June 2018

Tennessee Board of Pharmacy News

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TDH Requests Critical Review of Inventory Regarding Possible Risk of Growth in Pre-Filled Syringes at Health Care Facilities

The Tennessee Department of Health (TDH) is investigating a cluster of *Serratia marcescens* bloodstream infections that is part of a multistate outbreak linked to PosiFlush™ Pre-Filled Heparin Lock Flush Syringes and Pre-Filled Normal Saline Syringes manufactured by BD. During the investigation, it became clear that not all facilities were maintaining accurate inventory records (eg, not updating product and manufacturer information to reflect current usage). Up-to-date inventory records are critical to link an outbreak to particular products and/or lot numbers and are crucial for patient safety. Please review internal processes to ensure that inventory is accurate. BD issued a voluntary product recall on April 20, 2018. Clinicians and health care facilities that use these flush products manufactured by BD should consider finding an alternate supply, taking into consideration the known risk of infection with blood-borne pathogens when products are compounded or substituted unsafely.

Board Staff Delivers 'The Take-Home Message'

Tennessee Board of Pharmacy office staff and investigators would like to remind registrants of the following regulations. As always, registrants are encouraged to reach out to their investigators and the Board office staff with questions or concerns.

Compounding Sterile Preparations – Message of Extreme Importance

Quality assurance (QA) and quality control (QC) must be top priority for compounding sterile preparations (CSPs). Pharmacy management is strongly encouraged to designate an employee and/or team of employees (depending on the size of the organization and the level of CSPs) dedicated solely to QA/QC. Investigators are finding that detailed United States Pharmacopeia (USP) regulations such as glove finger sampling, media fills, assessments regarding aseptic technique, cleaning, and didactic testing with documentation are not being completed on time each year. Additionally, standard operating procedures for these areas of expertise are nonexistent, not updated or reviewed timely, and not followed even when the procedure exists. Because of these discrepancies, discipline from the Board has included civil penalties, additional monitoring, and revocation of the sterile compounding modifier. With the proposed rules of USP Chapters <797> and <800>, which increase the frequency of current regulation testing and assessment, **a dedicated team to comply with these regulations is essential and should be considered immediately.**

Compounding 'Nonsterile' HD Preparations – Preparing for December 1, 2019

More registrants are starting to ask about requirements for compounding nonsterile hazardous drug (HD) preparations, since certain drugs such as hormones and seizure and antifungal medications (just to name a few) are on the National Institute for Occupational Safety and Health list and will therefore follow USP Chapter <800> regulations.

Some basic requirements are as follows:

The compounding room requirement in USP Chapter <800> refers to the proposed rules of USP Chapter <797> as stated: "Due to the difficulty of cleaning HD contamination from surfaces, the architectural finish requirements (e.g., smooth, seamless, or impervious surfaces) described in *Pharmaceutical Compounding—Sterile Preparations* <797> also apply to nonsterile compounding areas." Therefore:

- An enclosed, separate room with walls, ceiling, and a door will be required.
- The room will have cleanable, smooth, impervious surfaces, etc.
- The room must have a negative pressure of 0.01 to 0.03 inches of water column relevant to the adjacent area.
- The primary engineering control (PEC) must always stay on if it is the source of the negative pressure for the room and will either be vented externally to the outside or have use of a redundant high-efficiency particulate air filter system.
- A sink for hand washing will be located at least one meter away from the PEC.

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National Pharmacy Compliance News

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NABPF
National Association of Boards of Pharmacy Foundation

FDA Requires Labeling Update on Opioid-Containing Cough and Cold Medicines

In January 2018, Food and Drug Administration (FDA) announced that the agency is requiring safety labeling changes to limit the use of prescription opioid cough and cold medicines containing codeine or hydrocodone in children younger than 18 years old because the serious risks of these medicines outweigh their potential benefits in this population. After safety labeling changes are made, these products will no longer be indicated for use to treat cough in any pediatric population and will be labeled for use only in adults aged 18 years and older. In addition, labeling for the medications will be updated with additional safety information for adult use. This update will include an expanded Boxed Warning notifying consumers about the risks of misuse, abuse, addiction, overdose and death, and slowed or difficult breathing that can result from exposure to codeine or hydrocodone. Additional information is available in FDA's news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592109.htm.*

