June 2019

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

Tennessee Department of Revenue Reminds Professionals of Privilege Tax

The Tennessee Department of Revenue reminds applicable registrants that the professional privilege tax was due on June 1, 2019. The fee is required regardless of whether the location of practice is in or out of state. For additional information, visit *https://www.tn.gov/content/tn/revenue/taxes/professional-privilege-tax.html.*

As of 2020, pharmacists will no longer be required to pay this tax. However, **the 2019 tax is still in effect. If not already paid, be sure to do so immediately.**

PC 124 Updates Opioid Limiting Law

Clarifications and changes to Public Chapter (PC) 1039 regarding the TN Together opioid law were approved by Governor Bill Lee on April 9, 2019, and designated as PC 124. Some of those updates are as follows.

- All prescriptions (written/printed/electronic) for a Schedule II controlled substance (CS) must contain all the legal requirements, **including a signature on the day the prescription is issued.**
- Emergency prescriptions are not specifically mentioned in PC 124. However, this legislation does mention that verbal orders are permitted when following the proper requirements. Therefore, an emergency verbal prescription is still allowed.
- Updated language clarifies that the ICD-10 code on the (no more than) three-day supply of opioid treatment and a maximum of 180 morphine milligram equivalent (MME) dosage is not required.
- On or after January 1, 2021, it becomes mandatory for Schedule II through Schedule V CS prescriptions to be sent electronically. If issued by a mid-level provider (ie, an advanced practice nurse or physician assistant), the prescription must include the name, address, and telephone number of the collaborating physician (once known as the supervising physician).
- Regarding partial fills, the April 9, 2019 date applies here and requires that any subsequent fill must remain and be completed at the pharmacy in which it was originally initiated. The partial fill must be completed within the six-month time frame from the date of issuance (unless required to be filled in less time under federal law).
- The date for software vendors to comply with the partial-fill process has been extended to January 1, 2021.
- Partial fills are no longer required unless signified by the health care practitioner. The notation "PF" by the health care practitioner has been added to regulation to signify that a partial fill is authorized if applicable. Note that Schedule II CS prescriptions are still only allowed for up to 30 days from the date of issuance on a partial fill due to federal regulations. Long-term care or terminally ill patient prescriptions continue to be allowed for up to 60 days.
- The terms "palliative care," "serious illness," "severe burn," and "major physical trauma" are defined, which clarifies opioid treatment regimens under the exempt status.
- The requirement to fill opioids for "more than minimally invasive" procedures (surgery) has been increased from the maximum of 20 days/850 MME to a maximum of 30 days/1200 MME.
- Opioid-containing preparations for cough and upper respiratory symptoms, **approved by Food and Drug Administration for such use,** may now be prescribed for a maximum of 14 days with no requirements regarding MME. The ICD-10 codes for these preparations are no longer required to be recorded on the prescription.

As not every detail is covered in this article, it is strongly advised to review PC 124 in its entirety at *https://publications.tnsosfiles.com/acts/111/pub/pc0124.pdf.*

Compounding Corner: Getting Ready for USP General Chapter <800> Nonsterile HD Compounding

As December 1, 2019, approaches, United States Pharmacopeia (USP) regulations will be updated, added, and put into

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National Pharmacy Compliance News

June 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 Launches Pilot Program to Improve Security of Drug Supply Chain With an Innovative Approach

Food and Drug Administration (FDA) has launched a pilot program allowing participants representing the various parts of the drug supply chain to pilot innovative and emerging approaches for enhanced tracing and verification of prescription drugs in the United States' supply chain. The program is in line with FDA's ongoing efforts to prevent suspect and illegitimate products from entering the supply chain, according to an FDA press release. Eligible manufacturers, repackagers, and other stakeholders can apply to participate in the program, which will inform the development of the enhanced electronic, interoperable track-and-trace system for industry set to go into effect in 2023 in accordance with the Drug Supply Chain Security Act (DSCSA), enacted by Congress on November 27, 2013.

The pilot technologies of this program may become part of FDA's enhanced expectations for reliable track-and-trace systems, which will be designed to reduce diversion of drugs distributed domestically and to keep counterfeit drugs from entering the supply chain. The DSCSA pilot project program is intended to help identify and evaluate the most efficient processes to comply with and apply drug supply chain security requirements and will aid in identifying attributes the system will need for enhanced product tracing and verification, as well as electronic means to share the information. FDA recently issued draft guidance on the use of product identifiers with a unique serial number to improve verification down to the package level. FDA has also provided draft guidance for verification systems to quarantine and investigate suspect and illegitimate drugs.

