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Tennessee Board of Pharmacy News

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Board of Pharmacy President and Vice President Elected

At the January 7, 2020 Tennessee Board of Pharmacy meeting, Dr Debra Wilson opened the floor for nominations as she has fulfilled her time as president of the Board. Dr Rissa Pryse was elected as the president and Dr Katy Wright as vice president.

Board Gives Direction for Future USP Standards

During the January 7, 2020 Board meeting, Dr Andrea Miller, pharmacist investigator, presented an overview of the recommendation to move forward with rules regarding "all" applicable United States Pharmacopeia (USP) standards. Miller explained that the latest appeals regarding USP Chapters <795> and <797>, and the addition of USP Chapter <825> were to be addressed by the USP panel, which met on January 21 and 22. Miller noted that even if the panel made no changes, the appeal process calls for a six-month window before going into effect. This window will give pharmacists at least that much time to get ready for the new regulations, and if changes are made, the time may likely be extended.

Regarding USP Chapter <800>, Miller noted that it is not part of the appeal but is viewed as informational until the latest version of USP Chapter <797> takes effect.

Also of note, some Tennessee pharmacies compound drug products and send them into other states, which may require an inspection to USP standards in order to gain or renew a nonresident license(s). With this regulatory addition, pharmacies may not need to hire an outside entity to conduct an inspection as Tennessee is a Blueprint state (meaning that Tennessee pharmacy investigators use the National Association of Boards of Pharmacy® (NABP®) Universal Inspection Form while inspecting compounding registrants as part of the Board's participation in the NABP Multistate Pharmacy Inspection Blueprint Program).

Miller concluded with the following summary points:

- Implementation is an important step forward for safety.
- Pharmacy staff members are patients too and should be protected from hazardous drugs (HDs).
- Harmonization with other regulatory agencies and accreditation entities will be paramount to pharmacy success.
- Regulation will be defined so as to leave little doubt of what documentation is required and what is considered adulterated/misbranded.

The Board passed the motion to move forward with all applicable USP standards.

TDEC Consultant Gives Overview of EPA and USP Chapter <800> Regulations Regarding Hazardous Waste

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

From a broad perspective, the connection between human health and the environment is easily seen; however, once we enter the regulatory "forest" for handling health care pharmaceuticals and HDs, it is only natural for confusion to occur. There is not enough time in the day to completely cover the *Federal Register*/white paper on the Environmental Protection Agency's (EPA's) regulations or discern the overlap/differences with the new USP Chapter <800> and its own list of reference documents. Hopefully this series of articles will help provide orientation and coordinates for understanding these regulations.

USP Chapter <800> Hazardous Drugs—Handling in Healthcare Settings, is easily confused with the final EPA hazardous waste (HW) pharmaceutical rule. The latter became effective at the federal level on August 21, 2019, and is still working its way through Tennessee's rulemaking process to integrate into Tennessee's HW regulations. Licensees can expect that process to take about a year. However, as of its federally effective date, a prohibition on sewering of all HW pharmaceuticals has been implemented and is effective at the state level. The central theme of EPA's rule is the effective management of HW pharmaceuticals, which are estimated to be between 5-10% of all pharmaceuticals on the market.

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National Pharmacy Compliance News

March 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.

DEA Proposes New Regulations to Address Opioid Epidemic

Drug Enforcement Administration (DEA) has announced proposed regulations to improve the agency's ability to oversee the production of opioids and other potentially dangerous drugs. The proposed regulation would further limit the quantities of medications that might be vulnerable to diversion and misuse. The proposal would also amend the manner in which DEA grants quotas to certain registered manufacturers to levels aligned with current manufacturing standards aimed at promoting quality and efficiency while also ensuring the country has sufficient quantities of Schedule II controlled substances (CS) necessary for medical, scientific, research, and industrial needs.

The proposal introduces several new types of quotas that DEA would grant to certain DEA-registered manufacturers. These use-specific quotas include quantities of CS for use in commercial sales, product development, packaging/repackaging and labeling/relabeling, or replacement for quantities destroyed. These quotas are intended to improve DEA's ability to respond quickly to drug shortages.

The proposed changes build on 2018 regulatory changes that gave a role to state attorney generals and other federal agencies in setting the aggregate production quotas for Schedule I and II CS. The proposed regulations are available in the October 23, 2019, *Federal Register* announcement at *https://www.federalregister.gov/documents/2019/10/23/2019-21989/management-of-quotas-for-controlled-substances-and-list-i-chemicals*.

FDA Issues Report on Root Causes and Solutions to Drug Shortages

Food and Drug Administration (FDA) has released a new report, *Drug Shortages: Root Causes and Potential Solutions,* which identifies root causes for drug shortages and recommends three "enduring solutions" to address the shortages. These recommendations include:

- creating a shared understanding of the impact of drug shortages on patients and the contracting practices that may contribute to shortages;
- developing a rating system to incentivize drug manufacturers to invest in quality management maturity for their facilities; and
- promoting sustainable private sector contracts (eg, with payers, purchasers, and group purchasing organizations) to make sure there is a reliable supply of medically important drugs.

