September 2015

Tennessee Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

665 Mainstream Drive • Nashville, TN 37243
http://tn.gov/health/topic/pharmacy-board

Tennessee Board of Pharmacy Meeting Dates – November Meeting Rescheduled

The Tennessee Board of Pharmacy extends an open invitation for all pharmacists, as well as the general public, to attend its public meetings in Nashville, TN. The following dates are scheduled for 2015 (665 Mainstream Drive, Nashville, TN 37243): September 1-2 and November 16-17. The meetings are currently scheduled to start at 9 AM on the first day, and at 8 AM on the second day, unless otherwise stated. As always, check for schedule changes on the Board website under the "Meeting Schedule" tab.

Board Office Offers Web Links to Help Navigate New Tennessee Department of Health/Board Website

As with all new websites, navigating can be a challenge. Some helpful links are as follows:

- Board website: *http://tn.gov/health/topic/pharmacy-board*
- Board Rules: *www.state.tn.us/sos/rules/1140/1140.htm*
- Statutes (off-site Lexis Nexis): *http://tn.gov/health/article/pharmacy-statutes*
- Disciplinary Actions: *www.tn.gov/health/article/boards-disciplinary-actions#dars*
- Live Stream Board Video (select Board of Pharmacy on left-hand side): *https://web.nowuseeit.tn.gov/Mediasite/Catalog/Full/98fe21d561e9489487745f0c7da678b221*

For additional assistance, please contact the Board office at 615/253-1299.

Disciplinary Action Report List

For information on the violation, please visit the disciplinary report website (RT = registered pharmacy technician).

April 2015 Report

Nikki Crews, RT, Knoxville, TN – Registration suspended.

Barry Gaines, RT, Memphis, TN – Registration suspended.

Wilishia Lyons, RT, Nashville – Registration suspended.

Christin Massey Ritchey, RT, Chattanooga, TN – Registration suspended.

April Danette McClearen Simmons, DPh, Cedar Grove, TN – License suspended.

Deebony McMurry, RT, Gallatin, TN – Registration suspended.

Sonja Wilson, RT, Chattanooga – Registration suspended.

May 2015 Report

Alexander Daniel Alderman, RT, Franklin, TN – Registration revoked.

Lucinda Adell Bellmore, RT, Cleveland, TN – Registration suspended.

Jonathan Brockway, RT, Brentwood, TN – Registration suspended.

Angelica Carlisle, RT, Millington, TN – Registration revoked.

Joshua Caruthers, RT, Nashville – Registration suspended.

Deal Drugs #337, pharmacy, Nashville – License placed on probation for two years with terms; assessed a total of $4,020 civil penalty.

Emily Anne Essary, RT, Dyersburg, TN – Registration suspended.

Food City Pharmacy #616, Knoxville – License placed on probation for two years with terms.

Food City Pharmacy #694, Knoxville – License placed on probation for two years with terms.

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Counterfeit Botox Found in the United States, FDA Warns

On April 16, 2015, Food and Drug Administration (FDA) alerted health care providers that a counterfeit version of Botox® was found in the United States and may have been sold to doctors' offices and clinics throughout the country. The counterfeit products may be identified by a missing lot number on the vial, missing information on the carton (next to LOT, MFG, and EXP), and a displayed active ingredient as "Botulinum Toxin Type A" instead of "OnabotulinumtoxinA." The counterfeit products were sold by an unlicensed supplier who is not authorized to ship or distribute drug products in the US, according to an FDA Drug Safety Alert. The agency advises health care providers to confirm that the distributor from which they purchase Botox is authorized by Allergan, the drug's manufacturer. No adverse events related to this product have been reported to FDA.

Medical practices that purchase and administer counterfeit, illegal, and unapproved medications from unlicensed or foreign sources are putting patients' health at risk, as patients may not be getting proper treatment, warns FDA. Wholesale drug distributors must be licensed in the states where they conduct business. Suspicious Botox products may be reported to FDA's Office of Criminal Investigations. More information is available on the FDA website at *www.fda.gov/Drugs/DrugSafety/ucm443217.htm*.

