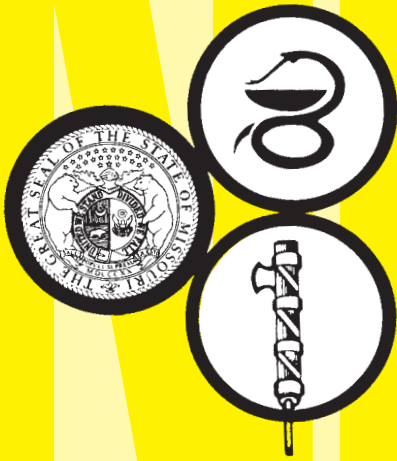


November 2004



Missouri Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

PO Box 625, Jefferson City, MO 65102

Legislation Changes Portions of the Practice Act

The 2004 legislature passed legislation affecting a number of agencies within the Missouri Division of Professional Registration. The Pharmacy Practice Act was amended with several important changes that went into effect on August 28, 2004. First, a number of changes were made to the technician registration law. Anyone now seeking registration as a technician must be, "at a minimum, legal working age" in order to qualify for registration. Changes were also made to enhance the application process as well as further define and refine language concerning the disqualification of applicants and registrants. An important addition to this section provides for the **mandatory reporting** of any registered technician by a hospital or licensed pharmacy of "any final disciplinary action taken against a technician or the voluntary resignation of a pharmacy technician against whom any complaints or reports have been made which might have led to final disciplinary action that can be a cause of action for discipline by the [Missouri Board of Pharmacy]." Pharmacists-in-charge should note this requirement and make sure that any such reports are filed on a timely basis with the Missouri Board of Pharmacy should the above conditions take place. Such reports are now a **requirement** under state law. The expedited hearing authority of the Board was amended to expand the authority to all licensees and registrants within the Practice Act instead of only pharmacists. The expedited hearing process is located in §338.055.4 and is used to take action against licensees who pose a "clear and present danger to the public health and safety." A new section of law grants authority to the Board for limited subpoena power. This will be used in situations where records are sought that are not otherwise available to the Board and are held at unlicensed locations. Subpoenas can be enforced through the Board applying to the circuit court for an order to obey the subpoena. A new section, §338.155, was enacted providing any person with immunity from civil damages as a result of providing information, reports, cooperating with the Board, or assisting the Board in any manner in the course of its investigations, hearings, or other proceedings conducted by or before the Board. In addition, it provides for sovereign immunity in situations where a physician or other authorized prescriber cooperates with the Board by writing a prescription or drug order at the request of the Board pursuant to an inspection or

investigation and treats such an individual as an agent of the state. Any licensee or registrant who fills a prescription that is presented by the Board as part of an inspection or investigation shall not be considered in violation of the law, provided that it is prepared and dispensed in a lawful manner. An amendment was made to pharmacy permit classifications. Class D: Home Health was changed to Class D: Nonsterile Compounding, and a new class was added, Class K: Internet. Those pharmacies with Class D classification on their permit or those pharmacies involved in nonsterile compounding should take steps to have the permit amended properly.

State Generic Formulary Law Requirements

The state generic substitution law has been around for many years. Pharmacists still note at times confusion over the law and how it applies to substitution practices. Pharmacists should take advantage of contacting their inspectors when questions arise concerning substitution requirements. The law requires that any substitution of a brand-name product with a generic counterpart must meet two criteria before the process can occur. First, the prescriber must provide authority to substitute by signing on the appropriate line on the prescription or provide authority through verbal or other documented means (electronic verification). Second, the drug must be considered a generic equivalent to the brand called for on the prescription. State law dictates that the Board use policy decisions made by Food and Drug Administration (FDA) in this matter. FDA has a process whereby a drug is considered first as to its equivalency to a particular brand-name product. If equivalency is established then a separate process is completed to consider the drug's rating of interchangeability. If the drug is rated as interchangeable with a parent or brand name product, then it will be provided an "A" rating and appear in the federal publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, or "Orange Book." If a generic drug is not considered interchangeable, it will be given a "B" rating. Each of these two ratings will appear as the first of two letters next to each manufactured product. The Board office will review the "Orange Book" each month and note any B-rated drugs. These will appear on the Board of Pharmacy Web site as an entry in the negative generic formulary. If the drug has no interchangeable generic counterparts, then it will be listed in the formulary. If the

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

drug has at least one interchangeable generic counterpart but has other generics that are not considered interchangeable, then a list of those companies whose products are interchangeable will appear. When this occurs and a manufacturer of a generic counterpart is not listed, that particular product cannot be used as a substitute on a brand-name prescription. When prescriptions are received that are written by generic name, any FDA-approved drug product can be used to prepare and dispense the prescription.