Additional information on the FDA pilot program is available in a February 8, 2019 announcement in the *Federal Register.*

FDA Announces New Efforts to Increase Oversight and Strengthen Regulation of Dietary Supplements

Noting that three in four Americans now take at least one dietary supplement on a regular basis, and that the dietary supplement industry has expanded to include as many as 80,000 different products for consumers, FDA Commissioner Scott Gottlieb, MD, has announced new plans to increase the agency's oversight of dietary supplements. These initiatives include communicating to the public as soon as possible when there is a concern about a dietary supplement on the market, ensuring that the regulatory framework is flexible enough to adequately evaluate product safety, and continuing to work closely with industry partners. FDA is also developing new enforcement strategies to respond to entities that violate standards established under the Dietary Supplement Health and Education Act of 1994.

On February 11, 2019, FDA sent 12 warning letters and five online advisory letters to foreign and domestic companies that are illegally selling more than 58 products. The products are illegally marketed as unapproved new drugs that make unproven claims about preventing, treating, or curing Alzheimer's disease, as well as a number of other serious diseases and health conditions, such as diabetes and cancer. In his statement, Gottlieb noted that most stakeholders in the industry act responsibly, but he expressed concern over the ability of bad actors to exploit the system by providing potentially dangerous products and making unproven or misleading claims about the health benefits supplements may offer.

FDA is planning a public meeting on this topic during the second quarter of 2019. For more information, view the FDA statement at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm631065.htm.*

Trump Administration Releases National Drug Control Strategy to Reduce Drug Trafficking and Abuse

As the opioid crisis continues to claim the lives of tens of thousands of Americans each year, the Office of National Drug Control Policy has released its *National Drug Control Strategy.* The *Strategy* breaks down the administration's priorities in addressing the crisis, with an emphasis on three areas: prevention, treatment and recovery, and reducing availability.

- **Prevention** efforts are focused on educating both consumers and caregivers about the dangers of opioid misuse and include a new national media campaign, continued efforts to expand prescription monitoring programs (PMPs), and improving the ability of state, local, and tribal communities to identify and prevent substance abuse.
- **Treatment and recovery recommendations** in the *Strategy* include improving access to naloxone, improving evidence-based addiction treatment, and eliminating barriers for accessing treatment.

- **Reducing availability** strategies are focused on disrupting illegal supply chains, defeating drug traffickers, increased cooperation with international partners, and combating illegal internet drug sales.

The document notes that the "most important criterion of success" is saving lives and calls for the federal government to work closely with state and local governments, as well as other stakeholders. Additional information, including the full strategy document, is available on the White House website at *https://www.whitehouse.gov/opioids.*

National Association of Boards of Pharmacy® (NABP®) and its member boards of pharmacy remain committed to advancing best practices for PMPs in the interest of public health. NABP's PMP data sharing system, NABP PMP InterConnect®, facilitates the secure transfer of PMP data across state lines and provides an effective means of combating drug diversion and drug abuse nationwide. In addition, NABP and its member boards continue efforts to educate consumers about prescription drug safety. The NABP $AWAR_XE$® Prescription Drug Safety Program's Drug Disposal Locator Tool has more than 6,000 disposal locations and continues to add new locations to provide consumers with a safe way to dispose of medication and help prevent misuse and abuse of prescription medications. For more information about PMP InterConnect and the $AWAR_XE$ program, visit the Initiatives section of the NABP website at *www.nabp.pharmacy.*

New Study Predicts Opioid Epidemic Will Worsen Over the Next Decade

More than 700,000 people will die from opioid overdoses between 2016 and 2025, and annual overdose deaths will reach nearly 82,000 by 2025, estimates a new study published to *JAMA Network Open.* The estimate is based on an analysis of data from the National Survey on Drug Use and Health and the Centers for Disease Control and Prevention from 2002 to 2015.

Researchers also projected that intervention efforts focused on lowering the incidence of prescription opioid misuse would help to reduce the number of deaths 3.8% to 5.3%, a figure the researchers described as "modest," due to the changing nature of the opioid crisis. The study notes that more people are directly initiating opioid use with illicit opioids rather than prescription drugs, and illicit opioids have become more lethal with the availability of illegally manufactured fentanyl.