In addition to these recommendations, the report outlines the agency's ongoing initiatives to mitigate drug shortages and legislative proposals in President Donald J. Trump's Fiscal Year 2020 budget. FDA also highlighted the need for international action, including global implementation of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use's (ICH's) *ICH Guideline Q12: Technical and Regulatory Consideration for Pharmaceutical Product Lifecycle Management,* which provides opportunities for regulatory flexibility in making post-approval changes to the product or its manufacturing process.

"We hope that the recommendations set forth in this report will help to set a framework that all stakeholders can assess and implement as we work together to further mitigate the public health impact that drug shortages have on American consumers," FDA stated. "In the meantime, the FDA's employees remain committed to working behind-the-scenes to anticipate and help mitigate shortages and make sure that patients have access to the drugs they need."

FDA's full statement is available at *https://www.fda.gov/news-events/press-announcements/statement-fdas-new-report-regarding-root-causes-and-potential-solutions-drug-shortages*.

HHS Announces Guide for Appropriate Tapering or Discontinuation of Long-Term Opioid Use

The United States Department of Health and Human Services (HHS) has published a new guide for clinicians intended to provide guidelines for tapering or discontinuing long-term opioid use. The guide, titled *HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics*, covers important issues to consider when changing a patient's chronic pain therapy. The guide also lists issues to consider prior to making a change, when initiating the change, and as a patient's dosage is being tapered, including the need to treat symptoms of opioid withdrawal and provide behavioral health support.

"Care must be a patient-centered experience. We need to treat people with compassion, and emphasize personalized care tailored to the specific circumstances and unique needs

of each patient," said ADM Brett P. Giroir, MD, assistant secretary for health in a press release. "This Guide provides more resources for clinicians to best help patients achieve the dual goals of effective pain management and reduction in the risk for addiction."

FDA Releases Draft Best Practice Document for Postmarket Drug Surveillance

As part of FDA's efforts to enhance the efficiency of its postmarket drug safety surveillance, the agency has released a new best practices document, *Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff*. The draft document outlines FDA's approach for timely postmarket analyses of drugs and biologics, and includes a high-level overview of tools, methods, and signal detection and evaluation activities, using varied data sources, for drug safety. The goal is to provide a broader context and a general overview of ongoing efforts and commitments.

"Our best practices document incorporates the guiding principle that postmarket safety surveillance is a dynamic and constantly evolving field," FDA said in a statement announcing the document's release. "By using a risk-based approach, the FDA takes into account the nature of the drug, its potential adverse events, the intended population, and the potential for serious outcomes, as well as the impact on individuals and the overall potential impact on the health of the public."

The full draft document can be accessed at *https://www.fda.gov/media/130216/download*.

FDA Issues Revised Draft Guidance on Regulation of Homeopathic Products, Withdraws 1988 Compliance Policy Guide

FDA is taking two new steps to clarifying their approach to regulating drug products labeled as homeopathic: revising draft guidance previously published in 2017, and withdrawing the Compliance Policy Guide (CPG) 400.400 issued in 1988. These moves were announced in a statement published on the FDA website. Homeopathic products are often marketed as natural alternatives to approved prescription and nonprescription products and are widely available in the marketplace. Homeopathic products, however, are marketed without FDA review and may not meet modern standards for safety, effectivity, quality, and labeling. FDA uses a risk-based approach to monitor these products and to evaluate reports of adverse events.

The revisions to the 2017 draft guidance provide further information about FDA's approach. The guidance details a risk-based enforcement policy prioritizing certain categories of homeopathic products that could pose a higher risk to public health. These include products with particular ingredients and routes of administration, products for vulnerable populations, and products with significant quality issues. FDA has invited public comment on the guidance before it is finalized. The full guidance and instructions for providing comment are available in the *Federal Register* announcement.

CPG 400.400, Conditions Under which Homeopathic Drugs May be Marketed, is being withdrawn due to inconsistency with the agency's risk-based approach to regulatory and enforcement action and is therefore being withdrawn. Specifically, FDA states that it has encountered multiple issues with homeopathic drug products posing significant risk to patients, even though the products, as labeled, appeared to meet the conditions of CPG 400.400.

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

DEA is warning health care providers and other members of the public of another increase in fraudulent phone calls attempting to extort money. Though the tactics change regularly, the callers typically claim to represent DEA and provide either fake names and badge numbers, or the names of well-known senior officials with DEA. The scammers then threaten legal action, including arrest, against the victim unless large fines are paid by wire transfer. Most recently, the scammers appear to be spoofing a DEA number based out of Salt Lake City, UT, according to a DEA press release.

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 a legitimate investigation or legal action is always 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.

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A key component to this rule is the definition of an HW pharmaceutical, which is broken down into three questions:

1. Is it a pharmaceutical and not a medical or biological waste, which are managed separately?
2. Is it a solid waste?
3. Is it an HW that has a P or U listing or a characteristic?