Licensing Actions

Pharmacists

Jeffery K. Connell, #29369, Goreville, IL – August 9, 2004.

Suspended until May 5, 2005, followed by probation for five (5) years. Pled guilty to one (1) count of making a false material writing and document, and one (1) count of misbranding a food or drug. Section 338.065, RSMo.

Charles M. Miller, #29253, Camden Point, MO – September 4, 2004.

Suspended for one (1) month, until October 3, 2004, followed by probation for five (5) years. Fraudulently billed insurance companies for commercially available product when a compounded product was dispensed, substituted compounded drugs for commercially available products without prescriber authorization, records not accurately reflecting what was dispensed. Section 338.055.2(4), (5), (6), (13), and (16), RSMo Supp 2002.

Aaron R. Roberts, #44313, Manchester, MO – September 14, 2004.

Revoked, cannot reapply for seven (7) years. Found guilty of one count of knowingly and intentionally distributing a mixture of substance containing a detectable amount of alprazolam, a felony. Section 338.065.

Valjean Vanwinkle, #41140, Olathe, KS – July 22, 2004. Probation for five (5) years from July 22, 2004. Pled guilty to one (1) count of conspiracy to possess hydrocodone, a felony. Section 338.065.

Pharmacies

Miller Professional Pharmacy, #5109, Platte City, MO – September 4, 2004. Probation for five (5) years. Fraudulently billed insurance companies for commercially available product when a compounded product was dispensed, substituted compounded

drugs for commercially available products without prescriber authorization, records do not accurately reflect what was dispensed. Section 338.055.(4), (5), (6), (13), and (16), RSMo Supp 2002; Section 338.056.1-5, RSMo 2000; 4 CSR 220-2.400(2); Section 338.100, RSMo; 4 CSR 220.080(2); and 4 CSR 220.2.010(1)(N).

Prescriptions By Mail, #2000171993, Las Vegas, NV – June 17, 2004. Revoked, cannot reapply for seven (7) years from June 17, 2004. Failure to investigate a prescription's validity, misbranding by dispensing a prescription it knew to be invalid, failure to retain prescription record. Section 338.055.2(5) as to misconduct and incompetence, (6), and (15), RSMo.

Drug Distributors

Kirk Welding Supply, Inc, #2003028696, Springfield, MO – June 17, 2004. Restricted license issued on Probation for three (3) years from June 17, 2004. Operated without a current license from June 30, 1998 to November 20, 2003; failure to secure and store nitrous oxide; failure to provide appropriate signage for nitrous oxide noting whether it was empty, full, or quarantined. Section 338.055.1, and 338.055.2(5), (6), (7), (13), and (15), RSMo Supp 2002.

Patterson Dental Supply, Inc, #900962, Springfield, MO – August 5, 2004. Probation for two (2) years from August 5, 2004. Changed its location and continued to operate without timely giving notice to the Board, failure to timely complete and submit change of manager-in-charge, inspection violations. Section 338.353(1), Supp. 2002.

Page 4 – November 2004

The *Missouri Board of Pharmacy News* is published by the Missouri 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.

Bob Holden - Governor

Joseph Driskill - Department Director

Marilyn Taylor Williams - Division Director

Kevin E. Kinkade, RPh - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor
& Executive Editor

Reneeta C. "Rene" Renganathan - Editorial Manager

Presorted Standard
U.S. Postage
PAID
Chicago, Illinois
Permit No. 5744

MISSOURI BOARD OF PHARMACY

700 Busse Highway
Park Ridge, Illinois 60068

National Association of Boards of Pharmacy Foundation, Inc