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Arkansas State Board of Pharmacy News

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New Board Members

Stephanie O'Neal

Governor Mike Beebe appointed Stephanie Goodart O'Neal to the Arkansas State Board of Pharmacy on August 30, 2011.

Stephanie graduated from Wynne High School and attended the University of Arkansas, Fayetteville and Arkansas State University, Jonesboro. She graduated from the University of Arkansas for Medical Sciences College of Pharmacy in 1974.

Stephanie was employed as a staff pharmacist from 1974-1997. From 1997 to present she has held the positions of CEO and manager of Wynne Medical Pharmacy.

Professional memberships include the Arkansas Pharmacists Association, American Pharmacists Association, National Community Pharmacists Association, and International Academy of Compounding Pharmacists.

Stephanie is married and has one son, two stepchildren, and two grandchildren. She has served on the Cross County Arts Council and Cross County Chamber of Commerce Board of Directors. She is a member of First United Methodist Church in Wynne, AR, where she is currently a member of the Administrative Council and a member of the Finance Committee. She has also served on the Staff Parish Relations Committee.

Joyce Palla

Joyce Palla was appointed to the Arkansas State Board of Pharmacy by Governor Mike Beebe in September 2011. Joyce is a retired Cost Center manager from Texas Instrument and former owner of Palla-Warner Gifts and Antiques in Arkadelphia, AR.

Joyce is a board member of the Clark County Economic Development Corporation and Tourism Bureau, Arkadelphia Children's Advocacy Center, and a Clark County election commissioner. She also co-chairs the Arkadelphia 2025 Commission, serves as president of the Clark County Extension Homemakers, and is vice president of the Clark County Women Democrats.

Joyce is a member of the Arkadelphia Rotary Club, Arkadelphia Primrose Garden Club, Governor's Mansion Association, and the Clark County Master Gardeners.

Immunization Requirements

The Board would like to review language that was included in Act 147 of 2011 entitled, "AN ACT TO CLARIFY THE AUTHORITY OF PHARMACISTS TO PROVIDE VACCINES AND IMMUNIZATIONS AND TO ADMINISTER CERTAIN MEDICATIONS; AND FOR OTHER PURPOSES." In this act, changes were made to specific language to define the criteria for what type of orders or authority protocols must be in place for individual medications that may be administered by a pharmacist. The current statute reads:

Arkansas Code §17-92-101 (16)

(A) "Practice of pharmacy" means the learned profession of:

(i) (a) Dispensing, selling, distributing, transferring possession of, vending, bartering, or, in accordance with regulations adopted by the Arkansas State Board of Pharmacy, administering drugs, medicines, poisons, or chemicals that under the laws of the United States or the State of Arkansas may be sold or dispensed only on the prescription and order of a practitioner authorized by law to prescribe drugs, medicines, poisons, or chemicals.

(b) Except in accordance with regulations adopted by the Arkansas State Board of Pharmacy as recommended by the Medications Administration Advisory Committee, the administration of medications shall be limited to the following classifications of medications: immunizations, vaccines, allergy medications, vitamins, minerals, antihyperglycemics, and antinausea medications.

(c) Influenza vaccines and influenza immunizations may be administered to a person seven (7) years of age and older under a general written protocol.

(d) Vaccines and immunizations other than influenza vaccines and influenza immunizations may be administered to a person from seven (7) years of age to eighteen (18) years of age under a patient-specific order or prescription and subject to reporting of the administration to the prescribing physician together with any reporting required under § 20-15-1203.

(e) Vaccines and immunizations other than influenza vaccines and influenza immunizations may be administered to a person eighteen (18) years of age or older under a general written protocol.

(f) Medications other than vaccines and immunizations may be administered to a person seven (7) years of age or older under a patient-specific order or prescription and subject to reporting of the administration to the prescribing physician.

