December 2018

Tennessee Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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https://www.tn.gov/health/health-program-areas/health-professional-boards/pharmacy-board.html

Error Noted in September 2018 Newsletter Regarding 2019 Meeting Dates

The 2019 Tennessee Board of Pharmacy meeting schedule is corrected in this *Newsletter.* See the last page for updated details.

Tennessee Departments Give Advisory Information Regarding Cannabis-Derived Products

Recently, Tennessee Board staff members have been asked questions regarding the sale and use of products derived from cannabis. An advisory released by Tennessee's Department of Health (TDH), Department of Mental Health and Substance Abuse Services, Department of Safety and Homeland Security, and Bureau of Investigations is now available and provides additional answers. The following links discuss the state and federal views. Note that according to the National Center for Complementary and Integrative Health of the National Institutes of Health, Food and Drug Administration (FDA) considers it illegal to sell products that contain tetrahydrocannabinol (THC) or cannabidiol (CBD) as dietary supplements, and illegal to sell foods containing added THC or CBD in interstate commerce.

CSMD Team Sends Message Regarding Prescription Reporting Requirements

Tennessee Public Chapter 1039 changes the prescription reporting requirements to the Tennessee Data Collection that populates the Controlled Substance Monitoring Database (CSMD). Dispensers of controlled substance prescriptions will need to ensure that their pharmacy dispensing system is compliant with the American Society for Automation in Pharmacy (ASAP) 4.2A (June 2017 version) on or before **January 1, 2019. The new fields in ASAP 4.2A (June 2017 version) will allow the dispensing site to be compliant with** Public Chapter 1039. Please share this information with the appropriate resource(s) involved in reporting on behalf of your dispensing Drug Enforcement Administration registration. Some of the changes are highlighted here.

Medical Necessity

On October 2, 2018, the CSMD committee determined in ASAP 4.2A (June 2017 version) that DSP24 Treatment Type, which is a situational field, will be utilized to report "medical necessity." When a prescriber is required to write "medical necessity" on the prescription, then the dispenser must submit a code to the Tennessee Data Collection. The DSP24 Treatment Type field, with an entry of 99, will be used to indicate "medical necessity" on the prescription.

ICD-10 Code

When a prescriber places an ICD-10 code on the prescription, the dispenser must submit the ICD-10 code to the Tennessee Data Collection. DSP25 Diagnosis Code, which is a situational field available in the new ASAP format, will be utilized. This field will only be populated when the ICD-10 code is listed on the prescription with no hyphens or dashes.

Partial Fills

Please note that Public Chapter 1039 also mandates partial fills be reported to the Tennessee Data Collection, and the new ASAP format will allow the dispensing site to be compliant. There are changes to DSP13 and the addition of DSP22 that will be used to be compliant.

The CSMD team has updated the Data Collection Manual, and it has been posted on the CSMD website, *https://www.tn.gov/health/health-program-areas/health-professional-boards/csmd-board.html.* Information on the TN Data Collection Manual is located in the About area in the next to last paragraph. The FAQ area will be updated soon. The Board recommends bookmarking this site to use as a resource for future questions.

National Pharmacy Compliance News

December 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.

SAMHSA Publishes Guidance for Treating OUD

To help broaden health care professionals' understanding of medications that can be used to treat Americans with opioid use disorder (OUD), the Substance Abuse and Mental Health Services Administration (SAMHSA) offers guidance on clinical best practices in the February 2018 publication titled *Treatment Improvement Protocol 63, Medications for Opioid Use Disorder.* The publication reviews the use of the three Food and Drug Administration (FDA)-approved medications used to treat OUD – methadone, naltrexone, and buprenorphine – and other strategies and services needed to support recovery for people with OUD.

Additionally, in February 2018, SAMHSA released the publication *Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants,* which offers standard approaches for health care professionals. This publication provides evidence-based treatment options, including pharmacotherapy with methadone, buprenorphine, and buprenorphine/naloxone, for pregnant women with OUD. The clinical guidance also helps health care professionals and patients determine the most clinically appropriate action for a particular situation and informs individualized treatment decisions. Both publications can be found in the Publications section of SAMHSA's website at *www.samhsa.gov*.