One way 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. Wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws, as well as NABP's VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo an on-site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the US drug supply.

Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization 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 provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

ISMP has been reflecting on the strength and resolve of many across the nation who have demonstrated an unparalleled commitment to keeping patients safe. Despite the many safety accomplishments in 2014, ISMP cannot help but mull over persistent medication safety gaffes that continue to be unresolved. ISMP would like to share seven persistent safety gaffes of 2014, in three parts, with NABP *National Pharmacy Compliance News* readers with the hope that they will join ISMP in bringing attention to these crucial issues and the compelling need for their resolution. Part one of the three-part series is below.

1) Patient Counseling: Still Only a Veiled "Offer" in Many States

The effectiveness of patient counseling in a community pharmacy to detect and prevent medication errors, and its link to improved medication adherence and positive clinical outcomes have been well documented in the literature. Yet, studies have placed patient counseling rates at only eight percent to 42%. An increase in the frequency and quality of patient counseling has been linked to state-specific regulations that require patient counseling for new prescriptions coupled with strict enforcement surveillance. States that require an "offer" to counsel have very low patient counseling rates. Patients often fail to recognize an offer to counsel when simply asked, "Do you have any questions?" or told to "Please sign here." They may not even know what to ask. This means that, with few exceptions, pharmacies in states that require only an offer to counsel will likely dispense a powerful opioid such as fentanyl transdermal patches and allow the patient or caregiver to walk out of the pharmacy without even a brief discussion about safe use and disposal. ISMP has long promoted mandatory patient counseling in community pharmacies for prescriptions for targeted high-alert medications.

For a list of high alert community medications, please visit *www.ismp.org/communityRx/tools/ambulatoryhighalert.asp.* ISMP hopes you will use this list to determine which medications require mandatory patient education in order to reduce the risk of errors and minimize harm.

2) Patients Impacted by Dispensing Errors: Callous Response From Pharmacists

When patients report dispensing errors to ISMP, they are usually more upset about the response they received when contacting the pharmacist or pharmacy manager than the actual error itself. All too often, consumers tell ISMP that pharmacy staff have responded in a callous manner when confronted with the possibility of a dispensing error, demonstrating a lack of empathy and concern for the adverse effects the patient might have experienced. While pharmacy staff may want to be more responsive to patients who report errors, they are often following corporate policies that are focused on legal concerns. As patients are continually encouraged to be active participants in their health care, they want and deserve honest disclosure of errors, and knowledge that there is an action plan to reduce the risk of it happening again.

Flurbiprofen-Containing Topical Medication May Be Dangerous to Pets, Cautions FDA

People who use topical medications containing flurbiprofen, a nonsteroidal anti-inflammatory drug (NSAID), should take care to prevent their pets from being exposed to the drug, recommended FDA in an April 2015 Safety Alert. The warning is in response to reports of cats in two separate households that became ill or died after their owners used topical medications containing flurbiprofen to treat

muscle, joint, or other pain. Two cats in one household developed kidney failure and recovered with veterinary care. Two cats in a second household developed symptoms that included reluctance to eat, lethargy, vomiting, melena, anemia, and dilute urine, and subsequently died despite veterinary care. A third cat in the second household also died after the owner stopped using the medication. Necropsies on the three cats found evidence that were consistent with NSAID toxicity. The pet owners had applied the drug to their own neck or feet, and not directly to the pet, and it is not known exactly how the cats became exposed to the medication, the Safety Alert notes.

Health care providers who prescribe or dispense topical pain medications containing flurbiprofen should advise patients with pets to take steps to prevent exposure of the pets to the medication. Additional information is available in the FDA Safety Alert available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm443386.htm*.

New FDA Drug Info Rounds Videos Available

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. The latest Drug Info Rounds videos are as follows.

- In "NDC Directory," pharmacists demonstrate how to use this quick, easy, online resource.
- In "FAERS," pharmacists discuss the FDA Adverse Event Reporting System (FAERS) and review three ways FAERS data is made available to the public.

Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. These videos and previous Drug Info Rounds resources are available on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm*.

