September 2019

Tennessee Board of Pharmacy News

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Executive Director and Lead Investigator Receive Awards at TPA Meeting

Tennessee Board of Pharmacy Executive Director Reginald "Reggie" Dilliard, DPh, and Pharmacist Investigator Terry Grinder, DPh, received awards at the June 2019 Tennessee Pharmacists Association (TPA) summer meeting.

The Barbara McAndrew Award, received by Dr Dilliard, is sponsored by the TPA and generously supported by Germantown, TN Pharmacist Paula Hinson, DPh (also a former Board member). It is presented in recognition of Barbara McAndrew, who served as the first public member of the Board. McAndrew actively promoted the profession of pharmacy and the ideals of pharmacist-provided care to the public, business community, government, and other health care providers. As stated by Dr Dilliard, "[McAndrew] set the standard, not just for consumer members, but for all members as she educated herself on pharmacy issues, served on task forces and many other committees whenever she could." Dr Dilliard said, "It was an honor to serve with her and to receive this award."

Next, the Tennessee Board of Pharmacy Award for Excellence in Public Health and Regulation is an award to recognize those individuals whose efforts to protect the public health and safety greatly furthered the goals and objectives of the Board. Individuals who qualify for this award show exemplary service to the public health through enforcement, regulation, or other public health initiatives.

Last year's recipient, former Director Kendall Lynch (deceased 2016), was the first recipient and as such, the award was named the Kendall Matthew Lynch Award for Excellence in Public Health and Regulation. It was accepted on his behalf by his widow, Carole Lynch.

This year's recipient, Dr Terry Grinder, reminisced about his conversations with his former director, mentor, and friend as he reminded the TPA audience of a well-known Kendall Lynch directive regarding the investigator position. "It is better to help them do it right than catch them doing it wrong."

As the Board's spokesperson, Dr Dilliard presented the award and expressed his appreciation for Dr Grinder's service. "Dr Grinder's dedication and value to the Board of Pharmacy and to the patients of Tennessee certainly make him deserving of this award, and I am extremely happy to be able to present it to him on behalf of the members of the Board of Pharmacy."

Board Office Staff Delivers the Take-Home Message

Board staff reminds registrants of the following regulations.

According to Board Executive Director Reggie Dilliard, the following are frequent violations heard by the Board:

- A nonexistent or not updated technician registry – a written/typed list of pharmacy technicians
- Lack of gabapentin inventory documentation completed on July 1, 2018
- Failure to counsel
- Dirty and disorganized pharmacy
- Inability to locate paperwork
- Expired drugs on the shelf, including return to stock medications
- Collaborative practice agreements not readily retrievable

The Board office has received interpretations from Drug Enforcement Administration (DEA) staff, including the following:

- The Controlled Substance Ordering System (CSOS) order must be closed in CSOS (check with the wholesaler to confirm, if needed). Printing the documentation and signing/dating is recommended, but this action does not close the order in CSOS (Code of Federal Regulations (CFR) 1305.22(g)). Each order not closed with the date of receipt in CSOS

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National Pharmacy Compliance News

September 2019

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 Changes Opioid Labeling to Give Providers Better Information on Tapering

Noting that the agency remains focused on striking the right balance between policies that reduce the rates of opioid addiction while still allowing patients and health care providers access to appropriate pain treatments, Food and Drug Administration (FDA) has announced required changes to the prescribing information for all opioid analgesic medications used in the outpatient setting. The changes, announced in a Drug Safety Communication, provide expanded information to health care providers on how to safely decrease the dose in patients who are physically dependent on opioids. FDA intends for this information to be used when health care providers and patients have decided together that a decrease in dose or discontinuation of opioids is appropriate.

"Rapid discontinuation can result in uncontrolled pain or withdrawal symptoms. In turn, these symptoms can lead patients to seek other sources of opioid pain medicines, which may be confused with drug-seeking for abuse," the agency said in the communication. "Patients may attempt to treat their pain or withdrawal symptoms with illicit opioids, such as heroin, and other substances."

