Board Office and Meeting Rooms Relocation Completed

After a slight delay, the Tennessee Board of Pharmacy office has officially relocated to 665 Mainstream Drive, Nashville, TN 37243. Please note this change of address for all future mailings and visits. Board meetings will be held at 665 Mainstream Drive and the meeting room names of Iris and Poplar have been retained from the former meeting rooms, not to be confused with the rooms at the French Landing address. Dates will be added as available on the Board Web site and in future Board Newsletters.

Pharmacist Disciplined for Pseudoephedrine Sale Without Determination of Medical Purpose

Recently, a Tennessee pharmacist was disciplined for lack of counseling, as stated in Statute 39-17-431(d), as follows in part:

“ . . (d) The pharmacist or pharmacy intern shall counsel with the person seeking to purchase the product as to the reasons for needing the product and may decline the sale if the pharmacist or pharmacy intern believes the sale is not for a legitimate medical purpose. . .”

For a review of Tennessee Public Chapter 292 in its entirety, visit the following Web link: www.tn.gov/sos/acts/107/pub/pc0292.pdf.

Guidance Given to Pharmacists Regarding Public Chapter 396 as it Pertains to Nurse Practitioner and Physician Assistant Prescription Writing

At the Board meeting held on November 14, 2013, the following policy was approved. Board Rules 1140-03-.03 and 1140-03-.04 state the requirements for valid prescriptions. In order to be deemed valid, a prescription need only satisfy the rules of the Board. Board rules do not require pharmacists to verify that a prescription issued by a nurse practitioner or physician assistant complies with the requirements imposed by 2013 Public Chapter 396 (SB 529, 2013). Enforcement of Public Chapter 396 is the responsibility of the Tennessee Board of Medical Examiners and the Tennessee Board of Nursing. Under current Board rules and applicable statutes, a pharmacy is not required to obtain, maintain, verify, or view copies of formularies issued by supervising physicians to mid-level prescribing practitioners who work for them.

To view the public chapter amendment, you may wish to visit the following Web link: http://state.tn.us/sos/acts/108/pub/pc0396.pdf.

Office of Civil Rights Agents May Visit Pharmacies

Since it has been reported that the Office of Civil Rights has been funded by the Patient Protection and Affordable Care Act to perform Health Insurance Portability and Accountability Act compliance checks (as opposed to just complaints), it is advised to check for credentials. A proper name badge with photo identification should be presented by the agent or inspector.

Board Gives Direction for Automated Dispensing System Pharmacy Waiver

As pharmacists-in-charge (PICs) request waivers for a pharmacy license to house automated dispensing systems, pharmacists many times are already currently acting as PIC from a previous waiver.

For clarity when requesting this waiver, the Board advises PICs to submit any other current location(s) with a working description of the pharmacy practice of each site to the Board. This list should include the address of each site, schedule of PIC’s site visit schedule (eg, weekly, monthly), how often the machine is restocked, the procedures for restocking the machine, any change in PIC, and/or any new pharmacy facility opening.
Enteric-Coated Aspirin Recalled for Potential Acetaminophen Mix-Up

In June 2013, Advance Pharmaceutical Inc initiated a voluntary recall of Rugby Laboratories label enteric-coated aspirin tablets, 81 mg (Lot 13A026; expiration date: January 2015) due to a complaint that a bottle labeled with this product name actually contained acetaminophen 500 mg tablets. This over-the-counter (OTC) product is packaged in bottles of 120 tablets with National Drug Code 0536-3086-41 and Universal Product Code 3 0536-3086-41 9. The affected lot was distributed nationwide by Rugby Laboratories to wholesalers and retailers. The manufacturer warns that inadvertently taking acetaminophen, 500 mg, instead of enteric coated aspirin, 81 mg, according to the directions on the label, can lead to an acetaminophen overdose and potential severe liver damage. The manufacturer indicates that consumers who take the dosage as indicated on the defective product labeling may be ingesting up to 24,000 mg of acetaminophen, which is about six times the maximum recommended daily dose of acetaminophen (4,000 mg).

Consumers who have bottles from the affected lot should stop using the product and return it to the pharmacy or store where it was purchased and should contact a health care provider if they are experiencing any problems that may be related to using the product. Food and Drug Administration (FDA) notes that any adverse reactions related to the use of the product should be reported to FDA’s MedWatch Program. More information about this recall is available on the FDA Web site at www.fda.gov/Safety/Recalls/ucm357909.

Barcoding Technology for Community Pharmacy

This article was prepared for ISMP, the Institute for Safe Medication Practices, which 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-F-AIL-SAFE (324-5733) 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.

