



SC Department of Labor, Licensing & Regulation – Board of Pharmacy

Kingtree Bldg, 110 Centerview Dr
PO Box 11927, Columbia, SC 29211-1927

Published to promote voluntary compliance of pharmacy and drug law.

Extended Policy for State Certification of Pharmacy Technicians

The South Carolina Board of Pharmacy has reviewed the situation surrounding the state certification of pharmacy technicians who were not completely qualified by the end of the application period on June 30, 2004. At its September 2004 Board meeting, the Board established the following policy regarding a one-time extension for state certification under the transition rules. This is a temporary policy and, upon expiration of this event, statutory requirements will be the sole criteria for becoming state certified.

Until December 31, 2004, the Board will accept applications and the supporting documentation for pharmacy technician state certification from those individuals who have not submitted the required information. Those individuals who passed the Pharmacy Technician Certification Board's (PTCB) examination on July 21, 2004, and those who complete and pass the examination offered in November 2004 may file these applications. Applicants may submit all hours of practical experience obtained on or before December 31, 2004. Those individuals who pass the November 2004 PTCB examination will not receive state certification until the Board office is notified of the examination results. The three documents required with the application will be as follows:

1. Affidavit of completion of 1,500 hours of supervised practice under the supervision of a registered pharmacist.
2. Copy of PTCB certificate or, where appropriate, notice of approval to test in November 2004.
3. Any required documentation for certification/registration not yet submitted.

Individuals with questions should contact the Board of Pharmacy office at 803/896-4700.

Next Board Vacancy

The next Board of Pharmacy member term begins July 1, 2005, and ends June 30, 2011. Any pharmacist interested in running as a candidate must:

- ◆ Reside in the First Congressional District;
- ◆ Be licensed and actively practicing pharmacy in South Carolina; and
- ◆ Before December 1, 2004, submit to the Board office a biography and petition bearing signatures of at least 15 pharmacists practicing in the First Congressional District.

After receiving biographies and petitions, the Board administrator will:

- ◆ Prepare and mail ballots by January 15, 2005, to all pharmacists licensed and residing in the First Congressional District and those pharmacists who certified on their last renewal application that they reside in the First Congressional District; and

- ◆ Certify as true and valid all ballots postmarked before February 15, 2005, and received by the Board office before February 25, 2005.

Before March 1, 2005, the Board will certify in writing to the governor the names of the three candidates receiving the most votes in the election along with the name of the person who the nominee replaces on the Board. The new member, when appointed by the governor, will take office on July 1 of that year.

If you are interested in becoming a candidate for this position or have any questions, please contact the Board office.

Continuing Education Offer Regarding Compounding and USP Chapter 797

The Board recognizes the importance of education regarding the changes to United States Pharmacopeia (USP) guidelines for sterile compounding. The South Carolina Pharmacy Association (SCPhA) has been working with the Board and its Compounding Task Force to review USP Chapter 797 and evaluate how these changes affect you. It is through this effort that SCPhA's Carolina Pharmacy Network Business School will be offering an intensive continuing education (CE) program that will explain the intentions of USP 797. All pharmacies engaging in sterile compounding should plan to attend to learn what the Board will be looking for during inspections; USP 797 expert, Eric Kastango, RPh, president of Clinical IQ, will provide education on how your pharmacy can meet the intentions of USP 797. The program is scheduled for Sunday, December 12, 2004, starting at 2 PM. The cost will be \$75 for CPN members and \$90 for non-members; the CE credit processing fee is \$10. Contact the SCPhA at 1-800/352-4033 to register.

Disaster Preparedness in South Carolina

In South Carolina, there is a plan in place to manage the response and recovery from any manmade or natural disaster. Pharmacists can play an integral role in that plan. Each county has an emergency plan in place through the South Carolina Emergency Preparedness Division. It is these offices that respond first to any type of disaster that occurs. In conjunction with state and county emergency officials, the Board of Pharmacy, Department of Health and Environmental Control, and the SCPhA have joined efforts to assist if a disaster situation occurs. A voluntary network of pharmacists would assist in the event of a catastrophic occurrence. Please consider assisting with this effort by joining this voluntary network so that pharmacists can do their part in helping during a disaster. To find out more, contact the SCPhA at 1-800/352-4033.

