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Alabama State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Technician Renewals

All registered pharmacy technicians are required to renew their registrations biennially with the fee being due on October 31, 2011, and delinquent after December 31, 2011.

In addition, every pharmacy technician shall, prior to re-registration, complete three hours of continuing education (CE) **annually,** one hour of which shall be "live" presentation.

In order to satisfy the CE requirement for 2010 and 2011, the hours must be approved by the Alabama State Board of Pharmacy (AlBOP) or the Accreditation Council for Pharmacy Education (ACPE) and be designated for technicians.

Technicians Who Fail to Complete CE Requirements for 2010/2011

Any technicians that failed to complete the required three hours of CE (one of which must be "live") during calendar year 2010 will be allowed to double their deficient hour(s) in 2011 before submitting their renewal application. (If you were deficient in "live" hours you must submit "live" hours.) You will not be allowed to renew online but must submit a paper renewal (these were mailed to each registered technician in September) to the attention of Rhonda Coker or Mitzi Ellenburg and must include **all** certificates of CE completed. The doubled hours for 2010 will be in addition to the three-hour requirement for 2011.

ACPE Approval for Continuing Education

Pharmacists and/or pharmacy technicians can go to the ACPE Web site, *www.acpe-accredit.org,* to find all available CE programs.

- **Home Page: Information for Pharmacists**
  1. Select CE Programs
  2. Click on the "Search P.L.A.N.® Now" link located along the top of the page
- **Home Page: Information for Pharmacy Technicians**
  1. Select Education and Training
  2. Click on the "What programs are available to me? Search P.L.A.N.® now!" link (this link is found at the bottom of page)

On the P.L.A.N. search page both pharmacists and technicians should follow instructions and use drop down boxes as needed to customize for their specific needs.

Or

- **Visit *www.albop.com***
  1. Select "Continuing Education"
  2. Scroll down on right until you see the heading "External links for Continuing Education"
  3. Select *www.acpe-accredit.org/pdfwebtool/plan/searchplan.aspx*

CPE Monitor Service

The CPE Monitor™ service is a national online continuing pharmacy education (CPE) tracking service that will authenticate and store data for completed CPE units received by pharmacists and pharmacy technicians from ACPE-accredited providers.

Starting in the latter part of 2011, many ACPE-accredited providers will begin requiring pharmacists and technicians to provide their National Association of Boards of Pharmacy® (NABP®) e-Profile ID, plus their birth date (mmdd), to receive credit for completed CPE. Participation data will be sent electronically from the provider to ACPE, then to NABP for recording into the matching e-Profile. This will eventually eliminate paper forms and the need to submit paper copies of CPE statements of credit for ACPE-accredited activities in Alabama.

Pharmacists and technicians, visit *MyCPEmonitor.net* to obtain your ID by creating your e-Profile. Any errors in an individual's e-Profile may result in unrecorded or mis-recorded CPE, with possible adverse consequences for licensees/registrants when renewing their licenses/registrations.

680-X-2-.08(4). Pharmacist Consultants of Pharmaceutical Services; 680-X-2-.09. Training for Preceptors; 680-X-12-.19(3) Parenteral Therapy

The three above stated Rules of the Alabama State Board of Pharmacy require additional training for pharmacists in each setting type, which **must** have prior approval by the Board of Pharmacy.

Amended Rules Effective October 3, 2011

680-X-2-.24 Precursor Drugs

(1) LISTED PRECURSOR CHEMICALS:

(a) All substances listed as precursor chemicals in any regulation set forth in the Code of Federal Regulations shall be considered and designated as a precursor chemical with the exception of those precursor chemicals designated or deleted as such under federal law to which the Board objects, after notice, in the manner provided in Code of Alabama (1975), § 20-2-181(c), all precursor chemicals listed in any federal regulation shall be considered and designated as precursor chemicals pursuant to the provisions of Code of Alabama (1975), § 20-2-180, et seq.

(2) LICENSE.

(a) Beginning in 2011 and every two years thereafter, any individual, corporation, partnership, association or other entity who is a manufacturer, wholesaler, retailer or other person who sells, transfers, manufactures, purchases for

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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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resale or otherwise furnishes any listed precursor chemicals as defined or designated by any federal or state law or rule must obtain a license. The license shall be issued only after the filing of an application with the Alabama State Board of Pharmacy and Board approval. The application shall contain information as required by and in conformity with any applicable federal or state law or rule.

(b) A biennial license fee in the amount of $500.00 shall be paid by all licensees to the Alabama State Board of Pharmacy by December 31 of any even numbered year. If not received by December 31, but is received in the Board's office no later than January 31 of the following year, a non-disciplinary administrative penalty of fifty percent (50%) of the prevailing renewal fee must be paid by January 31 of the following year in order to renew. This penalty shall be in addition to the prevailing renewal fee.

(3) PERMIT.

(a) A permit must be obtained from the Alabama State Board of Pharmacy each time any individual, corporation, partnership, association or other entity having a legitimate need for using any listed precursor chemical as defined or designated by law or rule of the Alabama State Board of Pharmacy obtains such chemical(s). The permit shall be issued only after the filing of an application with the Alabama State Board of Pharmacy and the Board's approval of that application. The application shall contain information as required by and conform with the requirements of all applicable laws or rules of the Alabama State Board of Pharmacy.

(b) A permit fee in the amount of $35.00 shall be paid to the Alabama State Board of Pharmacy each time any individual, corporation, partnership, association or other entity obtains any listed precursor chemical.

680-X-2-.40 Non-Disciplinary Penalty for Late Renewal of License, Permit, Registration, Certification, or Any Similar Document Issued

(1) In the event an application for renewal of any type of license, permit, registration, certification or any other similar document issued and required by the Alabama Pharmacy Practice Act, the Alabama Uniform Controlled Substances Act or any applicable Rule and the appropriate renewal fee is not received in the Board's office by December 31 of the applicable year, but is received in the Board's office no later than January 31 of the following year, a non-disciplinary administrative penalty of fifty percent (50%) of the prevailing renewal fee must be paid by January 31 of the following year in order to renew. This penalty shall be in addition to the prevailing renewal fee.

(2) This Rule is adopted pursuant to the Board's authority set forth in Code of Alabama (1975), § 34-23-33(b) and is in lieu of formal disciplinary proceedings.

Board of Pharmacy Law Seminar

The Alabama State Board of Pharmacy **will not** offer a law seminar in 2011.

Electronic Prescribing of Controlled Substances

Systems for electronic prescribing of controlled substances used at Supervalu pharmacies (in Virginia and California only at this time) are available for use after successfully meeting Drug Enforcement Administration certification requirements. Supervalu pharmacies in those states are the first to accept e-prescriptions for controlled substances, and Supervalu pharmacies in other states will soon begin to offer this service. To view the Supervalu press release visit *www.supervaluinvestors.com/phoenix.zhtml?c=93272&p=irol-newsArticle&ID=1604987&highlight.*

Reminder

Please notify the Board, in writing, of any change of address or employment.

Welcome

The members and employees of the Alabama State Board of Pharmacy wish to welcome **Todd Brooks,** its new drug inspector. Todd began his employment on June 16, 2011, and currently lives in Montgomery, AL. He will be relocating to south Alabama and be the inspector for that area.

Do You Know a Pharmacist or Technician Who Needs Help?

Call the Committee on Rehabilitating Impaired Pharmacists helpline at 205/981-2273. All calls are confidential.

The *Alabama State Board of Pharmacy News* is published by the Alabama State 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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