In addition to these changes, an FDA press release also announced that additional policies related to the opioid crisis are forthcoming. These include a requirement for immediate-release formulations of opioids to be made available in fixed-quantity packaging that contain doses more typical of what patients may need for common acute pain conditions and procedures. The full press release is available in the News and Events section of the FDA website.

DEA Warns of Scam Calls Targeting Pharmacists and Other DEA-Registered Providers

Health care providers and other members of the public have reported receiving phone calls from people claiming to represent Drug Enforcement Administration (DEA), and threatening legal action against them if a large fine is not paid immediately over the phone. According to a DEA press release, this scam used fake names and badge numbers, or the names of well-known senior officials with DEA, and threatened victims with arrest, prosecution, imprisonment, and revocation of their DEA numbers. The agency emphasizes that DEA will never contact practitioners by phone to demand money or any form of payment. DEA will not request any personal or sensitive information by phone, and notification of legitimate investigation or legal action is made via official letter or in person.

DEA asks anyone who receives a call from a person purporting to be a DEA special agent or other law enforcement official asking for money to refuse the demand and report the threat using the online form or by calling 877/792-2873. Reporting these calls will assist DEA in investigating and stopping this activity.

FDA Officials Outline 2019 Efforts to Improve Quality of Compounded Drugs

Recognizing the important roles compounded drugs can play in patient care, FDA plans to continue its efforts to improve the quality of compounded drugs. According to a statement posted to the FDA website, these priorities include:

- maintaining quality manufacturing compliance,
- strengthening and refining regulations on compounding from bulk drug substances,
- finalizing the agency's memorandum of understanding with the states, and
- issuing revised draft guidance for compounding by hospital and health systems.

"We've worked to refine our existing practices, shape new policies and increase the frequency of our communications with industry, Congress, states and patients concerning our programs," then-Commissioner Scott Gottlieb, MD, and Deputy Commissioner Anna Abram said in a statement published on the FDA website. "We anticipate that 2019 will be an equally productive year for the FDA's compounding program, with better quality continuing to be our top priority as part of our ongoing effort . . . to improve the quality of compounded products for consumers . . ."

In addition, Gottlieb and Abram's statement notes that the agency will continue to work closely with stakeholders on these steps and any other compounding-related measures not outlined in the statement.

China Agrees to Stricter Fentanyl Production Laws Following Pressure From US Lawmakers

China has announced that all variations of the powerful opioid product, fentanyl, will be treated as controlled substances (CS). According to a press release from Senator Tom Cotton, the announcement came after a bipartisan group of United States lawmakers, including Cotton, introduced Senate Bill 1044, a bill designed to apply pressure to the Chinese government to make all forms of synthetic opioids illegal and to provide US law enforcement with more tools and resources to go after illicit traffickers in China, Mexico, and other countries.

"Combating the flow of illicit fentanyl into our country is imperative in the fight to save American lives from the opioid crisis," Senate Minority Leader Chuck Schumer said in the press release. "We must hold China accountable for their role in the fentanyl trade. China's new regulation to make all fentanyl categories illegal is an important step and the administration deserves praise for their efforts to secure this change. However, we have to demonstrate that we will demand China enforce these laws and take strong action against opioid traffickers."

In a December meeting with President Donald Trump, China's President Xi Jinping promised to classify fentanyl as a CS following a 2018 report by the US-China Economic and Security Review Commission that found China to be "the largest source of illicit fentanyl and fentanyl-like substances" in the US, according to a report from NPR. The latest increase in opioid-related overdose deaths has been largely attributed to the availability of illegally manufactured fentanyl.

Two Lots of Transdermal Fentanyl Patches Recalled Due to Product Mislabeling

Alvogen, Inc, of Pine Brook, NJ, is recalling two lots of Fentanyl Transdermal System 12 mcg/h transdermal patches to the consumer level after a small number of cartons were found to contain 50 mcg/h patches. Though the 50 mcg/h patches are individually labeled correctly, accidental application of the higher dosage patch instead of the prescribed 12 mcg/h patch could result in serious, life-threatening, or fatal respiratory depression. The company has not received any reports of adverse events related to this issue.

