September 2020

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 Approves Extension of the Following Waivers

Rule 1140-03-.01(1): Face-to-Face Counseling Requirement

In order to reduce exposure and transmission of the coronavirus disease 2019 (COVID-19), effective immediately the Tennessee Board of Pharmacy has waived the requirement for patients to be counseled face to face, as stated in Rule 1140-03-.01(1). Counseling may be provided by a pharmacist by telephone or by other forms of technology or by alternative means. This waiver does **not** remove the requirement to counsel the patient; all efforts should be made to counsel a patient as before and should cover all aspects of counseling required in the rule. This waiver will remain in effect **through the end of 2020** unless the Board extends it.

Rule 1140-14-.12(2)(a): Stocking of ADMs in Long-Term Care Sites

In order to reduce the risk of exposure of patients in long-term care sites to COVID-19 with incursion of outside personnel, effective immediately the Board waives the requirement that filling/stocking of all medications in the automated dispensing system shall be completed by a pharmacist or pharmacy technician under the direct supervision of a pharmacist. The pharmacist-in-charge shall designate personnel on site who have sufficient training and shall be responsible for stocking the machines with the medications delivered by the pharmacy to the site. This waiver will remain in effect **through the end of 2020** unless the Board extends it.

Board Extends Funding to TPRN Program

At its May 5, 2020 meeting, the Board voted to continue to fund the Tennessee Pharmacy Recovery Network (TPRN) with a grant of $180,500 for another year. TPRN Program Director Baeteena Black was appreciative, stating "The advocates, who are all volunteers, and I appreciate and thank the Board for its confidence in and collaboration with TPRN for the work done by the program in protecting public safety and restoring pharmacy professionals to health and practice."

Black explained that since the mid-1980s, the TPRN program, working with the members of the TPRN Program Advocacy Committee, has provided a comprehensive peer assistance program consisting of assessment, referral for treatment, monitoring, and advocacy services for pharmacy professionals and student pharmacists needing assistance due to substance use disorder, including abuse of alcohol. She indicated that in September 2017, the TPRN program entered into a three-year grant contract with the state of Tennessee to provide the Board with a formalized program of peer assistance and rehabilitation of impaired pharmacy professionals licensed or registered in Tennessee. Black explained that under these provisions, TPRN has provided peer assistance to pharmacists, pharmacy technicians, and student pharmacists since that time.

If you need help or know an associate (pharmacist or pharmacy technician) who does, please contact Dr Baeteena Black, TPRN 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 the following website.

COVID-19 Spanish Language Resource Web Page Now Available

The Tennessee Department of Health (TDH) and Unified Command Group are providing additional COVID-19 materials and resources for Spanish-speaking Tennesseans through this link. This new web page includes videos, fact sheets, infographics, and other resources about COVID-19 testing; the Tennessee Pledge; and how to protect yourself, your family, your coworkers, and your community from COVID-19. Please click here to view the TDH news release in its entirety.

TDEC Consultant Explains Waste Disposal (Part III)

By Benjamin Almassi, Tennessee Department of Environment and Conservation (TDEC) Environmental Consultant 1

From IV prep, general compounding, spills, and expired drugs, to packaging and partially used vials, there is a

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National Pharmacy Compliance News

September 2020

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 Releases MOU on Human Drug Compounding Regulation and Oversight

Acknowledging the vital role states play in reducing the risks associated with compounded drugs, Food and Drug Administration (FDA) has made available a Final Standard Memorandum of Understanding (MOU) Addressing Certain Distributions of Compounded Human Drug Products, intended to be entered into between the agency and the states. The release of the MOU is required as part of its submission to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act of 1995. The MOU was developed in close consultation with the National Association of Boards of Pharmacy® (NABP®), as described in the Federal Food, Drug, and Cosmetic Act. The agency also engaged with states, pharmacies, associations, pharmacists, and other stakeholders.

Among the issues addressed in the MOU is the definition of the statutory term "inordinate amounts," which refers to compounded drugs that are distributed interstate. In addition, the MOU includes the risk-based oversight model from the 2018 revised draft MOU. States that sign the document agree to identify pharmacy compounders that distribute inordinate amounts (greater than 50%) of compounded drug products interstate, as well as report certain information to FDA about those compounders. FDA also provided clarity in the MOU on state investigations of complaints associated with compounded drugs distributed out of state. States that enter into the MOU will investigate complaints about drugs compounded at a pharmacy within their state and distributed outside of the state and advise FDA when they receive reports of serious adverse drug experiences or serious product quality issues, like drug contamination.

To help states to better investigate these issues, FDA has also announced an agreement with NABP to make an information sharing network available to the states. Through this network, states will be able to obtain information from pharmacies in their states and transmit that information to FDA.

"We anticipate the final MOU, once signed, will help to facilitate increased collaboration between the FDA and the states that sign it," said Janet Woodcock, MD, Director, Center for Drug Evaluation and Research, in an FDA Voices article. "Working together, we can help promote quality compounding practices and better address emerging public health concerns that may affect patients."