The researchers encourage policymakers to take "a stronger and multipronged approach" to reduce the impact of the ongoing opioid overdose epidemic. The full article is available at *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723405.*

FDA Warns of Potential Blood Pressure Medication Shortages Due to Recalls

FDA is warning health care providers and consumers of a shortage of angiotensin II receptor blockers, commonly used to treat high blood pressure. A growing list of medications containing valsartan, losartan, and irbesartan have been recalled from the market for containing an impurity that may present a cancer risk to patients. The issue was first detected in the summer of 2018, according to a statement posted to the FDA website. Since then, FDA has placed a Chinese manufacturer of the active ingredient on import alert to stop their imports, and FDA is working with other manufacturers to recall affected medications.

In the statement, FDA notes that the risk to individual patients remains very small, but that there is still reason to be concerned about the potential health risks. Medications with these impurities are believed to have been in the market for about four years.

"Now that these risks are identified, we're applying what we've learned to the evaluation of similar manufacturing processes where we now know these risks could arise," the statement notes. The FDA press release is available at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm629796.htm.*

FDA Releases Two Draft Guidances Related to REMS Programs

FDA has released two new draft guidances to ensure risk mitigation programs put in place for certain drugs and biologics, as required for approval, are working. The agency's primary risk management tool is FDA-approved product labeling. However, in limited cases, FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to help ensure a drug's benefits outweigh its risks.

The following guidances relate to the assessment of REMS programs:

- **REMS Assessment: Planning and Reporting Guidance for Industry** describes how to develop a REMS Assessment Plan.
- **Survey Methodologies to Assess REMS Goals That Relate to Knowledge Guidance for Industry** provides recommendations on conducting REMS assessment surveys to evaluate patient or health care provider knowledge of REMS-related information.

FDA states that the goal in providing this guidance for REMS is to ensure constant improvement of their safety programs and establish the most efficient and effective programs moving forward, to optimize patient care and keep consumers safe and healthy. More information on REMS is available on the FDA website at *https://www.fda.gov/drugs/drugsafety/rems.*

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effect. Nonsterile hazardous drug (HD) compounding has become a hot topic for investigators across Tennessee, so in an effort to respond to some of those inquiries, the following question and answer section is being published. (Note that USP General Chapter <800> regulations were finalized on February 1, 2016.)

Q. Does my floor need to follow the regulation of a coved floor if I do not plan to do any sterile compounding?

A. At this time, the chapter remains silent regarding coved floors being required in nonsterile rooms but **does indicate that the floors must be smooth.** Therefore, tile floors are unacceptable.

Q. Do the ceiling and walls also need to be smooth and washable?

A. Yes. The ceiling tiles need to be impervious and sealed so that the tile will not move when cleaning it. Due to the difficulty of cleaning HD contamination, surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the **nonsterile** compounding area must be smooth, impervious, free from cracks and crevices, and non-shedding.

Q. What are other requirements for the nonhazardous room?

A. Nonsterile HDs must be compounded within a containment primary engineering control located in a containment secondary engineering control (C-SEC). The C-SEC used for nonsterile compounding rooms must:

- be externally vented;
- be physically separated (ie, a different room from other preparation areas);
- have an appropriate air exchange of at least 12 air changes per hour (ACPH); and
- have a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas.

Q. Do I need a separate sink to wash the HD equipment, mortar, counting tray, etc?

A. USP General Chapter <800> indicates a sink must be used for handwashing and be located at least a meter away from the primary engineering control (PEC). USP does not appear to indicate that there must be a separate sink for washing the HD. However, if other duties such as handwashing and washing of mortars, beakers, etc, are performed, the sink would have to be cleaned each time and decontaminated before continued use. Therefore, it is strongly suggested to install a separate sink for handwashing.

Q. What personal protective equipment (PPE) is required for HDs?

A. USP General Chapter <800> requires pharmacies to maintain a list of HDs that include any items on the current National Institute for Occupational Safety and Health (NIOSH) list that a pharmacy employee handles. PPE includes gowns; head, hair, and shoe covers; and two pairs of chemotherapy gloves. For all other activities, pharmacy employees' standard operating procedures (SOPs) must describe the appropriate PPE to be worn regarding occupational safety plans and the assessment of risk. SOPs must be created for PPE based on risk exposure and the activities performed.

The USP General Chapter <800> frequently asked questions web page is a great place to review other questions as well.

