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Board Office Discusses COVID-19 Waiver of Rules Updates

For updates regarding waiver of rules directed by Governor Bill Lee's executive orders, please continue to visit the Tennessee Board of Pharmacy website. Unless extended, the waivers/exceptions for face-to-face counseling and stocking automated dispensing machines in long-term care facilities by nursing staff expire on June 30, 2020.

TDEC Consultant Explains Waste Disposal Regarding COVID-19

(Part II of Ongoing Series)

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

In the midst of the coronavirus disease 2019 (COVID-19) crisis, TDEC answered many questions related to the proper disposal of the increased volume of sampled specimens occurring at certain point-of-care pharmacies approved by the federal government. One of the most recently searched topics related to COVID-19 is its waste management. Policy and guidance from the Environmental Protection Agency, Centers for Disease Control and Prevention (CDC), and Occupational Safety and Health Administration are all in agreement that COVID-19 medical waste still falls within current standard practices for regulated medical waste management, as opposed to hazardous waste management.

Medical waste transported directly to a state-permitted municipal landfill must be treated (eg, autoclaved, incinerated) to render it noninfectious, and must undergo a special waste evaluation to confirm treatment compliance. Typically, health care facilities, including pharmacies that offer services such as walk-in clinics, will utilize third-party waste service providers specializing in collection, transportation, and treatment of infectious waste that already have special waste certifications for medical wastes from the state of Tennessee (they often also handle hazardous and nonhazardous pharmaceutical waste). These service providers handle this new waste as regulated medical waste, which includes, but is not limited to, common medical wastes generated from influenza testing and other respiratory illnesses (nasal/throat/nasopharyngeal swabs, etc). Once the waste has been accepted by this third party, per the contractual Waste Acceptance Policy in place and proper packaging requirements, no additional action is needed by the health care facility.

Although there are no additional safeguards of concern pertaining to COVID-19 waste management, there are CDC interim infection prevention and control recommendations for patients with suspected/confirmed disease in health care settings. COVID-19-related waste and all other regulated medical wastes generated from health care facilities are subject to normal state medical waste regulations. New CDC guidance related to the disposal of waste associated with COVID-19 will be updated on the Division of Solid Waste Management Department's website when made available.

Board Office Staff Delivers the Take-Home Message

Board staff reminds registrants of the following regulations:

- Wash hands before performing duties such as counting tablets and compounding medications.
- Clean trays between counting medications. Residue is often left on the counting tray and may cause allergic reactions or other cross-contamination issues. Continuing to disregard such practice may result in violation of Tennessee Code Annotated §53-1-108: Drugs or devices deemed adulterated.
- Review United States Pharmacopeia (USP) Chapter <800> FAQs if working in a pharmacy that will **not** be compounding hazardous medications. It is advised to read number 2 and number 65 specifically regarding the scope of USP Chapter <800> and "final dosage forms."

Sterile Compounding Corner

A recent Food and Drug Administration (FDA) Form 483 inspection cited a pharmacy for the following:

- Failure to obtain a Certificate of Analysis (CofA) with proof of endotoxin testing for the active pharmaceutical ingredient (API) used.

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National Pharmacy Compliance News

June 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.

President Trump Signs Legislation Extending Schedule I Status for Fentanyl Analogues

A law to extend the Schedule I status of fentanyl analogues for another 15 months was signed into law by President Donald J. Trump on February 6, 2020. Synthetic fentanyl analogues, often illegally manufactured, are widely believed to be fueling the "third wave" of the opioid crisis, as detailed in the October 2019 issue of *Innovations*® (pages 8-11), which can be accessed through the Publications section of the National Association of Boards of Pharmacy®'s website.

In February 2018, Drug Enforcement Administration (DEA) issued a temporary order to establish fentanyl-related substances as Schedule I. The Temporary Reauthorization and Study of the Emergency Scheduling of Fentanyl Analogues Act extends the DEA order, which was set to expire on February 6, 2020. The bill requires the Government Accountability Office to produce a report within 12 months on the public health and safety effects of controlling fentanyl-related substances, according to *Homeland Preparedness News*.

Drug Overdose Deaths Related to Prescription Opioids Declined by 13% in 2018

Fatalities related to the use of prescription opioids declined by 13% in the United States during 2018, according to the 2019 National Drug Threat Assessment released by DEA. Despite this encouraging news, the report makes it clear that the opioid crisis continues at epidemic levels. Specifically, controlled prescription drugs remain a major factor in the record number of overdose deaths since 2017. Benzodiazepines and antidepressants were involved in an increasing number of overdose deaths.