FDA Clarifies Compounding Rules, Offers Flexibility to Help Ease Drug Shortages During COVID-19 Pandemic

FDA noted it will use discretion in enforcing certain standards related to 503A and 503B compounding in an effort to ease drug shortages during the coronavirus disease 2019 (COVID-19) pandemic. During an American Pharmacists Association (APhA) webinar on April 30, 2020, the agency clarified it will "look to 503B compounders to grapple with drug shortages" and "turn to 503A compounders to fill in the gaps."

In addition, the agency clarified that medications on the FDA drug shortage list are effectively considered "not commercially available," which frees 503A and 503B compounding facilities from limits on compounding drugs that are "essentially a copy" of a product already available on the market. FDA also does not intend to take action if a 503A facility fills orders for a compounded drug that is essentially a copy of an approved drug that has been discontinued and is no longer marketed.

In April 2020, FDA issued a temporary guidance that granted flexibility for pharmacists to compound certain necessary medications under 503A for nonspecific patients hospitalized due to COVID-19. In addition, a temporary guidance was issued that granted enforcement flexibility for 503B outsourcing compounding facilities for drugs in shortage for patients hospitalized during the COVID-19 public health emergency. The guidance documents stipulate the conditions compounders must meet and are available at *https://www.fda.gov/media/137125/download.*

More information on these compounding rule clarifications is available in a May 5, 2020 press release on the APhA website.

CMS Allows Pharmacies to Temporarily Enroll as Clinical Diagnostic Laboratories for COVID-19 Testing

Centers for Medicare & Medicaid Services (CMS) has released a document detailing a process that allows pharmacies to temporarily enroll as independent clinical diagnostic laboratories. This process will allow those

facilities to seek Medicare reimbursement for COVID-19 tests, making it easier for them to provide that service during the pandemic.

"Up until this point in time, most pharmacies could only offer this as a cash service because they were not considered providers through CMS, and really a lot of the third-party payers really didn't have an interest in a fee-for-service type model," said Michael E. Klepser, PharmD, FCCP, pharmacy professor at Ferris State University, in an interview with *Bloomberg Law.* "The fact that CMS is saying we're now authorizing or allowing pharmacists to get reimbursed for these is a great door opening at the federal level and that's a huge, huge thing."

Chain pharmacies such as CVS, Walgreens, and Rite Aid are offering drive-through testing at many pharmacies throughout the country.

FDA Issues Updated Guidance for Compounding Pharmacies Experiencing PPE Shortages

FDA has issued an update for its guidance to pharmacy compounders that may experience shortages of personal protective equipment (PPE) during the COVID-19 pandemic. As compounders typically utilize PPE when performing sterile compounding, the updated guidance clarifies that the drugs can be compounded under the policy in a segregated compounding area that is not in a cleanroom. This policy has been adopted to ensure patients continue to have access to medicines they need during the pandemic, and to reduce the risks of compounding when standard PPE is not available.

In addition to FDA guidance, United States Pharmacopeial Convention has previously issued an informational document for compounders regarding garb and PPE shortages during the pandemic. The document includes recommendations for conserving garb and PPE and what steps might be considered in the case of shortages of garb and PPE used for both sterile and nonsterile compounding.

The updated guidance can be accessed through FDA's website by visiting *www.fda.gov/media/136841/download.*

HHS Expands Telehealth Access in Response to COVID-19

In an effort to prevent and respond to the COVID-19 pandemic, the US Department of Health and Human Services (HHS) has awarded $20 million to increase telehealth access and infrastructure for health care providers and families. The funds, which are awarded through the Health Resources and Services Administration (HRSA), will increase capability; capacity and access to telehealth and distant care services for providers, pregnant women, children, adolescents, and families; and assist telehealth providers with cross-state licensure.

"This new funding will help expand telehealth infrastructure that is already being used during the pandemic to provide essential care, especially to the most vulnerable, including pregnant women and children with special health care needs," said HHS Secretary Alex Azar in a press release. "This funding will also help clinicians use telehealth nationally by streamlining the process to obtain multi-state licensure."

HRSA's Maternal and Child Health Bureau awarded a total of $15 million to four recipients; each award supports a key area in maternal and child health, including pediatric care, maternal health care, state public health systems, and family engagement for children with special health care needs. HRSA's Federal Office of Rural Health Policy awarded a total of $5 million to two recipients through the Licensure Portability Grant Program, which will assist telehealth clinicians nationally on licensure and credentialing to meet emerging needs related to COVID-19.

Criminals Found Posing as CDC Representatives to Steal Money and Information

Centers for Disease Control and Prevention (CDC) is warning the general public of a new type of phone and phishing scam by criminals posing as CDC representatives, often requesting donations. According to CDC, most of these fraudulent activities are being conducted by phone, utilizing software to "spoof" phone calls to make them appear as if they are coming from phone numbers that may look familiar. CDC advises consumers to avoid answering calls from numbers they do not recognize, and to avoid sharing personal information over the phone. In addition, CDC notes that no federal agency will request donations from the general public. Suspicious phone calls may be reported to the Federal Communications Commission.