Mucinex Cold, Sinus, and Flu Medications Recalled Due to Possible Labeling Error

In April 2015, RB (formerly Reckitt Benckiser) of Parsippany, NJ, issued a voluntary recall of certain lots of liquid Mucinex® due to a potential error involving the over-the-counter medications' drug facts labels. While the front label of the recalled lots correctly lists the name of the product as well as the active ingredients, some bottles may not have the correct corresponding drug facts label on the back. The recall was initiated after a confirmed report from a retailer. The recalled medications include:

- MUCINEX FAST-MAX Night-Time Cold & Flu;
- MUCINEX FAST-MAX Cold & Sinus;
- MUCINEX FAST-MAX Severe Congestion & Cough; and
- MUCINEX FAST-MAX Cold, Flu & Sore Throat.

If mislabeled, consumers who purchase these products may be unaware of the side effects and potential risks associated with active ingredients such as acetaminophen, dextromethorphan, guaifenesin, phenylephrine, and/or diphenhydramine. RB is recalling these products as a precautionary measure to ensure consumers have all relevant facts and warnings; the company asks consumers to dispose of any unused product.

Additional information about the recall, including the lot numbers and expiration dates for the recalled medications and guidelines for safe disposal, is available on the FDA website at *www.fda.gov/Safety/Recalls/ucm444028.htm*.

Pharmacists Are Performing More Patient Care Activities, National Survey Indicates

Pharmacists are performing more patient care activities in a variety of health care settings and are spending less time in traditional dispensing roles, indicates the *2014 National Pharmacist Workforce Survey*. Specifically, the report found that 60% of pharmacists provided medication therapy management, and 53% performed immunizations in 2014, indicates a press release from the American Association of Colleges of Pharmacy (AACP). The survey was created using a random sample of 5,200 individuals selected from a list of 7,000 licensed pharmacists in the US. Response rate to the survey was 48%.

Additional details, including the full results of the survey and an executive summary, are available through the Resources section of the AACP website, *www.aacp.org*.

Potentially Lethal Drug Sold Globally as Diet Supplement, Warns INTERPOL

INTERPOL has issued a global alert for a drug known as 2.4-dinitrophenol (DNP), an illicit and potentially lethal drug sold as a dieting and body building aid. The "Orange Notice" warning about DNP was published in May 2015, following the death of a woman in the United Kingdom and the serious illness of a man in France. In the 1930s, DNP was used to boost metabolism and encourage weight loss, but it was taken out of circulation due to several deaths. Sold as a plain yellow powder, capsules, or cream, DNP is often illegally manufactured and sold via the Internet; unsafe manufacturing of the drug and potential contamination may be magnifying the dangers of taking the drug, notes INTERPOL.

Additional information is available on the INTERPOL website at *www.interpol.int/News-and-media/News/2015/N2015-050*.

HHS Announces New Interactive Training on Safe Opioid Use

The Department of Health and Human Services (HHS) has announced a new, interactive training course that teaches health care providers how to talk to patients about safely using opioids to manage chronic pain. The course, "Pathways to Safer Opioid Use," also teaches implementation strategies for meeting the opioid-related recommendations from the National Action Plan for Adverse Drug Event Prevention. Adverse drug events (ADEs) are the largest contributor to hospital-related complications and account for more than 3.5 million physician office visits each year, according to HHS. The training, which is offered at no cost, includes self-guided interactive videos with decision points to help users learn how to apply health literacy strategies to help patients understand and act on information to prevent opioid-related ADEs; identify individual risk factors, opioid medications, and interactions that place individuals with chronic pain at increased risk for opioid-related ADEs; recognize the importance of a multidisciplinary team-based approach to treating patients with chronic pain; and demonstrate the ability to combine the principles of the Health Literate Care Model and the biopsychosocial model.

Additional information, including a link to the National Action Plan for Adverse Drug Event Prevention, is available on the course website at *http://health.gov/hcq/training.asp#pathways*.

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Jordan Glenn, RT, Winchester, TN – Registration revoked; assessed costs not to exceed $2,000.