Barcoding technology is well-established in industries outside of the health care sector and is now being used within health care to enhance efficiency and safety, and in pharmaceutical wholesale operations to improve supply chain inventory and efficiency. Numerous studies prove the effectiveness and cost benefits of using barcoding technology during the drug dispensing process. About 75% of wrong drug or wrong dose errors are captured and corrected using barcode technology1 and there is sufficient evidence that barcode scanning is becoming the standard of practice in pharmacies. Although barcoding technology is mature with abundant evidence regarding its effectiveness, a 20062 study showed that only half (53.5%) of United States community pharmacies utilize a barcode scanner for verification/identification of medications. The study also revealed significantly lower adoption in independent pharmacies (11.5%) compared to chain pharmacies (62.6%).

According to a survey conducted by ISMP in 2009, the most frequently reported reasons for implementing barcode scanning for product verification included a desire to improve the accuracy and safety of the dispensing process, the ease with which the technology fits with pharmacy workflow, improvement of staff efficiency and inventory control, and a belief that the technology was necessary to stay in business. The most common reasons for not implementing barcode scanning for product verification, other than cost, included uncertainty regarding the “right” vendor product, satisfaction with the current system (without barcode product verification), and perceptions that the technology would reduce staff efficiency.

ISMP has developed a tool, Assessing Barcode Verification System Readiness in Community Pharmacies, to help address the reasons why barcode scanning has not been implemented and to facilitate the adoption of this technology in an estimated 27,327 community pharmacies that do not currently utilize it for product verification.

Given the resource commitment to purchase barcoding systems and the potential for technology to have a profound effect upon the work environment, this tool will help community pharmacy managers and owners better understand the issues related to barcode product verification systems. It will also help managers assess the pharmacy’s readiness for the technology, prepare for the selection of a system, and implement the technology effectively.

Barcode scanning to verify prescription products prior to dispensing improves the safety and quality of pharmacy care provided to patients and increases efficiency during the provision of pharmacy services. Although technology should not be seen as a panacea, it can be a useful tool when used appropriately and combined with other patient safety strategies.3 Does your pharmacy use barcode technology for product verification? If not, please access this free tool, at www.ismp.org/AHRQ/Default.aspx?link=sa.3


ISMP Launches Medication Safety Alert! Newsletter Tailored for LTCFs

ISMP has launched a new ISMP Medication Safety Alert! publication, Long-Term Care Advise-ERR, as a means to provide medication error prevention information tailored to assist staff and providers in long-term care facilities (LTCFs).

With ISMP Medication Safety Alert! publications making a significant impact on preventing medication errors, ISMP is now providing this new resource tailored to LTCFs. ISMP notes that medication errors reported to ISMP Medication Errors Reporting Program include reports from LTCFs. More information and a link to subscribe to this new publication are available in the Newsletters section of the ISMP Web site at www.ismp.org/newsletters/longtermcare.
FDA Warns of Rare Skin Reactions in Patients Taking Acetaminophen

FDA has issued a consumer update that warns of rare but serious skin reactions that may occur in patients taking acetaminophen. These complications include three serious skin reactions: Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), and acute general exanthemeous pustulosis (AGEP). SJS and TEN can both be fatal, and usually require hospitalization. Patients suffering from AGEP commonly recover within a few weeks after they stop taking the medication that caused the reaction.

Symptoms of these conditions include skin rashes, blisters, and widespread damage to the surface of the skin. Patients taking acetaminophen or other compounds that contain acetaminophen should be advised to stop taking the medication if they experience such symptoms and should consult their health care providers or seek an emergency department immediately.

FDA emphasizes that this information should be viewed within the context of millions of patients who, over generations, have used and benefited from acetaminophen and stresses that severe allergic skin reactions are an extremely rare condition. Further, the agency notes that many medications can cause allergic reactions, and skin allergy warnings have already been added to the drug labels of other categories of OTC analgesics including ibuprofen and naproxen.

“This new information is not intended to worry consumers or health care professionals, nor is it meant to encourage them to use other medications,” said Sharon Hertz, MD, deputy director of FDA’s Division of Anesthesia, Analgesia, and Addiction Products. “However, it is extremely important that people recognize and react quickly to the initial symptoms of these rare but serious side effects, which are potentially fatal.” The full consumer update is available on the FDA Web site at www.fda.gov/ForConsumers/Consumer Updates/ucm363010.htm.

Reminder to Purchase Drugs Only from Licensed Wholesalers, Including VAWD-Accredited Wholesale Distributors

To ensure that patients are receiving safe, FDA-approved medications, pharmacists and other health care providers should purchase prescription drugs either directly from the manufacturer or from wholesale drug distributors licensed in the US as advised by FDA. The agency provides a list of state agencies for assistance in verifying licensure at www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm.

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws and NABP’s VAWD criteria. NABP has recently revised the VAWD criteria to allow virtual manufacturers and virtual wholesale distributors—a growing segment of the pharmaceutical wholesale industry—to qualify for VAWD, as well as to implement other changes aimed to help to ensure that the drug supply chain remains secure.