FDA Issues Final Guidance Policy on Outsourcing Facilities

In May 2018, FDA issued a new policy designed to address any ambiguity around how to define the physical features and operations of outsourcing facilities. According to FDA Commissioner Scott Gottlieb, MD, the policy in the final guidance, *Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act,* will help to:

- ensure that compounded drugs are made under appropriate quality standards;
- provide transparency to patients and health care providers about the standards under which the compounded drugs that they purchase are made; and
- respond to stakeholder feedback requesting guidance on the meaning of "facility" under section 503B.

In the guidance, FDA explains that a section 503A establishment compounding drugs pursuant to patient-specific prescriptions may be located near or in the same building as the outsourcing facility provided that they are completely separate. As explained in the guidance, the boundaries between the section 503A establishment and outsourcing facility should be clear and may include permanent physical barriers, such as walls or locked doors, and the two operations should not share rooms, equipment, supplies, or pass-through openings (eg, they may not subdivide a room with temporary barriers such as curtains). The guidance further explains that the labeling should clearly identify the compounder who produced the drug. Lastly, the guidance reminds industry and stakeholders that all drug products compounded in an outsourcing facility are regulated under section 503B and are subject to current good manufacturing practice requirements, even if those drug products are compounded pursuant to patient-specific prescriptions. Additional information can be located at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm607339.htm.*

EU-US Mutual Recognition Agreement Now Operational Between FDA and 12 Member States

In January 2018, FDA confirmed the capability of four more European Union (EU) member states – Czech Republic, Greece, Hungary, and Romania – to carry out good manufacturing practice inspections at a level equivalent to the United States. With the addition of the four EU member states, FDA can now rely on inspection results from 12 EU member states. The mutual recognition agreement between the EU and US to recognize inspections of manufacturing sites for human medicines conducted in their respective territories is progressing as planned, with plans for the agreement to be operational in all EU member states by July 15, 2019, indicates a European Medicines Agency (EMA) press release. In 2017, FDA determined the agency will recognize eight European drug regulatory authorities in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom as capable of conducting

inspections of manufacturing facilities that meet FDA requirements. The EMA news release, "Four more EU Member States benefit from EU-US mutual recognition agreement for inspections," can be found in the News and Events section at *www.ema.europa.eu.*

US Surgeon General Advisory Urges More Individuals to Carry Naloxone

In an April 2018 advisory, US Surgeon General Jerome M. Adams, MD, MPH, emphasizes the importance of more individuals knowing how to use naloxone and keeping it within reach. Surgeon General Adams recommends that family, friends, and those who are personally at risk for an opioid overdose keep the drug on hand. As stated in the advisory, expanding the awareness and availability of naloxone is a key part of the public health response to the opioid epidemic. The Surgeon General advisory on naloxone is part of the Trump Administration's ongoing effort to respond to the sharp increase among drug overdose deaths, notes a US Department of Health and Human Services (HHS) news release. HHS also has a website, *www.hhs.gov/opioids,* with resources and information for individuals who want to fight the opioid crisis in their communities or find help for someone in need. The advisory and news release can be found at *www.surgeongeneral.gov*.

Expanding Pharmacists' Scope of Practice Linked to Improved Cardiovascular Outcomes

Elevating pharmacy involvement in patient care and using a team-based care model are among the effective strategies for preventing cardiovascular disease that were identified in a new guide developed by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention (DHDSP). The guide, *Best Practices for Cardiovascular Disease Prevention Programs: A Guide to Effective Health Care System Interventions and Community Programs Linked to Clinical Services,* describes the scientific evidence behind each strategy, including collaborative drug therapy management, enabled by a collaborative practice agreement, and medication therapy management. To be included in the guide, strategies had to be supported by multiple high-quality research studies that demonstrated evidence of effectiveness in controlling blood pressure or cholesterol levels. More details about the best practice strategies along with resources and tools for implementing the strategies identified by CDC's DHDSP can be found at *www.cdc.gov/dhdsp/pubs/guides/best-practices/index.htm.*

Pharmacists Are Critical to Drug Supply Chain Integrity, States FIP

Medicines are specialized commodities and, if they are not managed rationally or appropriately, they are equivalent to a dangerous substance, indicates the International Pharmaceutical Federation (FIP). In a May 2018 report, *Pharmacists in the supply chain: The role of the medicines expert in ensuring quality and availability,* FIP provides a global picture of the role of pharmacists in supply chains, the tasks currently undertaken by pharmacists in different countries, and pharmacists' unique competencies. Based on reviews of literature, survey data, and case studies from nine countries, pharmacists were identified as having expertise that is critical to supply chain integrity. According to FIP, pharmacists and those who are involved in the planning, procurement, manufacture, storage, and distribution of medicines must:

- ♦ consider how to most effectively use the skills of the staff and personnel available;
- ♦ provide and seek training where needed; and
- ♦ keep their systems and role descriptions under review in order to adapt to changing circumstances.

