March 2018

Tennessee Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

665 Mainstream Drive • Nashville, TN 37243
https://www.tn.gov/health/health-program-areas/health-professional-boards/pharmacy-board.html

Board Adopts Nonresidential Buprenorphine Treatment Guidelines as Policy

During the January 30-31, 2018 Tennessee Board of Pharmacy meeting, the Board voted to adopt the Tennessee Nonresidential Buprenorphine Treatment Guidelines as policy and directed Board office staff to place a link to the guidelines on the Board's website once the function to update the website is available.

"The 2018 Tennessee Nonresidential Buprenorphine Treatment Guidelines have been published and are being adopted as policy," said Dr Wesley Geminn, chief pharmacist with the Tennessee Department of Mental Health & Substance Abuse Services (TDMHSAS). "Public Chapter 112 of 2017 directed the commissioner for the Department of Mental Health and Substance Abuse Services, in collaboration with the commissioner for the Department of Health, to consult with expert stakeholders, including pharmacists, to develop these guidelines," he said. Dr Geminn added that common concerns with buprenorphine prescribing such as "benzodiazepine co-prescribing, prescribing of buprenorphine without naloxone, and counseling requirements are discussed while stressing importance of inter-professional collaboration." He further explained that the commissioners will review the guidelines and revise where needed each September beginning next year (2019). Registrants may view the guidelines here or by navigating to the TDMHSAS website.

Board Staff Delivers 'The Take-Home Message'

Board office staff and investigators would like to remind registrants of the following regulations. As always, registrants are encouraged to reach out to their investigators and the Board office staff with questions or concerns.

Professional Judgment/Professional Conduct

All registrants and pharmacy interns should review the following definitions/regulations before making work and personal life decisions. Whether at work, on vacation, posting to social media, or shopping at the local grocery store, registrants are representing "Tennessee Pharmacy," and the Board takes this code of conduct very seriously.

Among other regulations, the following requirements relate directly to pharmacy staff conduct and professional judgment:

- Tennessee Code Annotated (TCA) 63-10-204(47): **"'Unprofessional conduct' means the conduct of a pharmacist, pharmacy intern or pharmacy technician that is detrimental to patients or to the profession of pharmacy."**
- Board Rule 1140-01-.02 Violations Constitute Unprofessional Conduct: "(1) **Any person who violates any rule of the board may be deemed guilty of dishonorable, immoral, unethical or unprofessional conduct** within the meaning of *T.C.A. § 63-10-305(6).*"
- Board Rule 1140-02-.01 Pharmacists and Pharmacy Interns:

  (1) A pharmacist shall hold the health and safety of patients to be the first consideration and shall render to each patient the full measure of the pharmacist's ability as an essential health practitioner . . .

  (3) A pharmacist shall always strive to perfect and enlarge the pharmacist's professional knowledge and shall utilize and make available this knowledge as may be required in accordance with **the pharmacist's best professional judgment.**

  (4) A pharmacist shall observe the law, **uphold the dignity and honor of the profession, and accept its ethical principles. A pharmacist shall not engage in any activity that will bring discredit to the profession, and shall expose, without fear or favor, illegal or unethical conduct in the profession . . .**

  (11) A pharmacist shall provide pharmaceutical service:

  (a) Which is as complete as the public may reasonably expect;

  (b) Without discriminating in any manner between patients or groups of patients; and

  (c) Without compromising the kind or extent of services or facilities made available.

Pharmacy/Other Facility Closings or Transfers

When closing a registered location, do not relinquish the license until all prescription medications and/or devices are

continued on page 4

National Pharmacy Compliance News

March 2018

NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

FDA Draft Guidance Addresses Delayed Enforcement of DSCSA Requirements for Product Identifiers

Food and Drug Administration (FDA) issued a draft guidance for industry that informs manufacturers and other supply chain stakeholders that although manufacturers are to begin including a product identifier on prescription drug packages and cases on November 27, 2017, FDA is delaying enforcement of those requirements until November 2018 to provide manufacturers additional time and avoid supply disruptions. The compliance policy outlined in the June 2017 draft guidance, *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy,* applies solely to products without a product identifier that are introduced into commerce by a manufacturer between November 27, 2017, and November 26, 2018. While manufacturers work to meet product identifier requirements, they must comply with other Drug Supply Chain Security Act (DSCSA) requirements. The draft guidance can be accessed from FDA's website at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm565358.htm.*

Amount of Prescribed Opioids Remains High, Reports CDC

The amount of opioids prescribed remains approximately three times as high as in 1999, despite reductions in each year after 2010 through 2015. Centers for Disease Control and Prevention (CDC) researchers analyzed retail prescription data to assess opioid prescribing in the United States from 2006 to 2015 and county-level prescribing patterns in 2010 and 2015. According to a CDC report, results of the study showed higher amounts of opioids were prescribed in counties that had a greater percentage of non-Hispanic white residents, a higher prevalence of diabetes and arthritis, micropolitan status (ie, town/city; nonmetro), and higher unemployment and Medicaid enrollment rates. The researchers conclude that health care providers should carefully weigh the benefits and risks when prescribing opioids outside of end-of-life care, follow evidence-based guidelines (eg, CDC's *Guideline for Prescribing Opioids for Chronic Pain*), and consider non-opioid therapy for chronic pain treatment.