The HW determination is a crucial, step-by-step procedure that helps facilitate proper disposal, which will be covered in the next newsletter. This determination is independent of the National Institute for Occupational Safety and Health's list and USP standards, yet it often complements them as they have toxicity criteria. Critical issues during EPA inspections involve waste determinations, record keeping, improper container management and disposal, and inadequate training.

USP Chapter <800> concerns itself with HDs throughout the entire post-manufacturing life cycle – from receipt on arrival and storage, through use and disposal. Unlike the EPA rule (codified and incorporated into Part 266, subpart P of Subtitle C of the Resource Conservation and Recovery Act (RCRA)), USP Chapter <800> is part of the compendium of standards related to compounding drugs along with USP Chapters <795>, <797>, and <825>. The goal of this series is to walk a registrant through the context of waste determination in regard to RCRA and USP Chapter <800> regulations from the pharmacist's standpoint. In the meantime, specific questions may be submitted to the TDEC office at solid .waste@tn.gov or by calling 615/532-0780.

Clarifications Given on New Single-Sheet DEA Order Form 222

Pharmacists have had questions about the new DEA 222 single-sheet order form since it has become available. Note that instructions are located on the back of the single form and should be reviewed completely before use.

If acting as a purchaser, the pharmacy will now "make a copy" and keep it for two years. The original form is sent to the supplier where it will be kept for two years. **Closely review PART 1. Purchaser Information, specifically line #5. Failure to add the signature of authority immediately after the signature (ie, attorney-in-fact, designated agent, secretary),** may cause the form to be sent back unfilled and delay the order.

If the pharmacy is acting as a supplier (ie, sending Schedule I or II medications back to a reverse distributor or selling to another provider or pharmacy), the top of the instruction form indicates the following: **"If you are not an ARCOS reporter, you are required to provide a copy of the executed order form to DEA (21 CFR 1305.13)."** To the best of the Board's knowledge, very few, if any, pharmacies would be Automation of Reports and Consolidated Orders System (ARCOS) reporters unless also holding a manufacturer, wholesaler/distributor, or outsourcer license. The DEA order form directs the registrant to email the copy to **dea.orderforms@usdoj.gov.** No fax option exists, as indicated in the DEA response link. If you prefer to send a copy of the form by regular mail, DEA Supervisory Diversion Investigator James Stevens informed that it may be sent to the following address:

Drug Enforcement Administration
Attn: Registration Section/DRR
PO Box 2639
Springfield, VA 22152-2639

According to Stevens, the triplicate DEA 222 forms are still valid until October 30, 2021. He also explained that the (old) triplicate DEA 222 forms are still processed the same way as before. Do you have additional questions? Review the following link and/or contact your local DEA office. Stevens indicated that registrants may call the Nashville Diversion Group phone number at 571/362-7674 or 615/736-2559 and follow the prompts. Please note that 615/736-2559 is being ported over and will not work for a few weeks.

Board Office Staff Delivers "The Take-Home Message"

The Board staff reminds registrants of the following regulations:

- Investigators are finding **aripiprazole oral solutions** on pharmacy shelves that have been opened and stored without marking a new date of expiration. The bottle indicates that the drug can only be used for six months after opening, but not beyond the original expiration date, if shorter than the six-month period. Also, **oxcarbazepine suspensions** only have a seven-week expiration date once the seal is broken.
- Pharmacies and pharmacists continue to be found in violation of not counseling. The Board has consistently disciplined registrants with a fine of $1,000 per violation (eg, lack of five patients counseled equals $5,000). Remember that all refills require an offer to counsel by pharmacy staff and the pharmacist must counsel "face-to-face" on new prescriptions. The patient may decline counseling on the new prescription, but this action must also be performed "face-to-face" to the pharmacist.
- Speaking of counseling, are pharmacists discussing antibiotics/antivirals-once mixed expiration dates, asthma/chronic obstructive pulmonary disease/allergy medications that expire when opened or the foil packs are opened, insulin when opened/kept in fridge/kept at room temperature, ophthalmic drops, lidocaine patches, etc?
- USP requirements for storage and packaging have been updated. Click here for more information.

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TPRN Provides Assistance to Pharmacy Registrants

If you need help or know an associate (pharmacist or pharmacy technician) who does, please contact Dr Baeteena Black, Tennessee Pharmacy Recovery Network (TPRN) program director, by phone at 615/256-3023 or by email at bblack@tnpharm.org. More information including the reporting form, is located on the TPRN website.

Report Theft or Significant Loss

Per Title 21, Code of Federal Regulations, 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 DEA Form 106 and may do so online via the DEA website. Questions? Please contact a diversion investigator at 571/362-7674 or Supervisory Diversion Investigator James N. Stevens at 571/362-7113. You shall also satisfy the Board regulation to immediately report theft or loss and may do so 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 **2020** meeting schedule is as follows:

- May 5-6
- July 14-15
- September 15-16
- December 1-2

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 – Public Member

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