Latest NDTA Shows Opioids Pose Significant Impact to Public Health

Drug Enforcement Administration (DEA) indicates a significant shift in the overall drug threat reported by law enforcement over the last 10 years with opioids (including controlled prescription drugs, fentanyl and other synthetic opioids, and heroin) reaching epidemic levels and impacting significant portions of the United States. According to the *2017 National Drug Threat Assessment (NDTA)* report, every year since 2001, controlled prescription drugs, specifically opioid analgesics, have been linked to the largest number of overdose deaths of any illicit drug class, outpacing those for cocaine and heroin combined.

From 2007 to 2010, responses to the National Drug Threat Survey indicate cocaine was the greatest national drug threat, followed by a significant decline as the heroin threat increased between 2010 and 2016, eventually becoming the greatest national drug threat in 2015.

Illicit fentanyl and other synthetic opioids, primarily sourced from China and Mexico and shipped directly to the US or trafficked overland via Mexico and Canada, are contributing factors in the current synthetic opioid overdose epidemic. Traffickers in the US usually mix fentanyl into heroin products and sometimes other illicit drugs or press it into counterfeit prescription pills, often without users' awareness, which leads to overdose incidents, notes the *2017 NDTA.* To access the *2017 NDTA,* visit *www.dea.gov/divisions/hq/2017/hq102317.shtml.*

FDA Recognizes Eight European Drug Regulatory Authorities Capable of Conducting Inspections

FDA has determined it will recognize eight European drug regulatory authorities as capable of conducting inspections of manufacturing facilities that meet FDA requirements. The eight regulatory authorities found to be capable are those located in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom. This achievement marks an important milestone to successful implementation and operationalization of the amended Pharmaceutical Annex to the 1998 US-European Union (EU) Mutual Recognition Agreement, which enables US and EU regulators to utilize each other's good manufacturing practice inspections of pharmaceutical manufacturing facilities. "By partnering with these countries, we can create greater efficiencies and better fulfill our public health goals, relying on the expertise of our colleagues and refocusing our resources on inspections in higher risk countries," said FDA Commissioner Scott Gottlieb, MD, in a news release located at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm583057.htm.*

Incorrect Use of Insulin Pens at Home Can Cause Severe Hyperglycemia

The National Coordinating Council for Medication Error Reporting and Prevention has issued an alert on the incorrect use of insulin pens at home causing severe hyperglycemia in patients, including one reported fatality. The Institute for Safe Medication Practices National Medication Errors Reporting Program has received several reports of patients who failed to remove the inner cover of standard insulin pen needles prior to administering insulin. In the latest such event, a patient with type 1 diabetes did not know to remove the standard needle cover and was unaware she was using the pen incorrectly and had not been receiving any of the insulin doses; the patient developed diabetic ketoacidosis as a result and died.

Since insulin pens may differ between pens with automatic needle retraction devices and those with standard needle covers that require manual removal before administering insulin, it is imperative that removal of

needle covers be explained to patients who are issued standard insulin pens during their diabetes education. Pharmacists should verify that a patient understands the appropriate administration technique whenever pens and insulin needles are dispensed, notes the alert, which can be viewed at *www.nccmerp.org/sites/default/files/nan-20171012.pdf.*

FDA Advises on Opioid Addiction Medications and Benzodiazepines

Opioid addiction medications – buprenorphine and methadone – should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), advises FDA. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care providers can reduce these risks, notes a safety alert. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for minimizing the use of medication-assisted treatment drugs and benzodiazepines together.