Additionally, the researchers conclude that state and local jurisdictions can use these findings along with prescription drug monitoring program (PDMP) data to identify prescribing patterns that place patients at risk for opioid use disorder and overdose and to target interventions with prescribers based on opioid prescribing guidelines. The July 7, 2017 *Morbidity and Mortality Weekly Report,* "Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015," can be accessed on the CDC website at *www.cdc.gov/mmwr/index.html* in the Weekly Report section.

AMA Opioid Task Force Encourages Co-Prescribing Naloxone to At-Risk Patients

The American Medical Association (AMA) Opioid Task Force encourages physicians to consider co-prescribing naloxone when it is clinically appropriate to do so. The AMA Opioid Task Force offers several questions for determining whether to co-prescribe naloxone to a patient or a patient's family member or close friend, which may be found in the August 2017 document, "AMA Opioid Task Force naloxone recommendations," available on the AMA opioid microsite at *https://www.end-opioid-epidemic.org.*

The Naloxone section of the AMA opioid microsite also offers physicians multiple resources on co-prescribing naloxone in their practice and community. To help end the opioid epidemic, the AMA Opioid Task Force made several recommendations for physicians, including registering and using state PDMPs, training and education on evidence-based treatment, and promoting safe storage and disposal of opioids and medications.

Opioid Addiction Medications Should Not Be Withheld From Patients Taking Benzodiazepines or CNS Depressants

Opioid addiction medications – buprenorphine and methadone – should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), advises FDA. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care providers can reduce these risks, notes a safety alert. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for

minimizing the use of medication-assisted treatment drugs and benzodiazepines together.

Health care providers should take several actions and precautions and should develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. Additional information may be found in an FDA Drug Safety Communication announcement at *www.fda.gov/Drugs/DrugSafety/ucm575307.htm.*

New Study Shows Substantial Variation in the Availability of Pharmacies Across the Country

Despite the rising number of US pharmacies from 2007 to 2015, the availability of pharmacies varied significantly across local areas, indicates a new study. The study, *The availability of pharmacies in the United States: 2007–2015,* found that the number of community pharmacies increased 6.3% from 63,752 to 67,753 between 2007 and 2015. Although the number of pharmacies per capita remained at 2.11 per 10,000 individuals between 2007 and 2015, the researchers found substantial variation across counties. "Some counties have 13 pharmacies per capita, while others have none," said Dima Qato, lead study author and assistant professor of pharmacy systems, outcomes and policy, in a University of Illinois at Chicago (UIC) news release.

In 2015, counties in the highest quintile had nearly three-fold more pharmacies than those in the lowest quintile. Counties in the lowest quintile are located in the Pacific West, Southwest, and Great Lakes regions, while counties with the highest tend to be located in the Northeast, Southeast, Northern Appalachia, and Plains states. The researchers conclude that future programs and policies should address the availability of pharmacies and ensure that pharmacy characteristics, including accommodations such as multilingual staffing and home delivery, align with local population needs.

To view the study, visit *https://doi.org/10.1371/journal.pone.0183172.* The UIC news release is available at *https://today.uic.edu/access-to-pharmacies-limited-to-some-patients.*

Consent Decree Entered Against Outsourcing Facility Isomeric Pharmacy Solutions

Under a consent decree of permanent injunction entered in August 2017, Isomeric Pharmacy Solutions of Salt Lake City, UT, its owners, and chief operating officer are prohibited from manufacturing, processing, packing, holding, or distributing drugs until they comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its regulations, in addition to other requirements. Isomeric manufactured and distributed purportedly sterile drug products, including injectable and ophthalmic drugs, that were adulterated because the drugs were made under insanitary conditions and in violation of current good manufacturing practice requirements under the FD&C Act, according to the complaint for permanent injunction. The complaint also alleges that Isomeric manufactured and distributed unapproved drugs and drugs that were misbranded because their labeling did not bear adequate directions for use. Isomeric initially registered as an outsourcing facility in July 2015 and reregistered in December 2015 and January 2017. Additional information is available in an FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm570130.htm.*

FDA Issues Warning on Alcohol Pads or Benzalkonium Chloride Antiseptic Towelettes Made by Foshan

In September 2017, FDA alerted health care providers and patients to not use alcohol pads or benzalkonium chloride antiseptic towelettes made by Foshan Flying Medical Products Co, Ltd, located in China, due to lack of sterility assurance and other quality issues. These products are distributed by Total Resources International, of Walnut, CA, and Simple Diagnostics, Inc, of Williston Park, NY. The use of these alcohol pads and antiseptic towelettes could cause infections.

