LA 70808-2537
www.labp.com

New Board Members (04-10-193)

Governor Kathleen Blanco announced five appointments to the Louisiana Board of Pharmacy.

District 1: Michele P. Alderman, who practices at Memorial Medical Center in New Orleans, replaced Salvatore J. D'Angelo, who completed 39 years of service.

District 2: Reuben R. Dixon, who practices at Bywater Hospital in New Orleans, was reappointed.

District 4: J. Douglas Boudreaux, who practices at White's Compounding Pharmacy in Shreveport, replaced Clovis S. Burch, who completed 18 years of service.

District 6: Patsy L. Angelle, who practices at Prescription Compounds in Baton Rouge, replaced Wayne A. Camp, who completed six years of service.

District 7: Allen W. Cassidy, Jr, who practices at Cassidy's Pharmacy in Jennings, replaced Theodore S. Carmichael, who completed six years of service.

All of the new appointments are for a six-year term ending July 28, 2010. The Board welcomes the four new members and salutes their predecessors for their combined service to the Board of almost seven decades.

License and Permit Renewals for 2005 (04-10-194)

The Board office will begin printing pharmacist license and permit renewal applications on October 18, 2004. Any address changes submitted to the office after October 15 will not be reflected on your renewal applications. We will mail renewal applications during the week of October 25.

If you do not receive your renewal application by November 15, it is *YOUR* responsibility to obtain a renewal application. You may obtain a blank renewal application from the Board's Web site at www.labp.com.

Pharmacist License Renewal

- Licenses expire December 31, 2004; a pharmacist shall not practice with an expired license.
- If you need a current renewal on or before January 1, 2005, we suggest you submit your completed application and $75 fee to the Board office on or before December 1, 2004. Do not forget to answer the additional question concerning prior legal history in any jurisdiction – if it is not answered, or if there is no supporting information with a positive response, the application will be returned to you as an incomplete application.
- The renewal of an expired license will incur a 100% penalty as well as a lapsed license reinstatement fee, resulting in a total charge of $350.
- If it is important for you to know when your application is received in the Board office, we suggest you use a mailing service with tracking options (United States Post Office, UPS, FedEx, etc).

Pharmacy Permit Renewal

- Permits expire December 31, 2004; there is no more grace period, and a pharmacy may not operate with an expired permit.
- The renewal of an expired pharmacy permit or controlled dangerous substance (CDS) permit will incur a 50% penalty, resulting in a total charge of $150 for a pharmacy permit or $37.50 for a CDS permit.

Pharmacists, Technicians, and Interns (04-10-195)

If you are a pharmacist-in-charge (PIC), you must at all times ensure that all personnel allowed to perform professional functions in your prescription department are properly licensed, certified, or registered. If you are a staff pharmacist or relief pharmacist, it is your responsibility to ensure that

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National Pharmacy Compliance News

(Applicability of the contents of articles in the National Pharmacy Compliance News to a particular state or jurisdiction should not be assumed and can only be ascertained by examining the law of such state or jurisdiction.)

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.

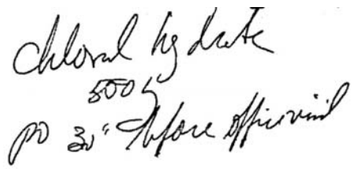
Patients taking these antidepressants should be monitored for behaviors associated with the drugs such as anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia, hypomania, and mania. Physicians are urged to closely monitor patients with bipolar disorder as monotherapy 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.

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.

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the employees assisting you in the prescription dispensing process are properly credentialed to perform their duties during your shift. If an inspection or investigation occurs while you are on duty and unqualified persons are performing duties under your supervision, then you will be identified as the responsible person in the investigative report filed by the Board's compliance officer.

Legislature Adopts Changes to Pharmacy Law (04-10-196)

Governor Blanco has signed into law two bills that changed different portions of the Louisiana Pharmacy Practice Act; they became effective on August 15, 2004.

Act No. 131 (HB 698) changed two sections of the pharmacy law: The first portion of the bill gave the Board the authority to purchase, possess, and dispose of immovable property (R.S. 37:1182.B.8). The second portion of the bill changed the law governing the scope of practice for pharmacy technicians, and requires the Board to adopt regulations to provide specific guidance in that area (R.S. 37:1212). The Board is currently in the process of promulgating a new chapter on technician regulations.

Act No. 811 (HB 1402) changed the section of pharmacy law that governs the transfer and donation of previously dispensed prescription medications to charitable pharmacies (R.S. 37:1226.2).

If you have a subscription to the *Louisiana Board of Pharmacy Laws and Regulations*, you should have already received an update that contained these changes. These changes have also been posted on our Web site at www.labp.com.

Different Format of Newsletter *(04-10-197)*

The Board is considering a change in format of this quarterly *Newsletter*. We have received a proposal to post an electronic – instead of printed – version of this *Newsletter*, both on our own Web site (www.labp.com) as well as that of the National Association of Boards of Pharmacy® (www.nabp.net). Given the significant costs of printing and mailing this *Newsletter* to our 14,000-plus clients, the Board is carefully reviewing the proposal. If you have any comments on this matter, please let us know.