Melodie Leigh Goodwin, DPh, Flora, MS – License reprimanded with terms.

Bridget Hensley, RT, Etowah, TN – Registration suspended.

Summer L. Holland, RT, Clarksville, TN – Registration revoked.

Lois Hoppstein, DPh, Maryville, TN – License revoked.

The Medicine Shoppe #739, pharmacy, Memphis – Assessed $1,550 civil penalty.

Jason C. McKewen, DPh, Marion, AR – License voluntarily surrendered.

Terry S. Moore, DPh, Cleveland – License voluntarily surrendered.

Medical Necessities & Services, LLC #3167, manufacturer/wholesaler/distributor, Columbia, TN – Assessed $200 civil penalty.

Oxygen and Sleep Associates, Inc, manufacturer/wholesaler/distributor, Orlando, FL – Assessed $500 civil penalty.

Recovery Care, LLC #3404, manufacturer/wholesaler/distributor, Memphis – Assessed $600 civil penalty.

Freddie Richmond, RT, Memphis – Registration suspended.

Bobbie Wilson, RT, Memphis – Registration suspended.

Cindy Lou Wilson, RT, Bartlett, TN – Registration revoked.

Phillip G. Yardley, RT, Knoxville – Registration revoked; assessed costs not to exceed $10,000.

June 2015

LaShonta Allen, RT, Memphis – Registration suspended.

Heather Clark, RT, Jasper, TN – Registration suspended.

Tiffany Paige Gordon, RT, Kingsport, TN – Registration suspended.

Brian D. Remley, RT, Cookeville, TN – Registration suspended.

Cynthia L. Surratt, RT, Finger, TN – Registration suspended.

Recent Public Chapters Passed That Affect Tennessee Practice of Pharmacy

To view the actual Public Chapter (PC), simply click on the desired PC hyperlinked in blue.

Addiction Treatment Act of 2015 (PC 396): PC 396 amendments prevent certain criminal drug charges from being filed against an individual who is experiencing a drug overdose or is in the company of an individual who is experiencing a drug overdose and seeks, or is the subject of a request for, medical assistance. Any such person is immune to penalties for a violation of a permanent or temporary protective order or restraining order or sanctions for a violation of a condition of pretrial release, condition of probation, or condition of parole based on a drug violation. This immunity does not provide protection against seizure of any evidence or contraband, limit the admissibility of any evidence in connection with the investigation or prosecution of a crime for an individual who does not qualify for the aforementioned exemptions, or limit the authority of a law enforcement officer to detain or take into custody a person in the course of an investigation or to effectuate an arrest for any offense not immune by the aforementioned exemptions. This immunity only applies to the person's first such drug overdose.

This bill further mandates that only doctors of medicine or doctors of osteopathic medicine are permitted to prescribe buprenorphine for opioid dependence, and it may only be prescribed for uses recognized by Food and Drug Administration. Excepted is a person who has a documented opiate addiction, receives treatment from a Drug Enforcement Administration (DEA)-registered addiction treatment practice, and is counted as one of the total allowable number of patients the provider is allowed to treat. Only pregnant women, nursing mothers, or patients with a hypersensitivity or documented adverse reaction to naloxone may be prescribed buprenorphine mono or buprenorphine without naloxone. These provisions do not apply to perioperative surgery or ventilator sedation performed in a licensed facility, or to inpatients and outpatients of a hospital.

The Tennessee Board of Medical Examiners and the Tennessee Board of Osteopathic Examination are required to promulgate rules establishing requirements for licensees to qualify as addiction specialists. This act took effect on July 1, 2015.

During discussion at the July 29-30, 2015 Board of Pharmacy meeting, Executive Director Reggie Dilliard, DPh, stated that pharmacists should be aware of PC 396 regarding buprenorphine, and if there is an issue, contact the prescribing practitioner and discuss and document the conversation so as to support the pharmacists' decision on whether to fill or deny the prescription. Always use sound, professional judgment. Pharmacists should refer to DEA Title 21 Code of Federal Regulations §1306.04 (regarding pharmacists' corresponding responsibility) in making decisions for appropriate dispensing. The Board continues to remind pharmacists to "think about what is best for the patient's care and discuss that with the prescribing practitioner on all issues of concern." Still have questions? Dr Dilliard may be reached at reginald .dilliard@tn.gov or 615/741-2403. You may also contact your area investigator by dialing 615/741-2718.