The company is notifying its distributors and direct customers by certified letter and is arranging for the return and replacement of all recalled products. Pharmacies are asked to stop dispensing any product subject to the recall. Consumers that have affected products should immediately remove any patch currently in use and contact their health care provider. Patients with unused product should return it to the point of purchase for replacement.

Additional information on the recall, including the affected lot numbers and customer service contact information, is available in a press release posted to the FDA website. Adverse reactions and quality problems can be reported to the FDA MedWatch Safety Information and Adverse Event Reporting Program.

FDA Releases Toolkit to Help Promote Safe Opioid Disposal

FDA has made a new resource available for consumers and health care providers to help promote and educate individuals about how to safely dispose of unused opioids. The free Safe Opioid Disposal – Remove the Risk Outreach Toolkit includes video, radio, and print public service announcements, social media graphics and posts, fact sheets, drop-in content, and website badges that health care providers and other interested individuals and organizations can use to promote the message of opioid safety. The toolkit and its resources can be accessed on the Ensuring Safe Use of Medicine section of the FDA website.

An additional resource available to help consumers find disposal kiosks available year round is the National Association of Boards of Pharmacy® (NABP®) Drug Disposal Locator Tool, available in the AWAR$_X$E® Prescription Drug Safety section of the NABP website, *www.nabp.pharmacy/initiatives/AWARxE.* With more than 6,500 disposal sites in the continually updated database, consumers can enter location information to find the nearest disposal sites to them using a map.

Additional information about the FDA campaign can be found at *https://www.fda.gov/drugs/buying-using-medicine-safely/ensuring-safe-use-medicine.*

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is considered a separate violation (currently noted as more than $15,000 per violation). If the CSOS documentation is printed, it should be filed separately, not attached to the invoice.

- A power of attorney (POA) form is required for each person who is authorized to order Schedule I and II controlled substances (CS). Be advised to have an original POA form readily available on site for inspection if using CSOS or hard copy DEA 222 order forms (CFR 1305.04 and CFR 1305.05).
- The right side of the DEA 222 forms must be filled out completely. Schedule II medication transfers must be performed with the use of a DEA 222 form. No borrowing or loaning is permitted on any drug.
- Biennial CS inventories are required, and frequent inventory audits are encouraged. Specific wording is required for an inventory to be considered acceptable. Actual counts are required for Schedule II CS.
- Biennial inventory counts for Schedule III-V may be estimated if the stock bottle does not contain more than 1,000 tablets or capsules.
- Biennial inventory must be completed as of opening of business or as of close of business and documented as such. This regulation includes 24-hour facilities. It is still recommended to also note the actual time of day in which the inventory began for the 24-hour facility (CFR 1304.04 and CFR 1304.11).

Investigator Note: Board investigators have frequently been working with DEA diversion investigators and a very common message, as indicated in a bullet point above, is as follows: "frequent inventory audits are encouraged." These reconciliation audits do not stop at counting medications. The example guide at the bottom of this page may be helpful for a reconciliation audit.

Perpetual inventories are helpful, but investigators have found that this type of audit is not foolproof and has given many pharmacists a false sense of inventory control. For additional assistance in understanding the reconciliation audit, contact any Board investigator or the Board office.

Legislative Update 2019: Board of Pharmacy

Public Chapter 87

This act redefines hemp in §43-27-101 to mirror the federal Hemp Farming Act of 2018. The act excludes hemp and any nonnarcotic substance approved by Food and Drug Administration that can lawfully be sold over-the-counter without a prescription from a schedule. A license from the Tennessee Department of Agriculture is required in order to produce hemp. The commissioner of agriculture shall promulgate rules within 120 days of this bill becoming law. This act took effect April 4, 2019.

Public Chapter 229

This act allows health care professionals to accept goods or services as payment in direct exchange of barter for health care services. Bartering is only permissible if the patient to whom services are provided is not covered by health insurance. All barters accepted by a health care professional must be submitted to the Internal Revenue Service annually. This act does not apply to health care services provided at a pain management clinic. This act took effect April 30, 2019.

