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News

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

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Upcoming Board of Pharmacy Vacancy

The next South Carolina Department of Labor, Licensing, and Regulation – Board of Pharmacy member term begins July 1, 2012, and ends June 30, 2018. Any pharmacist interested in running as a candidate must:

- Reside in the Sixth Congressional District;
- Be licensed and actively practicing pharmacy in South Carolina; and
- Before December 1, 2011, submit to the Board office a biography and petition bearing signatures of at least 15 pharmacists practicing in the Sixth Congressional District.

After receiving biographies and petitions, the Board administrator will:

- Prepare and mail ballots by January 15, 2012, to all pharmacists who certified on their last renewal application that they reside in the Sixth Congressional District; and
- Certify as true and valid all ballots postmarked before February 15, 2012, and received by the Board office before February 25, 2012.

Before March 1, 2012, 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.

Consultant Pharmacist Duties

According to §40-43-86(C) (1) of the South Carolina Pharmacy Practice Act, the consultant pharmacist must be consistent with the accepted standards of professional conduct and practice and responsible for compliance with all applicable laws and regulations including:

(a) establishing as applicable to the permit, policies, and procedures for the procurement, storage, compounding, dispensing, and distribution of drugs;

(b) establishing and supervising the record keeping system for the purchase, sale, possession, storage, safekeeping, and return of drugs;

(c) facilitating drug recalls and the removal of outdated and adulterated drugs;

(d) supervising all employees of the permit holder whose duties relate to the procurement, compounding, sale, distribution, and storage of drugs;

(e) acting as a drug information resource for the staff by bringing new and current drug information to their attention and being available by phone for questions; and

(f) performing written monthly inspections that are readily available.

The Board recommends that the consultant pharmacist review these responsibilities with the permit holder. If the consultant pharmacist delegates these duties to a technician or another pharmacist, the consultant pharmacist is ultimately responsible for ensuring that the monthly inspection reports are done and that they accurately reflect the inspection of the facility. The consultant pharmacist should check invoices to determine that the entity supplying the legend drugs has a permit with the South Carolina Board of Pharmacy. The consultant pharmacist must sign applications and agree in writing to assume the responsibilities outlined above; therefore, the consultant should be aware that if these responsibilities are not followed he or she may face disciplinary action from the Board.

Transferring On-Hold Prescriptions

At its September 2011 meeting, the Board of Pharmacy voted to allow **non-controlled** prescriptions on hold to be transferred if the prescription is assigned a prescription number at the time it is accepted at the pharmacy. This will allow the prescription to be tracked back to the original pharmacy.

Electronic Emergency Boxes

At its September 2011 meeting, the Board of Pharmacy voted to allow electronic emergency boxes (kits) to be used for **non-controlled** legend drugs in the long-term health care setting.

2011-2012 Influenza Vaccines Approved by FDA

Food and Drug Administration (FDA) announced that it has approved the 2011-2012 influenza vaccine formulation for all six manufacturers licensed to produce and distribute influenza vaccine for the United States. The vaccine formulation protects against the three virus strains that surveillance indicates will be most common during the upcoming season and includes the same virus strains used for the 2010-2011 influenza season. The Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) recommends that everyone six months of age and older receive an annual influenza vaccination. Details about the new vaccines are available in an FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm263319.htm,* and information about the ACIP recommendations are available on the CDC Web site at *www.cdc.gov/media/pressrel/2010/r100224.htm.*

Another TEAspoon – mL Mix-Up

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes 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, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

A few weeks ago ISMP heard from a mother whose child was accidentally given an overdose of an antibiotic. A pharmacist accidentally provided instructions on the prescription label for her child to receive 3.5 **TEA**spoonfuls of a liquid antibiotic for 10 days instead of 3.5 **mL.** The medication was dispensed in a 60 mL bottle. The child was given 3.5 **TEA**spoonfuls each day for three days. By the fourth day only one **TEA**spoonful (5 mL) was left in the bottle, so the mother called the pharmacy and learned that the dosage amount on the label was incorrect. The child experienced bouts of diarrhea and a yeast and fungal infection in the vaginal area.