Disciplinary Actions (04-10-198)

Although every effort is made to ensure the information is correct, you should call the Board office at 225/925-6496 to verify the accuracy of any listing before making any decision based on this information.

During its May 6, 2004 administrative hearing, the Board took final action in the following matters.

Shane Lawrence Calvin (Technician Certificate No. 5751), Formal Hearing: Certificate revoked, with no recourse for reinstatement; further, certificate holder was assessed $2,000 plus administrative and investigative costs. *Charges*: (1) unlawful acquisition of controlled substance by fraud or forgery, and (2) unlawful possession with intent to distribute a controlled substance in Schedule III.

Kavin Armstead (Technician Certificate No. 1130), Formal Hearing: Certificate was suspended indefinitely; further, certificate holder was assessed $500 plus administrative and investigative costs. *Charges*: (1) obtained a certificate by fraud or misrepresentation, and (2) failure to comply with continuing education (CE) requirements.

Scott Haines Acosta (Pharmacist License No. 16115), Formal Hearing: License was suspended indefinitely; further, license holder was assessed $2,000 plus administrative and investigative costs. *Charge*: failure to pay assessment from prior disciplinary proceeding.

Holmes Lowell Milliken (Pharmacist License No. 10297), Formal Hearing: License was revoked; further, license holder was assessed $5,000 plus administrative and investigative costs. *Charges*: (1) habitually intemperate or addicted to alcohol or habit-forming drugs, (2) failure to furnish to the Board information legally requested by the Board or its agent, and (3) probation violation.

During its August 19, 2004 administrative hearing, the Board took final action in the following matters:

Rite Aid Pharmacy No. 7280 (Pharmacy Permit No. 1697), Voluntary Consent Agreement: Permit holder was assessed administrative and investigative costs. *Charges*: (1) has departed from or failed to conform to minimal standards of acceptable and prevailing pharmacy practice, (2) failure of pharmacist to verify accuracy of prescription, and (3) failure of pharmacist to dispense correct drug prescribed.

Gabriel Rademene Edu (Intern Registration No. 41538), Voluntary Consent Agreement: Registration was revoked; further, respondent was assessed administrative costs. *Charge*: has engaged in the practice of pharmacy with an expired registration.

Community Pharmacy No. 1 (Pharmacy Permit No. 2908), Voluntary Consent Agreement: Permit was suspended for five years, with execution thereof stayed, then placed on probation for the suspensive period, beginning July 1, 2004, subject to certain terms; further, permit holder was assessed $2,500 plus administrative and investigative costs. *Charges*: (1) has departed from or failed to conform to the minimal standards of acceptable and prevailing pharmacy practice, (2) has failed to close the prescription department in the absence of the pharmacist, and (3) has permitted the dispensing of prescription medication in the absence of the pharmacist.

Mona Patrice Carter (Pharmacist License No. 14953), Voluntary Consent Agreement: License was suspended for

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one year, with execution thereof stayed, then placed on probation for the suspensive period, beginning on July 1, 2004, subject to certain terms; further, license holder was assessed $3,500 plus administrative costs. *Charges*: (1) has departed from or failed to conform to the minimal standards of acceptable and prevailing pharmacy practice, (2) has failed to close the prescription department in her absence, and (3) has permitted the dispensing of prescription medication in her absence.

Kendra Linette Eatmon (Technician Certificate No. 5714), Voluntary Consent Agreement: Certificate was suspended for one year, with execution thereof stayed, then placed on probation for the suspensive period, beginning on July 1, 2004, subject to certain terms; further, certificate holder was assessed $250 plus administrative costs. *Charges*: (1) has improperly dispensed prescription medications in the absence of a pharmacist, (2) has assisted another person in evading any local, state, or federal laws or regulations pertaining to the practice of pharmacy, and (3) has committed fraud in connection with the practice of pharmacy including but not limited to insurance fraud and Medicaid fraud.

The Corner Drug Store (Pharmacy Permit No. 2317), Voluntary Consent Agreement: Permit holder was assessed administrative and investigative costs. *Charges*: (1) has departed from or failed to conform to the minimal standards of acceptable and prevailing pharmacy practice, and (2) dispensation of prescription medications without valid prescriptions.

Margaret Renee Saunier (Technician Certificate No. 5511), Voluntary Consent Agreement: Certificate was revoked, with no recourse for reinstatement. *Charges*: (1) failure to submit to a medical evaluation, (2) failure to furnish information to the Board legally requested by the Board, (3) failure to notify the Board of any change in mailing address, and (4) failure to notify the Board of any change in employment.

