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Arkansas State Board of Pharmacy

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Recent Regulation Changes

The Arkansas State Board of Pharmacy, following a Public Hearing during the October 13, 2004 Board Meeting, promulgated new rules related to the minimum number of hours required for the pharmacist-in-charge (PIC) of a retail pharmacy, the hours of operation required for a retail pharmacy, and requirements for reporting certain known or suspected violations by a pharmacy intern. The following regulations have been amended:

Regulation 04-00-0002 – Time Requirements for Pharmacies and for the Pharmacist In Charge.

(a) Unless expressly provided otherwise in Board regulations, all pharmacies in Arkansas shall be open a minimum of forty (40) hours per week and have on duty an Arkansas licensed pharmacist in charge. The pharmacist in charge shall be on duty in the pharmacy:
  (1) a minimum of fifty (50) percent of the pharmacy hours for pharmacies open 64 hours per week or less, or
  (2) at least thirty-two (32) hours per week for pharmacies open more than 64 hours per week.

(b) Upon written application and appearance by the owner of the pharmacy before the Board, the Board may approve a minimum number of hours less than forty (40) per week for the pharmacy to be open to the public when the Board determines that the reduced number of hours would not be detrimental to the public health, safety, and welfare.

(c) In an emergency situation, the Executive Director of the Board of Pharmacy may determine that the health and welfare of the public might be in peril because of a community's limited access to pharmaceutical services if a pharmacy would be forced to close if it was required to remain open forty (40) hours per week. The Executive Director may approve a retail pharmacy operation for less than forty (40) hours per week for a limited period of time but not beyond the date of the next meeting of the State Board of Pharmacy. Thereafter, the owner of the pharmacy may request an exemption as provided for in section (b) above. The Executive Director must take into consideration the ultimate health and welfare of the patients in the area in making the determination.

Although the minimum number of hours required for the PIC has been reduced in all retail pharmacies, the PIC remains responsible for the security and accountability of all drugs, legend and/or controlled, stored in said pharmacy and is responsible for the validity and legality of all prescriptions upon which drugs are dispensed in said drugstore or pharmacy (Regulation 04-02-0005 (e)).

Regulation 02-01-0004 – Requirements for Internship Training.

(1) If the pharmacy intern is suspected to have, or evidence exists that a pharmacy intern may have violated any law or regulation regarding the practice of pharmacy, legend drugs or controlled substances, the preceptor shall notify the Board in writing, within ten days or immediately, if any danger to the public health or safety may exist. Any other pharmacist, whether practicing in the same pharmacy, who has such knowledge or suspicion, shall notify the Board in a like manner.

The language in this amendment reflects an identical requirement, as stated in Regulation 03-00-0002 (i), regarding pharmacy technicians. Suspected behavior regarding excessive alcohol and illicit drug abuse are included in criteria for notification to the Board.

Levothyroxine Sodium Substitution

Food and Drug Administration (FDA) has recently published ratings of various levothyroxine products with Therapeutic Equivalence Codes of AB1, AB2, and AB3. Listed in AB1 are products that have undergone therapeutic equivalence evaluations and are found to be therapeutically equivalent to Unithroid®; listed in AB2 are products that have undergone therapeutic equivalence evaluations and found to be therapeutically equivalent to Synthroid®; and listed in AB3 are products that have undergone therapeutic equivalence evaluations and found to be therapeutically equivalent to Levoxyl®. These product ratings can be found at www.fda.gov/cder/orange/supplement/cspreface.htm. The following reflects allowable substitution of levothyroxine sodium products under Arkansas law:

AB1. Unithroid may be substituted with:
  A. Levothyroxine sodium by Mylan.
  B. Levoxyl by Jones Pharma.

AB2. Synthroid may be substituted with:
  A. Levothyroxine sodium by Mylan.
  B. Levothyroxine sodium by Sandoz, which has been defined as the Alara Pharm product Levo-T® manufactured by Mova.

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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®), venlaxafine (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.

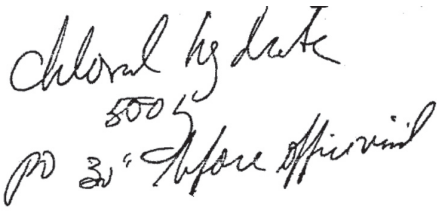
Patients taking these antidepressants should be monitored for behaviors associated with the drugs such as anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia, hypomania, and mania. Physicians are urged to closely monitor patients with bipolar disorder as monotherapy 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 847/391-4406 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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AB3. Levoxyl may be substituted with:

A. Levothyroxine sodium by Sandoz, which has been defined as the Alara Pharm product Levo-T manufactured by Mova.
B. Unithroid by Jones Pharma.
C. Levothyroxine sodium by Mylan.

Novothyrox® (Genpharm), Thyro-Tab® (Lloyd), and Levolet® (Vintage Pharms) are rated BX and may not be substituted for or used for substitution.

Emergency Office Stock Compounding for Veterinarians

The Arkansas State Board of Pharmacy has been asked to clarify aspects of the compounding regulation that relate to veterinary compounding. Regulation 07-00-0002 (m)(4) states, "Compounding for office stock for veterinarians is prohibited, except for compounds to be used in life-threatening situations where lack of immediate availability of the product could result in patient harm and no FDA-approved product is commercially available." The Board has determined that life-threatening situations are those specifically communicated to the pharmacist by the attending veterinarian and are based on the veterinarian's professional judgment. Compounding pharmacists must be able to communicate the specific life-threatening situation to Board inspectors.

Criminal Background Checks

Some license applicants with criminal histories or charges have misrepresented their personal history on the application form. These applicants have been issued provisional licenses, and they now need to provide to the Board all of the material they did not supply upon application if they wish to pursue licensure. They also must appear before the Board to explain why they lied on their applications. To eliminate this problem, the Board will soon begin online review of applicant criminal histories, and we will be able to verify the Arkansas criminal histories of applicants. Provisional licenses will not be issued if the applicant has any criminal history. Licenses will not be issued until the more complete national check is completed.

We have discovered that some pharmacists are attempting to complete fingerprint cards for technicians using inked stamp pads. Please do not do this! Taking fingerprints requires specific training and if the fingerprints are not done correctly, they will be rejected. This may result in a serious delay in processing. If you have any questions about the criminal background check or fingerprinting processes, please contact the Board office.

Nursing Home Consultants

State and federal regulations require all nursing homes to have a consultant pharmacist. In the process of converting our computer system, we discovered that consultant pharmacists have not kept us up-to-date as to when they changed their relationship with nursing homes. Our new computer system will allow us to track these relationships more efficiently. We will be working with the Office of Long Term Care to verify that both the consultant pharmacist and the nursing home have a valid relationship, and comply with regulations.

Computer Conversion

We are in the final stages of installing a new license software package. The new computer system should greatly improve our ability to manage licenses, inspections, and enforcement activities. But, like any other computer conversion, we may experience some problems working through the details. Please bear with us as we bring this system online in December. You should see significant improvements in our ability to respond to your needs in the future. We will advise you of enhancements as they become available to you.

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