Mix-ups between teaspoons and mL are common and have been happening for many years. ISMP first mentioned the problem in its June 28, 2000 newsletter article, "Oral liquid medications may be more vulnerable to errors than previously recognized" *(www.ismp.org/Newsletters/acutecare/articles/20000628_2.asp).* ISMP has received more than 50 similar errors in recent years, most resulting in patient harm. It is time to standardize to a single way of measuring liquid medications, using the metric system with volumes expressed in mL. If we all used the metric measurement when prescribing, dispensing, and administering medications, these types of mix-ups would no longer happen.

In response to ongoing errors, in June 2009, ISMP called for elimination of **TEA**spoonful and other non-metric measurements to prevent errors *(www.ismp.org/pressroom/PR20090603.pdf).* In May 2011, FDA published a guidance suggesting ways for manufacturers to improve the labeling of over-the-counter (OTC) liquid drug products to minimize the risk of accidental overdoses *(www.fda.gov/Drugs/DrugSafety/MedicationErrors/ucm253715.htm).* Unfortunately, the guidance still mentions both **TEA**spoon and **TABLE**spoon. The Consumer Healthcare Products Association has also published guidelines *(www.chpa-info.org/scienceregulatory/Voluntary_Codes.aspx#volumetricmeasure)* to improve the format for volume measures within the dosing directions for OTC products. The abbreviation "mL" is recommended for use on accompanying dosing devices that measure OTC oral liquid drug products so they match the dosing directions in labeling for children. The group has also told companies to avoid directions that mention tablespoon, cubic centimeters (cc), dram, fluid ounce (Fl Oz), and dropper(ful), and to use mL as the sole unit of measure in the dosing directions or, alternatively, mL **and** the **"TEA**spoonful" equivalent (eg, 5 mL (1 **TEA**spoon)).

While these are excellent moves to improve safety, ISMP would like to see the complete elimination of **TEA**spoonful amounts and the abbreviation "tsp." Doses expressed using mL alone would be the best way to eliminate the risk of mix-ups. The ISMP board fully supports this initiative and is currently in the process of approving a formal ISMP position on this issue. ISMP hopes the health care industry will also support this initiative.

'Know Your Dose' Campaign Aims to Prevent Acetaminophen Overdose

The Acetaminophen Awareness Coalition, has launched *www.KnowYourDose.org,* a Web site aimed to educate consumers about the dangers of acetaminophen overdose and how to ensure that the correct, safe dosage is administered. "Know Your Dose" stresses to patients the importance of checking the labels of both prescription and over-the-counter medications for the amount of acetaminophen contained in order to ensure that they do not exceed recommended maximum dosage levels. Health care providers may order a free Know Your Dose kit that includes materials to help educate patients about safely using medications containing acetaminophen. The kit includes posters, information cards for patients, and a display holder for use in distributing the cards. Members of the Acetaminophen Awareness Coalition include Alliance for Aging Research, American Academy of Nurse Practitioners, American Academy of Physician Assistants, American Pain Foundation, American Pharmacists Association, CHPA Educational Foundation, National Association of Boards of Pharmacy® (NABP®), National Association of Chain Drug Stores, National Community Pharmacists Association, National Consumers League, and the National Council on Patient Information and Education. The campaign was developed under advisement from the American Academy of Pediatrics, CDC, and FDA.