Charles' Pharmacy (Pharmacy Permit No. 4472), Voluntary Consent Agreement: Permit was revoked; further, permit holder was assessed investigative costs. *Charges*: (1) committed repeated occasions of negligence or incompetence in the practice of pharmacy, (2) has departed from or failed to conform to the minimal standards of acceptable and prevailing pharmacy practice, (3) has aided and abetted a pharmacist to engage in the practice of pharmacy with a suspended license, (4) has failed to secure the prescription department against unauthorized access, (5) has failed to properly secure the electronic record keeping system against unauthorized access to prescription records, (6) has aided and abetted the diversion of controlled substances, and (7) accountability for discrepancies in audits of controlled substances.

John Dwayne Baque (Pharmacist License No. 11850), Voluntary Consent Agreement: License was suspended for three years, with execution thereof stayed, then placed on probation for the suspensive period, beginning on July 30, 2004, subject to certain terms; further, license holder was assessed $3,000 plus hearing, administrative, and investigative costs. *Charges*: (1) committed repeated occasions of negligence or incompetence in the practice of pharmacy, (2) has departed from or failed to conform to the minimal standards of acceptable and prevailing pharmacy practice, (3) has aided and abetted a pharmacist to engage in the practice of pharmacy with a suspended license, (4) has divulged confidential information to a person other than as authorized by state or federal law, (5) failure as PIC to properly secure prescription department against unauthorized access, (6) failure as PIC to properly secure electronic record keeping system against unauthorized access to prescription records, and (7) accountability as PIC for discrepancies in audits of controlled substances.

Kevyn W. Woodward (Technician Certificate No. 3652), Voluntary Consent Agreement: Certificate was suspended for three years, with execution thereof stayed, then placed on probation for the suspensive period, beginning on July 1, 2004, subject to certain terms; further, certificate holder was assessed administrative and investigative costs. *Charges*: (1) has been convicted of a felony or other public offense involving moral turpitude, (2) has failed to report to the Board any adverse action taken against him in another jurisdiction, and (3) has departed from or failed to conform to the minimal standards of acceptable and prevailing pharmacy practice.

Krissy M. Lacobee (Technician Certificate No. 4500), Voluntary Consent Agreement: Certificate was revoked, with no recourse for reinstatement. *Charges*: (1) unlawful acquisition of controlled substance by fraud or forgery, (2) unlawful possession of Schedule IV controlled substance, and (3) departure from or failure to conform to the minimal standards of acceptable and prevailing pharmacy practice.

Kelly Michelle Cleveland (Technician Certificate No. 5191), Voluntary Consent Agreement: Certificate was revoked, with no recourse for reinstatement. *Charges*: (1) improper dispensation of prescription drugs, and (2) departure from or failure to conform to the minimal standards of acceptable and prevailing pharmacy practice.

Guy Francis Airey, III (Pharmacist License No. 16157), Voluntary Consent Agreement: License was suspended indefinitely; further, license holder was assessed $500 and administrative and investigative costs. *Charges*: (1) has obtained a license by fraud or misrepresentation, (2) has failed to comply with CE requirements, and (3) has failed to furnish information to the Board legally requested by the Board.

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James Carroll Bruce, II (Pharmacist License No. 11857), Voluntary Consent Agreement: License was suspended for 10 years, beginning on July 26, 2004; further, no application for reinstatement shall be accepted prior to July 25, 2009; further, license holder was assessed investigative costs. *Charges*: (1) has committed repeated occasions of negligence or incompetence in the practice of pharmacy, (2) has departed from or failed to conform to the minimal standards of acceptable and prevailing pharmacy practice, (3) has evaded local, state, or federal laws or regulations pertaining to the practice of pharmacy, (4) unlawful dispensation or possession with intent to distribute a Schedule II controlled substance, (5) unlawful dispensation or possession with intent to distribute a Schedule III controlled substance, (6) unlawful dispensation or possession with intent to distribute a Schedule IV controlled substance, (7) unlawful alteration of prescriptions for controlled substances, and (8) furnished false or fraudulent information in connection with audit of controlled substances.

The Board also issued Letters of Warning to three pharmacy permits, four pharmacists, and two pharmacy technicians; Letters of Reprimand were issued to two pharmacy permits, seven pharmacists, and one pharmacy technician. With respect to the reinstatement of lapsed credentials, the Board granted requests from five pharmacists and denied a request from one pharmacist.

With respect to impaired practitioners, the Board accepted the voluntary surrender of credentials from six pharmacists, two interns, and one pharmacy technician; granted reinstatement requests from three pharmacists; denied reinstatement requests from two pharmacists; and also granted requests for probation modification from three pharmacists.

Calendar Note (04-10-199)

The next Board meeting and administrative hearing will be held November 17-18, 2004, at the Board office in Baton Rouge. The office will be closed on November 11 in observance of Veterans' Day, November 25 for Thanksgiving Day, December 24 for Christmas Day, and December 31 for New Year's Day.

Special Note (04-10-200)

The *Louisiana Board of Pharmacy News* is considered an official method of notification to pharmacies, pharmacists, pharmacy interns, pharmacy technicians, and pharmacy technician candidates credentialed by the Board. **These *Newsletters* will be used in administrative hearings as proof of notification.** Please read them carefully. We encourage you to keep them in the back of the *Louisiana Pharmacy Law Book* for future reference.

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