Fentanyl and similar synthetic opioids also remain a major point of concern. Fentanyl maintained high availability through most of the US in 2018. Illegally manufactured versions of the powerful opioid continue to be smuggled into the US, primarily in the form of counterfeit pills made to look like prescription opioids and powder. Fentanyl remains the "primary driver" of the current opioid crisis, according to the report.

"Illicit drugs, and the criminal organizations that traffic them, continue to represent significant threats to public health, law enforcement, and national security in the United States," a DEA press release states. "As the National Drug Threat Assessment describes, the opioid threat continues at epidemic levels, affecting large portions of the United States."

Drug-Resistant Infections Are Increasing

A new report on antibiotic infections released by the Centers for Disease Control and Prevention (CDC) estimates more than 2.8 million antibiotic-resistant infections occur each year, and more than 35,000 Americans are dying annually as a result. While the report notes that prevention and infection control efforts in the US are working to reduce the number of infections and deaths caused by antibiotic-resistant germs, the number of people facing antibiotic resistance is still too high. "More action is needed to fully protect people," the report states.

The report lists 18 antibiotic-resistant bacteria and fungi and places them into three categories (urgent, serious, and concerning) based on clinical impact, economic impact, incidence, 10-year projection of incidence, transmissibility, availability of effective antibiotics, and barriers to prevention. It also highlights estimated infections and deaths since the last CDC report in 2013, aggressive actions taken, and gaps that are slowing progress.

The full report is available on the CDC website.

NASEM Report Recommends Framework for Opioid Prescribing Guidelines for Acute Pain

Contracted by Food and Drug Administration (FDA), a December 2019 report by the National Academies of Sciences, Engineering, and Medicine (NASEM) seeks to develop evidence-based clinical practice guidelines for prescribing opioids for acute pain. The report, *Framing Opioid Prescribing Guidelines for Acute Pain:*

Developing the Evidence, also develops a framework to evaluate existing guidelines, and recommends indications for which new evidence-based guidelines should be recommended.

As part of its work, NASEM examined existing opioid analgesic prescribing guidelines, identified where there were gaps in evidence, and outlined the type of research that will be needed to fill these gaps. NASEM also held a series of meetings and public workshops to engage a broad range of stakeholders who contributed expert knowledge on existing guidelines, and provided emerging evidence or identified specific policy issues related to the development and availability of opioid analgesic prescribing guidelines based on their specialties.

"We recognize the critical role that health care providers play in addressing the opioid crisis – both in reducing the rate of new addiction by decreasing unnecessary or inappropriate exposure to opioid analgesics, while still providing appropriate pain treatment to patients who have medical needs for these medicines," said Janet Woodcock, MD, director of FDA's Center for Drug Evaluation and Research in a statement. "However, there are still too many prescriptions written for opioid analgesics for durations of use longer than are appropriate for the medical need being addressed. The FDA's efforts to address the opioid crisis must focus on encouraging 'right size' prescribing of opioid pain medication as well as reducing the number of people unnecessarily exposed to opioids, while ensuring appropriate access to address the medical needs of patients experiencing pain severe enough to warrant treatment with opioids."

FDA will next consider the recommendations included in the report as part of the agency's efforts to implement the SUPPORT Act provision requiring the development of evidence-based opioid analgesic prescribing guidelines.

The report can be downloaded for free on the NASEM website.

New Research Shows Pharmacists Positively Impact Hospital Care Transitions

Patients who received focused attention from pharmacists during hospital stays expressed higher satisfaction, according to research presented at the American Society of Health-System Pharmacists Midyear Clinical Meeting and Exhibition. The study centered on the effect of pharmacists educating patients about medications as they transitioned out of hospital care. During the study, pharmacists reconciled patients' medications before discharge, talked with patients about the medications they were taking, and contacted them by phone after discharge to discuss their care.

Of the 1,728 patients included in the study, 414 received the full transition-of-care education protocol, including a follow-up pharmacist phone call. Those patients showed a 14.7% increase in the overall average mean score, as measured by the Hospital Consumer Assessment of Healthcare Providers and Systems survey, which assesses patients' perceptions of their care after discharge. A post hoc analysis also showed that 30-day readmission rates dropped from 17.3% to 12.4% when a post-discharge phone call was made to patients as a part of the study.

"Pharmacists play a multitude of vital roles for patients during a hospital stay, including comprehensive medication management and ensuring medication safety. Now, they can feel increasingly confident about their role in helping patients when transitioning from different levels of care. Our findings add to growing literature demonstrating that pharmacist involvement in hospital discharge improves outcomes and safety," said Katherine L. March, PharmD, BCPS, clinical pharmacy specialist at Methodist University Hospital in Memphis, TN, in a press release.