Policy on Late Pharmacist Renewals

The Board adopted the following policy regarding late renewal of pharmacist licenses at its June 2004 meeting. Pursuant to Sec-

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.

Continued from page 1

tion 40-43-110(D), pharmacist licenses not renewed by May 1 are considered lapsed. Reinstatement of a lapsed license must be granted upon evidence satisfactory to the Board that all requirements for renewal have been met. The reinstated license may be subject to disciplinary action for failure to renew the license within the prescribed period and, where appropriate, practice during the period that the license has lapsed.

Applications that are submitted for renewal after May 1 must meet renewal requirements and contain the appropriate fees and penalties. Applicants shall sign a pre-licensing agreement certifying that their license is subject to the right to impose sanction for unlicensed practice pursuant to 40-1-110 and 40-43-110(D) of the Rules and Regulations of the Board.

All applications for renewal received after April 1 must include the penalty fee of \$50. In addition, those applications for renewal received during the following windows of time will be subject to additional penalties as listed below.

May 1-15	Additional \$100
May 16-31	Additional \$150
June 1-15	Additional \$200
June 16-June 30.....	Additional \$250
After July 1	Disciplinary Proceedings before full Board of Pharmacy

Board of Pharmacy Meeting Calendar

The Board of Pharmacy welcomes all interested individuals to attend Board meetings held throughout the year. All meetings will be held at the Board office in Columbia. Please see the following calendar and plan to attend. For more information, please contact the Board office.

- November 17, 2004
- January 19-20, 2005
- March 16, 2005
- June 15-16, 2005
- September 28-29, 2005
- November 16, 2005

The Board also has many special committees that meet periodically throughout the year to address specific concerns for the pharmacy community. These meetings are held at the discretion of the committee chairperson. If you are interested in one of the following committees, please contact the Board office for more information.

- ◆ Compounding Task Force
- ◆ Nuclear Pharmacy
- ◆ Pharmacy Technicians
- ◆ Immunization Task Force
- ◆ Pharmacy Technology
- ◆ Pharmacy Benefits Management

- ◆ Recovering Professionals Program
- ◆ Medication Errors
- ◆ Legislative

Fees for Duplicate Licenses, Registrations, and Permits

Anyone who has a lost, stolen, or damaged Board of Pharmacy license, registration, or permit (pharmacists, pharmacy technicians, pharmacies, and interns) is required to submit a request in writing for a duplicate. This request must be accompanied by a check or money order for \$5 for replacement of the lost, stolen, or damaged license, registration, or permit.

Additionally, pharmacists who need a duplicate of their wall certificate signed by all Board members (sheepskin with calligraphy) must submit a request in writing accompanied by a check or money order for \$50 for replacement of this certificate.

Any duplication requests must notate the individual's license, registration, or permit number.

Notification of Address or Employment Changes

The Board requires that all licensees and registrants notify the Board of any changes of address or employment within 10 days of the change. This notification should be sent in writing to the Board office referencing the individual's license or registration number. Those individuals who fail to notify the Board appropriately may not receive important Board information and could be subject to disciplinary action.

Do not forget to submit these changes on time to avoid any problems!

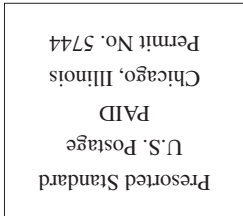
Board of Pharmacy Web Site

The Board is constantly updating its Web site for accuracy and accessibility. Various applications and information can be found online. Additionally, all laws, policies, and regulations of the Board are available for download at no charge. Please take some time for you and your staff to review this Web site, www.llronline.com/POL/pharmacy.

Page 4 – November 2004

The *South Carolina Board of Pharmacy News* is published by the South Carolina 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.

- Lee Ann F. Bundrick, RPh, Administrator - State News Editor
- Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
- Reneeta C. "Rene" Renganathan - Editorial Manager



National Association of Boards of Pharmacy Foundation, Inc
 700 Busse Highway
 Park Ridge, Illinois 60068
 SOUTH CAROLINA DEPARTMENT OF LABOR,
 LICENSING & REGULATION – BOARD OF PHARMACY