Public Chapter 264

This act permits the attorney general, reporter, and personnel to access confidential data from the Controlled Substance Monitoring Database upon request for the purposes of investigation or litigation of a civil action. Release of this information to other parties must be accompanied by an appropriate protective order. This bill was brought by the Office of the Attorney General. This act took effect April 30, 2019.

Public Chapter 319

This act expands the practice of dental hygiene to include prescriptive authority limited to fluoride agents, topical oral anesthetic agents, and nonsystemic oral antimicrobials

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Drug	Beginning Inventory Count	(+) Ordered (invoices)	(=) Total	(-) Dispensed	(-) Reverse Distributor and any recorded theft or destruction	(=) What should be on hand	(-) Ending Inventory	Difference +/-
Example Hydrocodone/ APAP 10-325 Tablet	**1,248 Tablets**	**500 Tablets**	**1,748 Tablets**	**-660 Tablets from dispense report**	**-30 Tablets from reverse invoice and -70 from diversion DEA 106 form**	**988 Tablets**	**Physical count today "hopefully" 988 Tablets**	**0 Tablets**

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provided that the product is not a CS under state and federal laws and does not require a license by DEA. A dental hygienist's prescriptive authority must be exercised under the general supervision of a licensed dentist, pursuant to board rules, and in compliance with all applicable laws concerning prescription packaging, labeling, and record-keeping requirements. A prescription written by a dental hygienist must be reviewed by a dentist within 30 days. The Tennessee Board of Dentistry shall promulgate rules to implement this act. This act took effect May 8, 2019, for the purpose of promulgating rules. For all other purposes, this act will take effect on July 1, 2020.

Public Chapter 327

This act requires the commissioner of health, by January 1, 2020, to study instances when co-prescribing naloxone with an opioid is beneficial and publish the results to each prescribing board and to the Board of Pharmacy. The findings shall be included in the chronic pain guidelines adopted by the Chronic Pain Guidelines Committee. This act took effect May 8, 2019.

Click here for other legislative updates.

Board Welcomes Newest Member of the Investigator Team

When the opportunity presented for Board Executive Director Reggie Dilliard to hire additional investigators, he immediately looked to past sterile compounding experience as an important requirement and hoped to find someone who could hit the ground running. New Investigator Patricia "Pat" Beckham, DPh, has done just that.

After graduating from Samford University Pharmacy School (now known as the McWhorter School of Pharmacy) in 1989, Dr Beckham began practicing in Tennessee. She gained institutional pharmacy practice experience working for Pharma Thera, the Veterans Administration Medical Center, and Saint Thomas Hospital for Specialty Surgery in Nashville, TN, where she also gained sterile compounding experience. Past retail experience includes working for Walgreens and Gray's Drug Store in Franklin, TN.

Dr Beckham does not hide her passion when it comes to sterile compounding. Her love for sterile compounding gained momentum as she gained employment with Precision Healthcare and Saint Thomas Hospital for Specialty Surgery. In 2008, she remembers staying ahead of the United States Pharmacopeia (USP) Chapter <797> target as she oversaw a remodel, moving away from the once prominent single compounding area with plastic curtains to a true cleanroom.

Dr Beckham's learning curve includes USP Chapter <797> compliance training in 2009 at the STAR (Skills Training, Academics and Resources) Center, located at Baxa Corporation's world headquarters near Denver, CO, along with over 21 years of sterile compounding experience.

After a few months of intensive investigator training, Dr Dilliard gave her the green light to inspect pharmacies, including sterile compounding facilities.

Dr Beckham and her family are members of the Forest Hills Baptist Church in Nashville, where she enjoys volunteering for the JH Ranch Outback America, serving in local and international missions. Along with her husband, daughters, and son-in-law, she is excited about the birth of her newborn grandson. Congratulations on the new addition to the family and welcome to the team, Dr Beckham!

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 **2019** meeting schedule is as follows:

- September 10-11 – **Canceled**
- November 5-6

The **2020** meeting schedule is as follows:

- January 28-29
- March 10-11
- May 5-6
- July 14-15
- September 15-16
- December 1-2

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