Methylene Blue and Linezolid May Interact With Certain Psychiatric Medications

FDA has issued two safety communications regarding adverse drug reactions in patients taking certain psychiatric medications, and also given methylene blue or linezolid (Zyvox®). Specifically, FDA has received reports of serious central nervous system reactions in patients taking serotonergic psychiatric medications who are also given methylene blue, a product commonly used in diagnostic procedures. FDA explains that "[a]lthough the exact mechanism of this drug interaction is unknown, methylene blue inhibits the action of monoamine oxidase A – an enzyme responsible for breaking down serotonin in the brain. It is believed that when methylene blue is given to patients taking seroto-

nergic psychiatric medications, high levels of serotonin can build up in the brain, causing toxicity. This is referred to as Serotonin Syndrome. Signs and symptoms of Serotonin Syndrome include mental changes (confusion, hyperactivity, memory problems), muscle twitching, excessive sweating, shivering or shaking, diarrhea, trouble with coordination, and/or fever." FDA has published a list of the serotonergic psychiatric medications that can interact with methylene blue, available at *www.fda.gov/Drugs/DrugSafety/ucm263190.htm#table,* and advises that "Methylene blue should generally not be given to patients taking serotonergic drugs." Exceptions and more information for health care providers and patients are available in an FDA Drug Safety Communication available at *www.fda.gov/Drugs/DrugSafety/ucm263190.htm.*

Similar reports of interactions between certain serotonergic psychiatric medications and the antibacterial drug, linezolid (Zyvox) have also been reported to FDA. FDA has published a list of the serotonergic psychiatric medications that can interact with linezolid, available at *www.fda.gov/Drugs/DrugSafety/ucm265305.htm#table,* and advises that "Linezolid should generally not be given to patients taking serotonergic drugs." Exceptions and more information about the linezolid interaction for health care providers and for patients are available in an FDA Drug Safety Communication available at *www.fda.gov/Drugs/DrugSafety/ucm265305.htm.*

NABP Looking For Item Writers to Develop New Questions for NAPLEX, MPJE, FPGEE, and PCOA

NABP is seeking individuals to serve as item writers for the North American Pharmacist Licensure Examination® (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), the Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), and the Pharmacy Curriculum Outcomes Assessment® (PCOA®).

Pharmacists in all areas of practice and faculty from schools and colleges of pharmacy are encouraged to apply. To be considered as an item writer for the NAPLEX and MPJE, pharmacists must have at least two years of pharmacy practice experience.

Item writers will be selected based on the specific needs of the programs. Those who are chosen will be asked to attend a workshop at NABP Headquarters with travel, lodging, and ancillary expenses paid by NABP.

Attendees will receive detailed instructions and training materials describing the item-writing process and content-related requirements for their designated examination. Item writers will then be asked to develop new test items that will be considered for inclusion in NABP licensure and certification and assessment examination programs.

The NAPLEX is an examination consisting of 185 selected-response and constructed-response test questions, the majority of which are asked in a scenario-based format, that covers important information about the knowledge, judgment, and skills an entry-level pharmacist is expected to demonstrate. The three competency areas of the examination are:

- Assess pharmacotherapy to ensure safe and effective therapeutic outcomes
- Assess safe and accurate preparation and dispensing of medications
- Assess, recommend, and provide health care information that promotes public health

The MPJE is a computer-based examination that consists of 90 select-response items. It combines federal and state-specific questions that test the pharmacy jurisprudence knowledge of prospective pharmacists on the following areas:

- Legal aspects of pharmacy practice, including responsibilities with regard to the distribution and dispensing of pharmaceuticals and for the care of patients
- Licensure, registration, certification, and operational requirements
- Regulatory structure and terms of the laws and rules that regulate or affect pharmacists, pharmacies, manufacturers, and distributors

The FPGEE is a comprehensive examination consisting of 250 multiple-choice questions that measures four major pharmacy content areas:

- Basic biomedical sciences
- Pharmaceutical sciences
- Social/behavioral/administrative pharmacy sciences
- Clinical sciences

The PCOA is a 220-question, multiple-choice assessment that is administered to pharmacy students in all four professional years. The assessment follows a blueprint that reflects actual curriculum hours established through a national sample of PharmD programs in the US and is broken down into the following four areas:

- Basic biomedical sciences
- Pharmaceutical sciences
- Social, behavioral, and administrative pharmacy sciences
- Clinical sciences

Interested individuals should mail or fax a letter of interest indicating their current practice/educational setting, specialties/certifications, and years of experience, along with a resume or curriculum vitae via mail to NABP Executive Director/Secretary Carmen A. Catizone at 1600 Feehanville Drive, Mount Prospect, IL 60056; via e-mail at exec-office@nabp.net; or via fax at 847/391-4502.