FIP's report and news release can be located at *www.fip.org/news_publications.*

Emergency Department Visits for Opioid Overdoses Rose 30%

From July 2016 through September 2017, reports of emergency department (ED) visits for opioid overdoses – including prescription pain medications, heroin, and illicitly manufactured fentanyl – rose 30% in all parts of the US, according to a CDC report. The Midwest saw opioid overdoses increase 70% during this time period. According to the March 9, 2018 *Morbidity and Mortality Weekly Report*, coordinated action between EDs, health departments, mental health and treatment providers, community-based organizations, and law enforcement can prevent opioid overdose and death. People who have had an overdose are more likely to have another; thus, being seen in the ED is an opportunity for action. EDs can provide naloxone, link patients to treatment and referral services, and provide health departments with critical data on overdoses. The CDC report, "Vital Signs: Trends in Emergency Department Visits for Suspected Opioid Overdoses — United States, July 2016–September 2017," can be accessed at *http://dx.doi.org/10.15585/mmwr.mm6709e1.*

FDA Response Clarifies Track and Trace for Some Pharmacy Medication Transfers

Board Pharmacy Investigator Andrea Miller sent two scenario questions to FDA's track-and-trace team regarding pharmacy transfer of medications and received the following answers.

First Scenario

I work at Pharmacy A. Pharmacy B wishes to purchase one sealed bottle of amoxicillin 500 mg 100 capsules from me. I must include track-and-trace paperwork. Does this mean I need a third party to provide this, or can I just attach the invoice where I ordered it from my wholesaler? Would Pharmacy A need to be registered as a wholesaler to sell to Pharmacy B?

Answer to First Scenario

Pharmacy A, in this scenario, is engaging in wholesale distribution under the federal Drug Supply Chain Security Act (DSCSA), and as such would be required to be a registered wholesale distributor in order to complete this transaction. Wholesale distribution is defined as, "the distribution of a [prescription] drug . . . to a person other than a consumer or patient." There are exceptions to this definition, but none include dispenser to dispenser sales of product as described in this scenario.

In the first scenario, Pharmacy A, when selling the sealed bottle of 100 capsules to Pharmacy B, must provide transaction information, transaction history, and a transaction statement for the product prior to, or at the time of, the transaction. See section 582(d)(1)(A)(ii) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). For additional information about exchanging product tracing information, we suggest that you review FDA's Draft Guidance entitled "DSCSA Standards for the Interoperable Exchange of Information for Tracing of Certain Human, Finished, Prescription Drugs: How to Exchange Product Tracing Information," available at *https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm424895.pdf.*

Additionally, please see FDA's Drug Supply Chain Security Act Product Tracing Requirements Frequently Asked Questions web page, specifically question 4, available at *https://www.fda.gov/drugs/drugsafety/drugintegrityandsupplychainsecurity/drugsupplychainsecurityact/ucm487301.htm*.

Second Scenario

Pharmacy A is wanting to sell the same amoxicillin to a dentist's office. Does Pharmacy A need to be a wholesaler for this? My understanding is that if the pharmacy is to finish out a prescription for a patient, there is no need for paperwork, but I am confused on when I need to be a wholesaler versus a dispenser who sometimes will sell products to other licensed/registered entities.

Answer to Second Scenario

In this scenario, Pharmacy A is planning to sell the same product to a dentist's office. This example would likely not require licensure as a wholesale distributor to complete this transaction. One of the exemptions to the definition of wholesale distribution is for "distribution of minimal quantities of a drug by a licensed retail pharmacy to a licensed practitioner for office use." Should that definition be met, the pharmacy need not be a licensed wholesale distributor to complete the transaction to the dentist's office. See section 503(e)(4)(D) of the FD&C Act.

