March 2005

Kentucky Board of Pharmacy

NEWS

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Published to promote voluntary compliance of pharmacy and drug law.

2005 Pharmacist License Renewals

License renewals for 2005 were mailed to all Kentucky Board of Pharmacy-licensed pharmacists the second week of January. Pharmacists continuing to practice after the February 28, 2005 licensure expiration deadline without a renewed license and a signed pocket card are in violation of the statute. Pharmacists should have proof of general pharmacy continuing education (CE) completed and certified by December 31, 2004, at their primary place of practice available for review by the pharmacy and drug inspectors.

Pharmacy Permit Renewals

Pharmacy permits expire on June 30, 2005. Renewal applications will be mailed out in early May to all pharmacies or corporate coordinators in order to allow time for processing. Failure to submit your renewal application by June 15, 2005, may result in unnecessary interruption of deliveries to your pharmacy. All incomplete applications will be returned.

Kentucky Pharmacists Recovery Network

Submitted by Bobby Kron, PharmD Candidate

For the past two months I have had the pleasure of working closely with Brian Fingerson on rotation (an academic assignment under the University of Kentucky College of Pharmacy) with the Kentucky Pharmacists Recovery Network (KYPRN) and the committees for the professions of pharmacy, dentistry, and physical therapy that deal with impairment in their respective professions. I initially chose this rotation during Dr Sheila Botts' Chemical Dependency class after hearing Brian speak to our class. I was very intrigued and felt somewhat ignorant when it came to the subject of chemical dependency or addiction. I thought, what better way to learn about the subject than to immerse myself into the subject by taking the rotation.

Fellow classmates have often asked me, why this rotation and why two months with Brian? My answer is simple. This subject matter is a necessity for us as future health care professionals. Chemical dependency or addiction is very prevalent in today's society, and we as part of the health care system need to fully understand this disease in order to fully participate in the helping process. In a past *Newsletter*, Brian urged the members of our pharmacy profession (and other health professionals as well) to educate themselves about our "best kept secret." Well, now I am urging the College of Pharmacy to seriously consider putting Chemical Dependency into our core curriculum. We as future pharmacists need to have a strong understanding of this disease in today's society.

For more information or if you or anyone you know has a problem or question, contact Brian Fingerson at 502/749-8385 or kyprn@insightbb.com.

Legislative Review

Beginning January 1, 2005, the term of each Board member shall be four (4) years pursuant to KRS 315.150(3). The previous term was a three (3)-year appointment.

Beginning April 11, 2003, 201 KAR 2:270 established regulations for expungement concerning minor violations. Expungement means that the affected records shall be sealed, the proceedings to which they refer shall be deemed not to have occurred, and the affected party may properly represent that no record exists regarding the matter expunged. The following violations are considered minor in nature: failure to timely renew a license or permit, failure to timely obtain required CE, and failure to timely obtain required HIV/AIDS CE. A pharmacist seeking expungement of a record of a disciplinary action resulting from a violation above and who has not been the subject of a subsequent violation of the same nature for a period of three (3) years after the date of completion of disciplinary sanctions imposed for the violation sought to be expunged must submit a written request to the Board. The Board shall consider each request and shall, if the conditions are met, expunge the record relating to the subject disciplinary order.

Also beginning April 11, 2003, 201 KAR 2:280 established regulations for prescription dispensing for formulary compliance. A pharmacist may dispense a therapeutic equivalent drug product under the following conditions: the ordering practitioner has indicated "formulary compliance approval" on the prescription, in one of the following ways: 1. in the practitioner's own handwriting or 2. by checking a "formulary compliance approval box" on a preprinted form. The pharmacist receives a formulary change as a consequence of the patient's third party plan and the product that is designated as "preferred" by the third party formulary is in the same therapeutic class as the prescribed drug. The pharmacist must notify the ordering practitioner in an original writing or by facsimile that he/she engaged in formulary compliance and the name of the therapeutic equivalent drug that was dispensed within twenty-four (24) hours of the formulary compliance substitution.