Please note, applications are accepted on a continuous basis and kept on file for a period of five years. For more information about item writing, contact NABP at custserv@nabp.net.

Clarification Regarding Pradaxa Storage and Handling Requirements

An FDA alert released in March 2011 details important storage and handling guidelines for Pradaxa® (dabigatran etexilate mesylate) capsules, as reported in the third quarter NABP *National Pharmacy Compliance News.* As a point of clarification, the FDA-approved Pradaxa label states that once opened, the product must be used within 30 days. FDA is currently reviewing data that indicate no significant loss of potency up to 60 days after the bottle is opened as long as Pradaxa is stored in the original bottle and the handling requirements are met. An FDA Drug Safety Communication available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm249005.htm* provides more details, and the manufacturer's Pradaxa safety information is available at *www.pradaxa.com* by clicking on the link for "Important Storage & Handling Information" at the top of the page.

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Call-In Prescriptions

By statute, registered pharmacy technicians **cannot** initiate or receive call-in prescriptions. Only **state-certified** pharmacy technicians may initiate or receive call-in prescriptions from a licensed practitioner or his or her agent after the supervising pharmacist carefully considers the individual's abilities and/or qualifications and agrees to allow the state-certified pharmacy technician to perform this duty. If a registered pharmacy technician performs this duty, the pharmacist-in-charge, the supervising pharmacist, and the registered pharmacy technician may be subject to discipline by the Board.

Transferring Non-Controlled Prescriptions

By statute, registered pharmacy technicians **cannot** initiate or receive the transferring of non-controlled prescriptions. Only **state-certified** pharmacy technicians may initiate or receive the transferring of non-controlled prescriptions after the supervising pharmacist carefully considers the individual's abilities and/or qualifications and agrees to allow the state-certified pharmacy technician to perform this duty. If a registered pharmacy technician performs this duty, the pharmacist-in-charge, the supervising pharmacist, and the registered pharmacy technician may be subject to discipline by the Board.

Pharmacists Administering Legend Drugs

By definition, pharmacists may administer legend drugs **when there is a valid prescription.** Administering pharmacists should have completed appropriate training for the legend drug to be administered. The requirements in the South Carolina Pharmacist Administered Influenza Protocol is an excellent source for guidance if you are planning on administering legend drugs.

§40-43-30. Relevant definitions in the South Carolina Pharmacy Practice Act:

(1) "Administer" means the direct application of a drug or device **pursuant to a lawful order of a practitioner** to the body of a patient by injection, inhalation, ingestion, topical application, or any other means.

(39) "Pharmacist" means an individual health care provider **licensed by this State to engage in the practice of pharmacy.** A pharmacist is a learned professional authorized to provide patient care services within the scope of his knowledge and skills.

(44) "Practice of pharmacy" means the interpretation, evaluation, and dispensing of prescription drug orders in the patient's best interest; participation in drug and device selection, **drug administration,** prospective drug reviews, and drug or drug-related research; provision of patient counseling and the provision of those acts or services necessary to provide pharmacy care and drug therapy management; and responsibility for compounding and labeling of drugs and devices, (except labeling by a manufacturer, repackager, or distributor or nonprescription drugs and commercially packaged legend drugs and devices) proper and safe storage of drugs and devices and maintenance of proper records for them; or the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, education, management, and control of pharmacy.

It is recommended that you check with your legal department and/or insurance carrier to make sure that you are completely covered. This information does not address every legal issue, which might arise in the context of administering legend drugs, including but not limited to professional **insurance** coverage.

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 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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