FDA placed all drug products made by Foshan on import alert on May 23, 2017, to stop these products from entering the US. However, FDA is concerned these products might still be in distribution in the US. FDA also sent Foshan a warning letter on August 1, 2017, for violations of current good manufacturing practice regulations. FDA initially contacted Foshan regarding a recall on May 25, 2017, and had several follow-up meetings with the company. Foshan has not taken action to remove its alcohol pads or antiseptic towelettes from the market. The safety alert posted to FDA's website may be found at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm574576.htm.*

Pharmacies and health care facilities that have alcohol pads and antiseptic towelettes labeled by Total Resources or Simple Diagnostics should immediately stop using them and discard the products. Adverse events or side effects related to the use of these products may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch/report.*

continued from page 1

removed by proper invoice transfer or destroyed, if applicable, per Board Rule and Drug Enforcement Administration (DEA) Code of Federal Regulations (CFR) if regarding controlled substances (CS). See the Board's closing or transfer guidelines for more specifics here.

Contact Board Investigator Scott Denaburg at scott.denaburg@tn.gov for a sample invoice regarding "proper" invoice transfers, if needed.

Counseling

A patient presenting a new prescription (ie, a prescription with a new prescription number, a reassigned prescription number due to completed refills or an expired prescription) shall be counseled "face to face" by the pharmacist. The patient may decline counseling, but shall decline **to the pharmacist face to face.**

A patient obtaining a refill shall be given the offer **for the pharmacist** to counsel. The "offer" may be given by pharmacy staff such as the pharmacy technician or cashier, but the pharmacist must perform the counseling. The patient may decline counseling to the pharmacy staff to satisfy the requirement. However, signing an electronic, manual, or paper record does **not** satisfy the counseling offer regulation.

Automated Dispensing Systems Located Off Site

As automated dispensing systems (ADS) begin to replace pharmacy licenses at some off-site locations, there has been some concern of proper supervision, transport of drugs, security, and accountability.

Under Board Rule 1140-01-.01 Definitions, the following is stated (emphasis added):

> (4) "Automated Dispensing System" means a mechanical or electronic system **outside the premises** of an institutional or long-term care pharmacy that performs operations or activities, other than compounding or administration, relating to pharmacy services, including the storage, dispensing, or distribution of drugs and the collection, control, and maintenance of all transaction information, to provide security and accountability for such drugs.

Rule 1140-04-.15 and 1140-14-.12(2)(a)(2) respectively in part indicate that prepacked cartridges, unit-dose packages, or containers may be sent to the off-campus site to be loaded into the machine by personnel designated by the pharmacist-in-charge (PIC) provided that a pharmacist performs verification of proper fill and labeling; the medications are transported in secure, tamper-evident containers; the ADS uses barcoding, microchip, or other technologies for accuracy; and the drugs are delivered by the institutional or long-term care pharmacy depending on the applicable rule.

It is notable that the **"other technologies"** part of the rule was presented at the January 31, 2018 Board meeting. Dr Rick Coleman, PIC with AmPharm, Inc, located in Parsons, TN, presented a three-part verification system that includes:

- First verification: Pharmacy technician is prompted to place medication in the correct ADS drawer by light technology and a PIN number that must be used to store the medication and also retrieve the medication for dispensing.
- Second verification: Nurse on site.
- Third verification: Pharmacist uses cell phone technology with the certified pharmacy technician's cell phone to visually verify that the technician is properly placing the medication in the correct location of the drawer. Dr Coleman indicated that this action would allow the pharmacist to remain at the main pharmacy site, but still be able to meet the regulation of pharmacist's supervision of placement. A manifest is signed by all verifiers and kept at the main pharmacy. The Board approved this model for AmPharm, Inc.

Repackaging

Investigators continue to find pharmacy repackaged products without all the required labeling. It is advised to review Board Rule 1140-03-.08. Repackaging label requirements include:

- Name and strength (and quantity, if more than one in the container)
- Manufacturer's name and lot or control number
- Expiration date
- Cautionary labels, if applicable

Note that a batch number may be used if a record is kept to link it back to the manufacturer's name and lot number.