Medication Errors

Submitted by Ashley McNeil, PharmD Candidate

Depakote® ER 500 mg or DR 500 mg? Glucophage® 500 mg or XR 500 mg? Wellbutrin® 150 mg, SR 150 mg, or XL 150 mg? Several highly prescribed medications have recently become available with the only difference between them being their release mechanisms. Since the name and strength of these medications are the same, yet their dosing intervals are quite different, care must be taken to protect

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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.

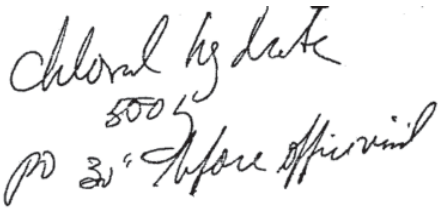
Patients taking these antidepressants should be monitored for behaviors associated with the drugs such as anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia, hypomania, and mania. Physicians are urged to closely monitor patients with bipolar disorder as monotherapy 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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the patients we serve from receiving too much or too little of their needed medication.

The Board of Pharmacy has recently received several complaints pertaining to this problem. For example, a prescription was written for Depakote 500 mg, which should have been filled for the DR 500 mg. The prescription was filled with Depakote ER 500 mg, which has a different dosing interval and could have resulted in inadequate treatment of the condition due to not enough medication being administered. Pharmacists should take precautions in reviewing and filling prescriptions to avoid mistakes that could bring harm to patients.

The National Coordinating Council for Medication Error Reporting and Prevention recognizes these types of medication as being "error-prone" and gives some recommendations for steps to take to avoid these errors.

1. Always check orders for completeness. If there is any question as to which product is designated, call the prescriber to clarify. There can also be education of the prescriber to let him or her know that there are several different releases of the same medication. The patient profile can also be used to determine what the patient has been previously taking.
2. Arrange medications in a way to distinguish the different releases of the same medication. Do not put two drugs that differ only in their release right next to each other on the shelf. Signs could also be posted next to the like drugs to caution pharmacists/pharmacy technicians to double-check that they have the right medication.
3. A series of checks of the medication should also be performed while filling to ensure the right medication is being dispensed. Read the label three times; for example, when obtaining the product from the shelf, when actually filling the prescription, and when returning the product back to the shelf. A second check by an individual other than the person responsible for filling the prescription is also desirable. Other ways to check the product include the National Drug Code, computer systems, and even the patient profile.
4. Counseling patients can also be used to verify that the correct medication was dispensed. Ask the patient what medication he or she was expecting. If he or she only says the name of the drug – for example, Wellbutrin – question him or her to determine which release he or she was expecting, such as SR or XL.

A medication error, whether it actually reaches the patient or is caught while still in the pharmacy, should be evaluated to help prevent future occurrences. An identification of the problem with the system or process of dispensing can bring about a new system or process that alleviates the problem. Medication errors happen, and drugs that differ only in their release mechanism are likely candidates for an error due to great similarities. Formulating a system or plan to prevent errors with these types of medications greatly reduces the chance of their occurrence.

New Pharmacy and Drug Inspector

On December 1, 2004, B. Steve Hart started as a pharmacy and drug inspector for the Board. His territory consists of Jefferson County, Central and Southcentral Kentucky. Steve and his wife, Lisa, and their children reside in Frankfort, KY. Steve is a 1984 graduate of Samford University in Birmingham, AL. Prior to his employment with the Board of Pharmacy, he worked as the pharmacy development manager for Rite Aid.

New Executive Secretary II

On January 1, 2005, Lisa Atha started as Executive Secretary II for the Board. Prior to coming to the Board of Pharmacy she was with the Kentucky Transportation Cabinet as an executive secretary for nine years. Lisa and her husband, Jeff, and their children live in Frankfort, KY.

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