If you have additional questions, the DSCSA is available at *www.fda.gov/drugs/drugsafety/drugintegrityandsupplychainsecurity/drugsupplychainsecurityact/ucm376829.htm.* We advise those interested to review the law closely to understand how it may affect them. We also encourage you to frequently visit our DSCSA website, where we provide updates and informational resources, at *https://www.fda.gov/drugs/drugsafety/drugintegrityandsupplychainsecurity/drugsupplychainsecurityact/default.htm.*

Additionally, specific questions may be emailed to Drug Track and Trace at drugtrackandtrace@fda.hhs.gov.

Inter-Pharmacy Marketplace Business May Cause Interstate Violations if Not Appropriately Licensed

If a pharmacy is using an inter-pharmacy marketplace business to buy or sell prescription medications (prescription only), **for a specific patient,** there is a federal provision that allows the transfer that is found in the DSCSA. However, it does **not** supersede state regulation regarding the requirement for a state license if doing business in Tennessee. The pharmacy must be licensed by the Board or the transaction is in violation per Board Rule 1140-01-.08 (3), which states in part:

> No out-of-state pharmacy practice site, manufacturer outsourcing facility, oxygen supplier or wholesaler/distributor shall conduct business in the state of Tennessee until such pharmacy practice site, manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor obtains the required license from the board.

Therefore, provided that the pharmacies involved in the transfer of the **"specific patient only"** medication are both licensed by the Board, the transaction would then fit in the

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rule. Moreover, it is advised to check with other state laws as there may be additional licensing to transfer into that state from Tennessee. It has come to the attention of the Board that these inter-pharmacy marketplace businesses help to match pharmacies and send mailing information so that one pharmacy can mail to the other. However, it is explained that the pharmacy receiving the medication does not know where the medication is coming from until it is received. Therefore, there is no way to know if the sending pharmacy is licensed properly with the Board until after the violation occurs.

Eidson Steps Down as Governor Haslam Appoints New Board Member

As Dr Kevin Eidson completes his six-year term with the Board, the members wish him a fond farewell.

Governor Bill Haslam has officially selected Melissa McCall, PharmD, a Kingsport, TN, resident, as Eidson's replacement. Dr McCall has accepted the appointment for the next six-year term.

A pharmacy professional services manager for the Tri-Cities division of K-VA-T Food Stores, Inc, Dr McCall currently oversees daily operations for 38 Food City Pharmacy locations spreading across Northeast Tennessee, Southwest Virginia, and Eastern Kentucky. Her career with Food City Pharmacy began with a year as a floating pharmacist before adding responsibilities such as health and wellness program counselor, diabetes educator, and pharmacist-in-charge.

Dr McCall is a graduate of the 2010 inaugural class of Gatton College of Pharmacy (GCP) at East Tennessee State University (ETSU). She later earned her master's of business administration degree in 2013 from Milligan College, located in Johnson City, TN. She is a member of the Tennessee Pharmacists Association and the GCP Alumni Engagement Task Force, and was a member of the GCP Honor Code Committee from 2007 to 2010. She currently holds certifications in CPR, diabetes, and immunization delivery and was awarded the Claude P. Varney award for volunteerism from K-VA-T Food Stores, Inc, in 2015.

Along with her husband Josh Jessee, who is also a pharmacist, and daughter Addison, Dr McCall attends the First Baptist Church of Kingsport, and enjoys traveling, outdoor activities, and supporting ETSU and University of Tennessee athletics.

Board Executive Director Reginald "Reggie" Dilliard, DPh, commented on Dr Eidson's time on the Board in a recent email. "We will miss his experience and expertise on the Board," Dilliard said. "We look forward to welcoming our new member and all that she may bring in our efforts to protect the safety of Tennessee patients."

"I appreciate the warm welcome from everyone," McCall said via email. "I am honored and humbled to serve the state in this capacity and look forward to meeting everyone and getting started!" Welcome aboard, Dr Melissa McCall!

Public Chapter 675 Requires TDH to Accept Opioid Abuse or Diversion Allegations

Effective January 1, 2019, Public Chapter 675 requires registrants to either provide documentation individually to employees or post a sign concerning the reporting of opioid abuse or diversion to TDH. This sign is required to be posted in a conspicuous but non-public location. The Board is communicating this information to ensure compliance with the law and to improve the reporting of abuse and misuse of opioids to the proper authorities. Read Public Chapter 675 for additional information.

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:

- January 8-9
- March 12-13
- May 8-9
- July 16-17
- September 10-11
- November 5-6

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.

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