Health care providers should take several actions and precautions and should develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. Additional information may be found at *www.fda.gov/Drugs/DrugSafety/ucm575307.htm.*

Only About 3% of Pharmacies and Other Entities Voluntarily Maintain a Prescription Drug Disposal Bin, GAO Reports

In response to the US Senate Judiciary Committee's request to review DEA's requirements for authorized collectors of prescription drugs and participation rates, the US Government Accountability Office (GAO) found that only about 3% of pharmacies and other entities eligible to collect unused prescription drugs for disposal have volunteered to do so. As of April 2017, 2,233 of the 89,550 eligible entities had registered with DEA to use disposal bins to collect unused prescription drugs. The majority of the authorized collectors were pharmacies, followed by hospitals or clinics. Factors that affected voluntary participation in maintaining disposal bins for the public included cost, uncertainty of proper implementation, and participation in other drug disposal efforts.

GAO found that participation rates varied by state. Connecticut, Missouri, and Maine had the lowest participation rates as of April 2017. North Dakota had the highest participation rate, followed by Alaska. The report, *Preventing Drug Abuse: Low Participation by Pharmacies and Other Entities as Voluntary Collectors of Unused Prescription Drugs,* is located on the GAO website at *www.gao.gov/products/GAO-18-25.*

One in Five Drivers Uses a Prescription Drug That Can Impair Driving Despite Receiving Warnings

A new study that analyzes data from the National Roadside Survey of Alcohol and Drug Use, 2013-2014, found that one in five drivers has taken prescription drugs that could impair driving despite having been warned about the risks. The authors of the study, "Receipt of Warnings Regarding Potentially Impairing Prescription Medications and Associated Risk Perceptions in a National Sample of U.S. Drivers," indicate that of the 7,405 random drivers who completed the prescription drug portion of the survey, almost 20% reported recent use (within the past two days) of a potentially impairing prescription drug.

Compared to people who were prescribed antidepressants (62.6%) and stimulants (57.7%), those who were prescribed sedatives (85.8%) and narcotics (85.1%) were most likely to report receiving warnings about the potential of these drugs to affect driving from their health care provider, pharmacy staff, or medication label.

Several European countries have introduced color-coded categories (ie, no, minor, moderate, and major influence on driving) to drug labeling to increase patient safety. Beyond labeling, the authors of the study note it is important that health care providers consistently communicate with patients about their medications' driving-related risks. The study was published online in the *Journal of Studies on Alcohol and Drugs* on October 31, 2017, and can be found at *https://doi.org/10.15288/jsad.2017.78.805.*

PTCB CPhT Program Earns Accreditation From the American National Standards Institute

The Pharmacy Technician Certification Board's (PTCB's) Certified Pharmacy Technician (CPhT) Program has earned accreditation from the American National Standards Institute (ANSI) Personnel Certification Accreditation Program through December 2022. ANSI is the first personnel certification accreditation body in the US to meet internationally accepted practices for accreditation. "We were the first pharmacy technician certification program to receive accreditation by the National Commission for Certifying Agencies (NCCA) in 2006, and now we are the first and only program to achieve ANSI accreditation," said PTCB Executive Director and Chief Executive Officer William Schimmel in a news release. More details are available in PTCB's December 18, 2017 news release, which can be found in the News Room section of *www.ptcb.org.*

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Basic Nonsterile Compounding

Investigators are finding that nonsterile compounding pharmacies are lacking in record-keeping documentation. It is expected that a record be kept of the following for each component in the compound (see USP Chapter <795> for additional information):

- Name of component, strength, and dosage
- Source(s), lot(s)/batch(es), and quantity used of each
- Total quantity compounded
- Expiration date (if component was manufactured)
- Beyond-use date (BUD) (if component was compounded)
- Master formula (with calculations)
- Name of person who prepared, checked, and performed the QC
- Record linking final preparation to the patient's prescription (or other control if needed for recall purposes)

Investigators continue to find either no BUD or a date beyond use for preparations still in stock to be dispensed. Pharmacists are strongly encouraged to check these products immediately and remove any out-of-date products. A procedure to include these drugs in the expiration date removal process is strongly suggested.

New Applications for Pharmacy Technicians to Be Completed Online Only

The Board is no longer accepting paper pharmacy technician applications for new applicants. Applicants must complete the registration application online. However, technicians renewing their registration may continue to apply by mail.