(g) A general written protocol under subdivisions (16)(A)(i)(c) and (e) of this section and patient-specific orders or prescriptions under subdivisions (16)(A)(i)(d) and (f) shall be from a physician licensed by the Arkansas State Medical Board and practicing in Arkansas or within fifty (50) miles of the Arkansas border;

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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Compounding

Recently the Board discussed questions and comments that have come up regarding compounding in pharmacies. As a couple of points for clarification, regulations require a pharmacy to have the equipment necessary to perform any compounding or product preparation that is offered by the pharmacy. This would include not only glassware, torsion balances, or scales but would mean that the pharmacy must have appropriate facilities and hoods with current certification if needed. The Board inspectors continue to inspect pharmacies for both sterile and nonsterile compounding activities via targeted inspection forms for these activities. Another important note on compounding is that a pharmacy can only sell compounded medications that it has produced in that specific permitted facility. There is no allowance for a pharmacy to sell a product that has been compounded in another permitted pharmacy.

LTC Service

Another point that the Board discussed in August was service to long-term care (LTC) residents. The Board continues to receive anecdotal calls regarding pharmacies that either are unable or unwilling to provide full service to LTC patients. To be perfectly clear, if you are serving patients in a LTC setting, you must offer 24/7 coverage for those patients. The Board has also heard of multiple instances where the patient is using one pharmacy through his or her freedom of choice but whenever there is a need for emergency medication or an IV preparation, the pharmacies are unable to offer this service and simply tell the LTC facility or nurse to find another provider for this service. To be clear, whenever a pharmacy is serving a patient in a LTC facility, the servicing pharmacy is responsible for taking care of the patient's needs and should have a contract in place with another pharmacy to ensure coverage for all of these services. This is not an issue where you can just send the prescriptions somewhere, this is a federal government requirement to have a contract in place to ensure these services are provided for the patient's care. In this discussion, the Board pointed out that the pharmacist consultant for the LTC facility has a professional obligation to notify the Board if a pharmacy is not fully providing these services as outlined in Board Regulation 05-00-0003(a)(2).

Pharmacist License and Other Permit Renewals

Renewal reminders have been sent out for pharmacists, in-state retail pharmacies, and out-of-state retail pharmacies. This year the Board of Pharmacy sent reminder cards to show once again how to link to its Web site and renew permits. These reminders were sent to the mailing address on record with the Board office. As with past years, part of the renewal process will be for pharmacists to report their continuing education (CE) for the last two years. As a reminder, the CE requirements for the current biennium include a total of 30 hours of CE credit with 12 of the hours being live hours and 12 hours being Accreditation Council for Pharmacy Education accredited. Specific questions regarding CE should be directed to Board staff. Only CE attained during the 2010-2011 biennium will count toward this requirement. Please remember that Board regulations require pharmacists to retain certificates of participation for proof of CE for a period of four years. To renew your pharmacist or pharmacy permit, visit the Board of Pharmacy Web site at *www.arkansas.gov/asbp* and click on the heading CURRENT RENEWAL INFORMATION for full instructions to renew your permit. These permits expire on December 31, 2011.

The Arkansas State Board of Pharmacy allows a renewal grace period until March 31, on permits; however, there is a $20 penalty on permit renewals if not renewed by February 1, a $40 penalty if not before March 1, and if a permit is not renewed by April 1, then the license/permit is void. This means that in order to get a pharmacist license reactivated, an individual must apply for reinstatement and undergo a criminal background check, which includes fingerprinting and payment of reinstatement fees.

Special Notice About the Arkansas State Board of Pharmacy Newsletter

The Arkansas State Board of Pharmacy has designated this *Newsletter* as an official method to notify pharmacists licensed by the Board about information and legal developments. Please read this *Newsletter* and keep it for future reference because this *Newsletter* will be used in hearings as proof of notification of the *Newsletter's* contents. Please contact the Board office (501/682-0190) if you have questions about any of the articles in this *Newsletter.*

Arkansas Pharmacy Support Group Help Line
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