The revised VAWD criteria responds to changing business models and helps safeguard drugs in distribution at a time when there is an increased risk of counterfeit and substandard drugs entering the legitimate US drug supply chain. In particular, the criteria have been revised to provide stronger assurance that drugs diverted from pharmacies and unlawful sources are prevented from entering into the supply chain.

For a listing of VAWD-accredited facilities, please visit www.nabp.net/programs/accreditation/avwd.

Voluntary Recall of Unexpired Sterile Products After Reports of Adverse Events

FDA has announced a voluntary recall of all lots of unexpired sterile products produced by Specialty Compounding, LLC, in Cedar Park, TX. FDA received reports of 15 adverse events at two hospitals (Corpus Christi Medical Center Doctors Regional and Corpus Christi Medical Center Bay Area) potentially related to the use of these sterile products. Affected patients received an intravenous infusion of calcium gluconate supplied by the company.

Patients who were administered the injectable drug products are at risk of life-threatening infections. The recall applies to all unexpired sterile compounded medications dispensed by the company, including all strengths and dosage forms. Recalled products were distributed directly to hospitals and physicians’ offices in Texas, and to patients located nationwide (with the exception of North Carolina). No calcium gluconate was shipped outside the state of Texas. Health care providers and patients should stop using all recalled products and return them to Specialty Compounding.

Veterinarians Not Eligible for NPIs, CMS Clarifies

Centers for Medicare and Medicaid Services (CMS) has become aware of cases in which veterinarians are told, incorrectly, that they must provide a National Provider Identifier (NPI) number for prescriptions they have written to be dispensed. The agency has issued a clarification, stressing that veterinarians do not meet the regulatory definition of “health care provider,” and thus may not obtain NPI numbers. The clarification also states that “Any entity that insists veterinarians obtain an NPI [is] attempting to require veterinarians to obtain NPIs fraudulently.” CMS also notes that “if a veterinarian fulfills the definition of ‘health care provider’ in a profession other than furnishing veterinary services,” such as if they are also a nurse practitioner, “the veterinarian would be eligible for an NPI but would select a Nurse Practitioner code (not a Veterinarian code) from the Healthcare Provider Taxonomy Code Set when applying for an NPI.”

Pharmacists & Technicians: Don’t Miss Out on Valuable CPE Credit.

Continuing pharmacy education (CPE) providers who are accredited by the Accreditation Council for Pharmacy Education (ACPE) have integrated CPE Monitor® into their systems and are requiring pharmacists and pharmacy technicians to provide a National Association of Boards of Pharmacy® (NABP®) e-Profile ID number and date of birth (MMDD) in order to process ACPE-accredited CPE credit. Visit www.MyCPEmonitor.net to set up your NABP e-Profile and register for CPE Monitor and avoid possible delays in your CPE reporting.

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.
Pharmacy ‘Technician Student’ Not Included in Ratio

At the November 14, 2013 meeting, the Board clarified that a student enrolled in a formal pharmacy technician training program, while performing experiential rotations as a part of the academic curriculum, is permitted to work and will not count in the pharmacist-to-pharmacy technician ratio. Also, as stated in Board Rule 1140-02-.02(2)(b), be advised that “...The student shall wear a school-issued identification badge. ...” Pharmacists are advised to retain documentation from the pharmacy technician school that indicates each student’s rotation schedule for any on-site inspection by the Board investigator.

Board Welcomes New Investigators

As of October 1, 2013, three new investigators were hired in response to a continuing increase in registrants and the desire to more closely regulate sterile compounding pharmacies.

As a native Tennessean and graduate of the Drake University PharmD program located in Des Moines, IA, Dr Andrea (pronounced ahn’-drē-ah) Miller has joined the investigator team. Miller brings over 13 years of retail pharmacy experience working as an intern for Wal-Mart Pharmacy and then as a licensed pharmacist for Walgreens Pharmacy, working seven of those years as a pharmacy manager. She compounded nonsterile medications, practiced medication therapy management, and is a certified immunizer. Miller was an affiliate faculty member of Lipscomb University College of Pharmacy and has mentored pharmacy students for the last two years. She has been a member of the American Pharmacists Association (APhA) for about 14 years and is also a member of the Tennessee Pharmacists Association (TPA). Miller assumes the responsibility of inspecting the following counties near the middle of the state, including Robertson, Sumner, Trousdale, Macon, Clay, Wilson, Smith, Jackson, Overton, Putnam, White, Dekalb, Cannon, Rutherford, Williamson, Marshall, Bedford, Moore, and Lincoln counties.