A pharmacist must have the proper facilities and packing material and must verify the "purity, integrity, safety, and effectiveness of the prescription drug." **Also, do not forget that this action may only take place at the pharmacy practice site (not in the trunk of a car in the parking lot, even if the parking lot is a pharmacy parking lot).**

Recording OTC Sales of Codeine Cough Syrup

Investigators continue to find improper record keeping regarding the over-the-counter (OTC) sales of codeine cough syrup. As DEA has warned, agents are beginning to perform more random pharmacy audits. It is advised to review CFR 1306.26. Remember the following:

- Only the pharmacist may dispense no more than 120 mL in a 48-hour period.
- The purchaser must be at least 18 years old.
- Identification is to be shown if the purchaser is unknown to the pharmacist, including proof of age.
- The record book is to be a **"bound book"** and is to contain the **pharmacist's initials (this needs to be done at the time of purchase),** purchaser's name and address, quantity of the drug, and the date of purchase.
  - The regulation stipulates that only a pharmacist may dispense the drug, which excludes the pharmacy technician and intern.
  - The cashier may ring the sale once the pharmacist has completed the dispensing requirements.

Vaccine/Other Drug Storage

Remember to date multidose vials such as vaccines that are kept in the refrigerator. Investigators are finding opened vials that have no beyond-use date.

continued on page 5

continued from page 4

Centers for Disease Control and Prevention guidelines include continuous monitoring if storing vaccines in the refrigerator. Do not forget to monitor temperature and test alarms regularly, especially the systems with a minimum/maximum setting versus a data logging system.

Sterile Compounding

Investigators continue to find that newly hired employees are not performing the **three** different glove finger sampling tests. After the initial testing, only one sampling is required per year, or every six months if compounding high risk. Note that more testing is preferred, and the proposed United States Pharmacopeia Chapter <797> regulations will result in more frequent testing when they go into effect in December 2019.

Board Welcomes New Investigator

During the January 30-31, 2018 Board meeting, members welcomed their most recent investigator hire to the team. Dr Derek Johnston is now covering Shelby County and has already started inspecting the area.

Having graduated from the University of Tennessee College of Pharmacy in 2004, Dr Johnston brings additional nonsterile compounding knowledge to the pharmacy investigator crew, including the areas of fertility, pediatrics, and pain management. He worked as a pharmacist and later became PIC for Walgreens and Rite Aid pharmacies in the Memphis, TN area. Dr Johnston is an American Pharmacists Association certified immunizer and has trained others in medication therapy management and glucose, cholesterol, and blood pressure screening. When not working, Dr Johnston enjoys spending time with his family, which includes his wife, Kristen, and his three children, Ainsley, Calder, and Toran. He admits to being an animal lover, owning three dogs and a cat. Welcome aboard, Dr Johnston.

Tennessee DEA Office Gives Guidance for Reporting Theft or Loss

Per Title 21, CFR, Section 1301.76(b), registrants must notify their local DEA office in writing of the theft or significant loss of CS **within one business day of discovery.** Tennessee registrants may now satisfy this requirement by submitting all relevant information via email to **tntheftorloss@usdoj.gov. Registrants must still complete a DEA Form 106,** available online via the DEA website. If you have questions, please contact DEA Diversion Investigator James N. Stevens at 615/736-7343. You may also satisfy the Board regulation to report by sending a copy to Dr Terry Grinder at terry.grinder@tn.gov.

Board Meeting Schedule

The Board extends an open invitation for all registrants and the general public to attend its public meetings at 665 Mainstream Drive, Nashville, TN 37243. The meetings are currently scheduled to begin at **8 AM.** Pharmacists may receive up to two hours of live continuing education, valid for their Tennessee pharmacist license, on a full meeting day, and one hour on a half-day. As always, **check for schedule changes** on the Board website under the Meeting Schedule tab.

The **2018** meeting schedule is listed as follows:

- March 13-14
- May 1-2
- July 17-18
- September 11-12
- November 27-28

Tennessee Board of Pharmacy Members

Dr Mike Dickenson – President
Dr Debra Wilson – Vice President
Dr Rissa Pryse – Board Member
Dr Katy Wright – Board Member
Dr James "Adam" Rodgers – Board Member
Dr Kevin Eidson – Board Member
Mrs Lisa Tittle – Public Board Member

The *Tennessee Board of Pharmacy News* is published by the Tennessee Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) 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 NABPF or the Board unless expressly so stated.

Mike Dickenson, MBA, DPh - Tennessee Board of Pharmacy President & Newsletter Editor
Reggie Dilliard, DPh - Executive Director & Newsletter Editor
Scott G. Denaburg, BA, PharmD - Contributor, Tennessee Board of Pharmacy Investigator
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Amy Suhajda - Communications Manager