More information on the scams is available on the CDC website at *https://www.cdc.gov/media/phishing.html.*

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vast variety of activities overseen by multiple regulatory bodies, including the state boards, the Department of Transportation, the Occupational Safety and Health Administration, Drug Enforcement Administration (DEA), and the Environmental Protection Agency (EPA). Of the 2,000-4,000 drugs stocked in typical hospital pharmacies, approximately 4-5% are subject to EPA hazardous waste (HW) regulations through the Resource Conservation and Recovery Act (RCRA). These HW pharmaceuticals are now banned from all sewering. EPA places the burden of proof for making an HW determination on the generator (eg, pharmacy). This action could be performed independently or with a third party, which would make the process easier and streamlined. Compliance assessments get tricky when considering non-regulated pharmaceutical wastes such as chemotherapeutic agents, drugs meeting National Institute for Occupational Safety and Health/Occupational Safety and Health Administration Hazardous Drug Criteria for safe handling, and endocrine disruptors. Some fall within RCRA as HW pharmaceuticals. As an example, only nine chemotherapy drugs are either P- or U-listed HW chemicals. What does this mean? In future articles, when COVID-19 is behind us, an in-depth look will be provided along with other regulatory nuances (such as sole active ingredients and empty containers). For now, let us establish a framework:

HWs are divided into two categories: listed wastes and characteristic wastes. Listed wastes appear on one of four lists of HW (F, K, P, and U). HW pharmaceuticals found on two of these lists, P and U, contain commercial chemical products. P-listed wastes are chemicals first and therapeutic agents second. A primary criterion for a P-listed drug is an oral lethal dose of 50 mg/kg (LD50) or less. These include epinephrine (P042, but not salts), warfarin >0.3% (P0081), and phentermine CIV (P046, it is best to use the CAS#). Chemicals are U-listed primarily for toxicity. These include lindane (U129) and mercury (U150, eg, thimerosal). To be P or U listed, the drug waste must contain a sole active ingredient (not ancillary functioning as a mobilizing or preserving agent) on the P or U list, and it must not have been used for its intended purpose. Characteristic wastes are regulated because they exhibit certain properties – **ignitability** (D001, eg, erythromycin gel 2%), **corrosivity** (D002, strong acids/bases), **reactivity** (D003, rare), and **toxicity** (D004-D043, eg, barium sulfate). The details of each of these properties can be explored with TDEC's online determination matrix.

A future article will cover guidance on managing combinations of HW, contaminated personal protective equipment, and best management practices.

DEA Gives Additional Guidance on Proper Filing of Old Triplicate Form 222 vs New Single-Sheet Form 222 When the Registrant Pharmacy Is the Supplier

According to DEA Nashville District Office Diversion Group, some registrants are sending DEA Form 222s to the incorrect locations. Be advised that the new DEA Form 222 single forms are to be scanned and emailed to the address located in the upper right corner of DEA Form 222 (dea .orderforms@usdoj.gov) when the **pharmacy is considered the supplier.** The investigator indicated that these **new DEA Form 222 copies are not to be sent** to the **local** DEA offices and that the scan/email is the preferred option, but understands that some pharmacies do not have that capability at this time. For those pharmacies that lack the technology to scan/email, regular mailing to the following address is acceptable: **Drug Enforcement Administration, Attn: Registration Section/ DRR, PO Box 2639, Springfield, VA 22152-2639.**

However, the investigator noted that one form that is to be mailed to the local DEA office is Copy 2 of the old triplicate DEA Form 222 (see local offices listed below). Do you have additional questions? Contact a DEA diversion investigator:

- **West Tennessee Office:** Diversion Group Supervisor Jacqueline Jordan
  571/362-2274; Jacqueline.R.Jordan@usdoj.gov
  50 North Front Street, Memphis, TN 38103
- **Middle Tennessee Office:** Diversion Group Supervisor James Stevens
  571/362-7674; James.N.Stevens@usdoj.gov
  801 Broadway Suite 500, Nashville, TN 37203
- **East Tennessee Office:** Diversion Group Supervisor Mark Armstrong, II
  865/584-9364; Mark.A.Armstrong@usdoj.gov
  624 Reliability Circle, Knoxville, TN 37932

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. Because of COVID-19, past meetings have been conducted using WebEx on the first day instead of the two days listed. Therefore, it is advised to c**heck for**

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schedule changes on the Board website under the Meeting Schedule tab.

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

- September 15-16
- December 1-2

The **2021** meeting schedule is as follows:

- January 26-27
- March 9-10
- May 4-5
- July 13-14
- September 14-15
- November 16-17

Tennessee Board of Pharmacy Members

- Dr Rissa Pryse – President
- Dr Katy Wright – Vice President
- Dr Adam Rodgers – Board Member
- Dr Melissa McCall – Board Member
- Dr Richard Breeden – Board Member
- Dr Debra Wilson – Board Member
- To Be Announced – Board Member
- To Be Announced – Public 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.

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