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- ◊ **Inspector Notes:** Check the CofA closely and obtain the correct API for sterile compounding whether compounding less than or more than 25 products in a batch. Investigators may view the compounding sterile preparation (CSP) as adulterated/insanitary.

- Failure to perform aseptic processing to mimic the worst-case, most challenging, and stressful conditions during the media fill testing process.
  - ◊ **Inspector Notes:** The facility compounds high-risk CSPs and believed that a high-risk process would be considered the most challenging and stressful. However, the agent indicated that the longer process and several different additives of preparing total parenteral nutrition (TPN) was the most challenging. Therefore, it is strongly suggested that if a pharmacy compounds both of these types of risk levels, it may be prudent to have staff perform a media fill test for both types of compounding. Use media instead of drug through the TPN machine, and use media for the high-risk process as well.
- Failure to monitor pressure differentials correctly and document.
- Failure to keep light fixtures sealed properly (lack of caulk or gasket).
- Failure to use a sterile disinfectant agent in the ISO Class 5 area.
  - ◊ **Inspector Notes:** Specifically, PREempt RTU is available in a sterile and nonsterile version and the nonsterile bottle was being used. Pharmacy staff must use sterile disinfectants/cleaning agents in ISO class areas and on sterile preparations/additives during transfer into the ISO class areas.

The agent also mentioned that pass-through(s), even from non-classified areas to classified areas, should be surface sampled. For additional FDA Form 483 inspections and FDA information regarding inspections, click here.

DEA Lessons Continue

During a joint investigation, Drug Enforcement Administration (DEA) diversion investigators cited a registrant for failure to follow certain Codes of Federal Regulations (CFRs). History continues to repeat itself as diversion investigators find registrants in violation. Please review the following CFRs and links.

Regarding complete and accurate records, see CFR §1304.21(a). Investigators performed a physical reconciliation drug audit using counts from the last controlled substance (CS) biennial or completed inventory. In this case, 10 drugs were chosen. All units were expected to be accounted for to the unit (ie, pill, capsule, filmtab). History proves that performing the minimum two-year CS count with no reconciliation fails to meet the "accurate" standard. It is strongly recommended to perform CS audits much more frequently so "complete and accurate records" may be proven. A reconciliation audit will require the registrant to find all inventory and invoices for any particular CS, including broken units, destroyed but still on premises (eg, Did the registrant count these in the CS inventory at the time of the audit?), and/or returned to reverse distributor units. Misplacing any of this information or forgetting that some inventory is kept in a different area of the pharmacy during the audit may cause the registrant to be in violation. Investigators indicated that whether showing an overage or shortage, the citation is considered with the same severity. It is strongly suggested that personnel, at any given time of day, know how to run the proper dispensing reports. Registrants have claimed that will-call prescriptions were not taken out of inventory until sold at point-of-sale. It is important for the registrant to know the system and get the correct reports printed, or again, the audit will not balance.

The Electronic Record Link

See CFR §1305.22(g). A situation occurred where one of the pharmacy's drug wholesalers was acquired by another wholesaler. The DEA investigator directed the pharmacist to navigate to the computer link that is created in the Controlled Substance Ordering System (CSOS) when an order is received and accepted by physical input of acceptance. The pharmacist was unable to retrieve the wholesaler files that were no longer available by that route. The files were retrievable, but not by the electronic link requested by the DEA investigator. Therefore, the pharmacy was cited. It is strongly suggested to find a solution to this issue immediately.

Lack of Authorization 'Changes' to Apply/ Renew Registrations With DEA

See CFR §1301.13(j):

> Each application, attachment, or other document filed as part of an application, shall be signed by the applicant, if an individual; by a partner of the applicant, if a partnership; or by an officer of the applicant, if a corporation, corporate division, association, trust or other entity.

Therefore, if the designated individual, partner, or officer is no longer valid (eg, retired, terminated), DEA must be notified so that the new applicant can be authorized to give authority for others to act as power of attorney (POA), etc. If this action is overlooked, the pharmacist-in-charge or others using CSOS are not considered officers, or lack POA authority from an acting officer of the company. Therefore, a violation may ensue.

Disposal of CS

See CFR §1317 and DEA Form 41 (used in institutional pharmacy practice). Also be aware of Board rule 1140-03-.11, which prohibits self-disposal other than by a Board-approved agent or reverse distributor. Board rule 1140-03-.03(8)(b) also allows destruction if an entity obtains a registration with DEA as a collector, per CFR §1317.40.

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:

- July 14-15
- September 15-16
- December 1-2

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