PC 476: Currently, the top 50 prescribers of controlled substances in the state are annually identified and sent a letter notifying them of their inclusion on this list and

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asked to respond with a justification for their prescribing patterns. This legislation expands on this list and requires the top 10 prescribers from all of the combined counties having populations of fewer than 50,000 to also be on this annual list.

Separate from this provision, the bill also specifies that a provider of home medical equipment or a service that provides its own company-branded insulin pumps and related supplies does not have to have a physical place of business in the state if the provider maintains an employee presence in the state, is accredited by The Joint Commission, and maintains a 24/7 service telephone number.

This act took effect on April 22, 2015.

PC 371: This act defines biological product and interchangeable biological product. It also explains the proper dispensing and reporting that shall take place between prescriber, pharmacist, and patient. It is advised to read this PC in full detail and contact the Board office as questions arise.

PC 261: This act provides for the practice of telehealth. It outlines the following:

Defines a health care provider. Establishes a provider-patient relationship by mutual consent and mutual communication. Specifies that telehealth does not create a new standard of care. Allows a physician to prescribe by means of telemedicine and follow all prescribing applicable statutes, such as checking the Controlled Substance Monitoring Database. Pain management clinics are not permitted to be telehealth providers. There is no separate telehealth license required by the Board of Medical Examiners.

Diabetic Testing Supplies That Are Tax Exempt (PC 274): Effective July 1, 2015, Tennessee Code Annotated 67-6-314(7) is amended as follows regarding supplies that are now tax exempt: "Any syringe used to dispense insulin for human use and diabetic testing supplies for human use, including lancets, test strips for blood glucose monitors, visual read test strips, and urine test strips."

Drug Take-Back Provisions (PC 40): Known as the "Ensuring Patient Access to Pharmacy Drug Disposal Programs Act of 2015," PC 40 permits, Tennessee pharmacists/pharmacies to voluntarily participate in the legal take-back of prescription drugs if the provisions of this statute are strictly followed, as well as DEA regulations, including "collector" registration status. It is advised to review the following links as a guide to that strict adherence.

- PC 40: *www.tn.gov/sos/acts/109/pub/pc0040.pdf*
- Board Policy (Board rules to be promulgated): *www.tn.gov/assets/entities/health/attachments/BOP_disposal_policy_scc_11_7.pdf*
- DEA Regulations: *http://www.deadiversion.usdoj.gov/drug_disposal/index.html*

And, speaking of drug take-back programs …

DEA Releases Plans for 10th Prescription Drug Take-Back Event

According to DEA Acting Administrator Chuck Rosenberg in a recent press release, the next National Prescription Drug Take-Back event is scheduled for September 26 from 10 AM - 2 PM local time. Sites may be located at *https://www.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e1s1* and clicking Login, or by going directly to the DEA website.

Help Is Available for Impaired Pharmacists Through the Tennessee Pharmacists Recovery Network

If you need help or know an associate who does, please contact Baeteena Black, Tennessee Pharmacists Recovery Network program director, by phone at 615/256-3023 or by email at bblack@tnpharm.org.

An information link (including the reporting form) is located at *www.tnpharm.org/member-center/tn-pharmacists-recovery-network.*

Mandatory Practitioner Profiles

The Board reminds licensees that the Mandatory Practitioner Profile Questionnaire for Licensed Health Care Providers must be completed and updated as information changes. To obtain a copy of the Mandatory Practitioner Profile Questionnaire, visit *http://tn.gov/health/article/pharmacy-applications* and click on "Mandatory Practitioner Profile Questionnaire (PH-3585)."

Completed/updated profiles should be submitted by mail to the Tennessee Department of Health, care of the address provided as part of the questionnaire instructions.

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