Q. Can I compound nonsterile 5-fluorouracil (5-FU) in a powder hood?

A. No stipulation could be found that prohibits compounding 5-FU in a powder hood, which is also known as a containment ventilated enclosure (CVE), since it is being used in a nonsterile platform and will provide negative pressure. However, this drug is in the class of antineoplastic drugs and is in the NIOSH Table 1 category. Specific cleaning of the CVE is paramount before compounding other drugs in this PEC, and wipe tests are expected if compounding this type of drug. Alternatively, a separate PEC for antineoplastic compounding would be optimal.

Q. Can pouring "finished" antineoplastic product (eg, megestrol acetate) into another bottle have a risk assessment?

A. In certain situations it may be permissible. See question 16 of the USP General Chapter <800> frequently asked questions web page for this answer.

(The following questions are answered by Tennessee Board of Pharmacy Investigator Andrea Miller, PharmD, CISCI.)

Q. Must we have special storage for commercially available products that are on the NIOSH HD list, or can they be on the shelf with all the other medications?

A. My first suggestion would be to read USP General Chapter <800> and then the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings for suggested handling precautions, including PPE and the table listing of medications that are hazardous. USP also has an app that can assist facilities with knowing if a medication is hazardous and what precautions may be needed.

After reviewing those documents, the facility may construct a list of medications that it handles on the NIOSH list. NIOSH Table 1 medications must be handled with

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USP General Chapter <800>-compliant containment, which means negative pressure. If a facility works with active pharmaceutical ingredients (APIs), such as estradiol powders, testosterone powders, etc, it also has to fully comply with USP General Chapter <800> containment.

For medications that are on NIOSH Table 2 and Table 3 that are commercially available, the pharmacy may perform an assessment of risk that details how the facility is going to handle that HD since it does not intend to fully comply with USP General Chapter <800> containment strategies. Examples of this risk assessment include PPE the facility workers will wear, designated counting trays, appropriate cleaners to deactivate/decontaminate, storage, designated employees to handle certain tasks, etc. I encourage some type of mechanism for the facility staff to recognize an HD medication so they know the cleaning/decontamination or other risk assessment strategies that must be utilized with that medication. Some sites have ordered stickers or use a special type of mylar sticker color to indicate an HD, and others have completely segregated out the HD medications.

Currently, only NIOSH Table 1 medications or APIs need to be stored in negative pressure rooms with 12 ACPH. The other HD medications depend on the risk assessment for the facility.

Q. Can drugs on the NIOSH HD list be used in a counting robot? For instance, some high-volume drugs like spironolactone, estradiol, and finasteride are on the list.

A. As far as automation in a robot or counter, I would not recommend including any HD medications in there unless the facility was confident in its assessment of the risk to its employees as well as patients who could receive potential, unintended exposure. A lot of the automation will use the same "chute" or dispensing funnel, which does not get cleaned as it should. Could you guarantee to your pregnant patient or employee that the finasteride from a different cell did not touch or contaminate her levothyroxine?

Q. Can we count these substances on devices like an Eyecon® or through a Kirby Lester automated counting machine by Capsa Healthcare, without those devices being considered contaminated?

A. If the facility has an Eyecon machine, the ones that I am familiar with are able to easily clean/decontaminate the plastic tray and remove any particulate. I do not believe a Kirby Lester automated counting machine is as easily cleanable and able to be decontaminated due to how the machine counts the medication with a chute. I would almost equate this to having a dedicated counting tray and no automation for sulfa or penicillin medications due to the chance of cross contamination and ensuring the tray gets cleaned appropriately after each use. You may wish to check with the manufacturer regarding any process for decontamination procedures before using this type of device.

Helpful Links

- USP chapters, specifically USP General Chapter <800> (This is not free access.)
- NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016
- FAQs: <800> Hazardous Drugs—Handling in Healthcare Settings
- Generic internet search for an HD sticker
- CriticalPoint Pearls of Knowledge February 2017: Performing an Assessment of Risk
- *Pharmacy Today* article, "Compounding nonsterile preparations: USP <795> and <800>"
- *Pharmacy Today* article, "ASHP updates guidelines on handling hazardous drugs"
- Consensus Statement on the Handling of Hazardous Drugs Per USP Chapter <800> published by Accreditation Commission for Health Care, Pharmacy Compounding Accreditation Board, International Academy of Compounding Pharmacists

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:

- 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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