March 2005

Kansas State Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Pharmacist License Renewals

License renewal applications will be mailed in May 2005 to every current odd-numbered licensed pharmacist at his or her mailing address of record. The mailing address of record should be the residential address and not a United States Post Office box. K.S.A. 65-1633 requires pharmacists who change their residential address to notify the Kansas State Board of Pharmacy within 30 days by letter, so make sure that you are up-to-date before renewals go out. The Board of Pharmacy office must receive the correctly completed renewal application, with the required fee of $150, no later than June 30, 2005.

Do not send continuing education (CE) certificates to the Board office unless specifically requested to do so. Approximately 10% of pharmacists renewing this year will be audited and they should receive a letter notifying them sometime after July 31, 2005, that they are being audited. The Board will maintain a list of pharmacists on the Board's Web site after July 31, 2005, of those who are being audited for CE. If you see your name on the list but have not received notification from the Board of an audit, you need to contact the Board office and ask for Karen Hollon. You must have a total of 30 hours of CE and will be required to provide proof of such if audited.

As of the writing of this *Newsletter* the Department of Revenue has proposed a legislative change that would require every professional licensing agency to obtain proof from the licensee that he or she has tax clearance from the Kansas Department of Revenue before a license may be issued or renewed. This legislation will mandate that the Board provide the Department of Revenue with your name, address, and social security number. This bill is patterned after similar legislation in Missouri and there is a likelihood that this bill will pass in the 2005 Kansas Legislative Session. What this means is that a licensee or registrant will not be given a license or renewal if he or she is delinquent in his or her Kansas taxes or delinquent in the filing of tax returns. This will not include any person who is under an audit, on a payment plan, under an administrative appeal, subject to a pending court case, or pending bankruptcy. The current language of the bill does propose a grace period whereby the Department of Revenue may waive any penalties if you contact the Department before the law goes into effect and make arrangements to get into compliance. None of this is law at this time. If you are interested in the Department of Revenue's voluntary compliance information, you can review it at www.ksrevenue.org/voluntary.htm.

Failure to Transfer a Prescription When Requested

The Board of Pharmacy recently considered several cases in which pharmacists have refused to transfer a prescription in a timely manner when requested to do so. While it is an understatement to acknowledge that pharmacists are busy people, the Board reminds you that your responsibility to the patient's well-being should be your ultimate concern. A prescription transfer should be accomplished within the same day, ideally within an hour or two of receiving the transfer request. In refusing to transfer a prescription in a timely manner when asked, you potentially put a patient's safety at risk. You also place yourself in jeopardy of being cited for professional misconduct. K.S.A. 65-1656 (a) states, "Nothing contained in the pharmacy act of the state of Kansas shall prohibit a pharmacist licensed in this state from filling or refilling a valid prescription for prescription drugs not listed in [S]chedule II of the uniform controlled substance act, which is on file in a pharmacy licensed in any state and has been transferred from one pharmacy to another by any means, including by way of electronic data processing equipment." The conditions and exceptions are listed in this statute, so you may wish to review these.

Employee Responsibility to Report Diversion

Reports of listed chemical diversion by fellow employees are not only a necessary part of an overall employee security program, but also serve the public interest at large. 21 C.F.R. 1309.73 states that it is Drug Enforcement Administration's (DEA) position that an employee who has knowledge of diversion from his or her employer by a fellow employee

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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.

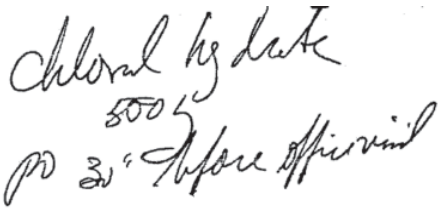
Patients taking these antidepressants should be monitored for behaviors associated with the drugs such as anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia, hypomania, and mania. Physicians are urged to closely monitor patients with bipolar disorder as monotherapy 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 847/698-6227 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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has an obligation to report such information to a responsible security official of the employer. The employer shall treat the information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing the information. A failure to report information of chemical diversion will be considered in determining the feasibility of continuing to allow an employee to work in an area with access to chemicals. The employer shall inform all employees concerning this policy. K.S.A. 65-1652 also gives immunity to any person reporting to the Board of Pharmacy in good faith any information that the person may have relating to alleged incidents of malpractice or the qualifications, fitness, or character of a licensee/registrant. This immunity also applies to communications to any committee or agent of the Board such as the Committee on Impaired Pharmacy Practice.

Technician Registration

All technicians must be registered with the Board before they can begin working. Pursuant to K.S.A. 65-1663 it is unlawful to function as a pharmacy technician in this state unless you are registered with the Board. This law went into effect in July 2003 and technicians were to be registered by October 2004. Each pharmacy shall maintain a list of the names of pharmacy technicians employed by the pharmacy and shall post in a conspicuous location the names of the technicians on duty. Pursuant to K.A.R. 68-5-15 the pharmacist-in-charge (PIC) shall ensure that each technician is in compliance with training requirements. The PIC shall permit the technician to perform those tasks that the technician has been trained to do. These functions must be nonjudgmental in nature. Training must be offered and documented within 180 days of the technician's employment in the pharmacy.

Prescription Requirements for ARNPs in Kansas

Advanced registered nurse practitioners (ARNPs) may prescribe drugs in Kansas so long as they have a written protocol authorized by a responsible physician. The protocol shall specify a precise and detailed medical plan of care for each classification of disease or injury in which they are authorized to prescribe. The protocol shall also specify the drugs that the ARNP may prescribe. The protocol must be kept at the ARNP's principal place of practice. All written prescription orders **shall** contain the name, address, and telephone number of the responsible physician; include the name, address, and telephone number of the practice location of the ARNP; be signed by the ARNP with the designation letters "A.R.N.P."; and contain any DEA number issued to the ARNP when a controlled substance is prescribed. Any prescription received from an ARNP licensed out of state must meet these same requirements.

Board Meeting Dates

The next Board meeting will be held on June 7-8, 2005, at the Clubhouse Inn & Suites in Topeka, KS. The subsequent Board meeting dates are September 20-21, 2005, and December 6-7, 2005, in Topeka, KS. The meetings are open to the public and pharmacists attending may receive CE credit for their attendance.

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