Also given the nod after serving from 2006 to 2012 on the Board and as president of the Board in 2011, Dr Albert “Larry” Hill apparently just did not get enough excitement! With his recent Board experience and as a previous owner of three independent community practice pharmacies (Chase Drugs, Chase Pharmacy, and Wartburg Pharmacy), Hill brings a wealth of business and retail pharmacy experience with him to the field. He graduated from the University of Tennessee College of Pharmacy (UTCOP) program with a bachelor of science in 1985, and acted as preceptor for UTCOP, South College School of Pharmacy, East Tennessee State University Bill Gatton College of Pharmacy, Lipscomb University College of Pharmacy and Health Sciences, and Belmont University College of Pharmacy. Hill holds certifications in diabetes patient care, asthma/rhinitis disease management, and immunization. He is a member of the National Association of Boards of Pharmacy®, TPA, APhA, and the National Community Pharmacists Association. Hill also has experience in hospital pharmacy (Cumberland Medical Center, Crossville, TN) and in long-term care pharmacy practice (nursing home consultant for the Pharmaceutical Services Group in Rockwood, TN). Hill will inspect counties in the upper to middle-eastern areas of Tennessee, including Pickett, Fentress, Morgan, Roane, Loudon, Blount, Knox, Henderson, Scott, Campbell, Claiborne, Union, Grainger, Hamblen, and Hancock counties.

Last but not least, the Board welcomes to the field, Dr Robert “Just call me Bob” Shutt. Graduating from the UTCOP with a bachelor of science in 1974, Shutt worked as a staff pharmacist for Medco Drugs before becoming an independent retail pharmacy owner of Super Drugs Pharmacy in Savannah, TN, in 1980. He served as a former member of the Board from 1999 to 2005, and as president in 2004. Shutt has greatly shortened the learning curve as he has been trained by and is a member of the Professional Compounding Centers of America. He was a member of the Hardin County General Hospital Board of Directors, and has previous experience as a consultant pharmacist in long-term care. Shutt has been a member of APhA and TPA since 1974. He has served as mayor of Savannah since 1999, and was named Hardin County “Man of the Year” in 1997. He was previously appointed to the Hardin County Drug Task Force Team and has served as a member of the Board of Directors for the American Heart Association, Hardin County Public Library, Hardin County Skills, and the Darryl Worley Cancer Treatment Center. Shutt’s previous political experiences as a chairperson for past governor and senate races, along with his board of pharmacy experience, will most certainly increase his understanding of current statutes, rules, and laws. Shutt’s current counties include Lauderdale, Tipton, Haywood, Fayette, Hardeman, Madison, Carroll, Henderson, Chester, McNairy, Hardin, Decatur, Benton, Humphreys, Perry, Wayne, Dickson, Hickman, Lewis, Lawrence, Maury, Giles, and Crockett counties.

Remember that all investigators should present the proper credentials with a photo identification badge when inspections and/or investigations take place.

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Investigator contact information is as follows.

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To contact the Board office directly, please use the following phone number: 615/741-2718.

When recently communicating with Kendall Lynch, DPh, former executive director, he remembered when the Board steered him toward using a more educational approach with registrants when possible. “The charge handed to me by the Board when I was hired,” said Lynch, “was to change the Board’s current attitude and activities and embrace licensee education and assistance as a means to support [the] Board’s primary mission.” Lynch continued, “I simply used various opportunities and methodologies to reach out to our licensees and encouraged them to realize the Board was interested in helping them embrace and implement compliance rather than ignore it. It is much easier to educate and assist than it is to prosecute, especially when the violation does little to impact public health, safety, and welfare,” Lynch added.

Since that time, other executive directors including Drs Kevin Eidson, Terry Grinder, and Andy Holt, have all conveyed similar messages. Current Executive Director Reggie Dilliard continues this philosophy and encourages all registrants to be proactive in asking for guidance from the Board.

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**Tennessee Board of Pharmacy Meeting Dates**

The Board extends an open invitation for all pharmacists as well as the general public to attend its bimonthly meetings in Nashville, TN. The following dates are scheduled for 2013-2014 (Address is 665 Mainstream Drive, Nashville, TN 37243, unless otherwise specified):

- December 11, 2013, Special Meeting
  - 220 French Landing, Tennessee Room, Nashville, TN (sterile compounding/gap analysis discussion)
  - January 22-23, 2014, Poplar Room
  - March 11-12, 2014, Iris Room
  - May 28-29, 2014, Poplar Room
  - July 22-23, 2014, Iris Room
  - September 10-11, 2014, Poplar Room
  - November 5-6, 2014, Iris Room

Please check the Board Web site as these dates can be subject to change. Meetings generally begin at 9 AM.

**Tennessee Board of Pharmacy Members**

Dr Charles (Buddy) Stephens – President
Dr Jason S. Kizer – Vice President
Dr William J. Bunch – Board Member
Dr Mike Dickenson – Board Member
Dr Kevin Eidson – Board Member
Dr Nina Smothers – Board Member
Ms Joyce McDaniel – Public Board Member

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