Schedule II CS With Diagnosis of Obesity and Weight Reduction Conflicts With State Statute

As a new federally controlled substance (CS) Schedule II medication, Evekeo® (amphetamine sulfate), comes to market with an indication by Food and Drug Administration (FDA) for weight reduction, be advised of **Tennessee Code Annotated 53-10-109. Prescription of certain stimulants for weight control prohibited,** which states:

> (a) No amphetamine classified as a Schedule II stimulant under § 39-17-408(d) shall be prescribed for the purpose of assisting a patient to gain or lose weight.
>
> (b) A violation of this section is a ground for license denial, suspension or revocation.

Note that Vyvanse® (lisdexamfetamine) has an indication for binge eating. There is no mention of weight loss or reduction. In law, the strictest rule applies.

Naloxone Information, Collaborative Pharmacy Practice Agreement, and Training Are Available

TDH has dedicated a web page to help educate and combat the overdose of opioid medications. This page includes a dashboard to help navigate to a collaborative pharmacy practice agreement that is to be completed and kept in the pharmacy, a training module regarding the use of naloxone, and other valuable information for health care professionals and the general public. Contact TDH or the Board for additional information.

FDA Gives Guidance on Proper Drug Disposal

As more questions arise on the suggested avenues for safe disposal of medications, FDA has released information including the following:

- How to dispose of unused/expired medicine
  - ◊ Medicine take-back options
  - ◊ Disposal in the household trash
  - ◊ Flushing certain potentially dangerous medicines in the toilet
- Impact of flushing medicines on the environment
- List of medicines recommended for disposal by flushing
- Medication disposal questions and answers

Please visit FDA's web page on drug disposal for more detailed information.

DEA Tip Regarding the Power of Attorney

Dr Terry Grinder, lead investigator for the Board, has received information from Drug Enforcement Administration (DEA) indicating that all former employees acting as power of attorney and any previous pharmacist-in-charge (PIC) acting as power of attorney must be revoked. The new PIC then issues new power of attorney status to the new employees needing the requirement to order Schedule II CS. The change in the power of attorney also impacts the Controlled Substance Ordering System (CSOS). Therefore, the CSOS Help Desk must be contacted for assistance with the updates.

DEA's order for power of attorney and revocation action is available at *https://www.deadiversion.usdoj.gov/21cfr/cfr/1305/1305_05.htm.* CSOS may be accessed at *https://www.deaecom.gov.*

TennCare Changes to the Coverage of Opioids

Effective January 16, 2018, TennCare implemented an edit on agents in the short-acting and long-acting narcotics classes of the Preferred Drug List that impacts all first-time and non-chronic opioid users. According to the Tennessee Pharmacists Association, TennCare has issued two notices with the following effective dates:

- **Effective May 7, 2018,** TennCare enrollees who are residents in Medicaid-certified nursing facilities and intermediate care facilities and receive their medications through the TennCare pharmacy benefit may also receive coverage for up to a 45-day supply of opioids, not to exceed 40 morphine milligram equivalents per day in a 90-day period, with prior authorization.

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- **Effective July 1, 2018,** all pharmacies participating in the TennCare or CoverKids pharmacy program must have a valid TennCare-issued Medicaid ID.

For more information, view the pharmacy provider notice or visit the TennCare Opioid Strategy web page.

Governor Signs Public Chapter Regarding Dispensing During a Disaster

Governor Bill Haslam signed Public Chapter 615, which allows a pharmacist in Tennessee to dispense dosage units up to the amount needed to secure a valid prescription from the patient's prescriber, not to exceed a 20-day supply, during a disaster. **Effective July 1, 2018,** the law authorizes the pharmacist to use professional judgment in determining a legitimate source for the prescription information, such as a prescription label, a verbal medical or prescription order, or "any other means determined to be legitimate in the professional judgment of the pharmacist." The complete language for Public Chapter 615 may be viewed here.

New Regulations to Be Discussed

Be advised to view the following regulations regarding pharmacy practice, which Governor Haslam recently signed into Public Chapter. More details will be included in the September *Newsletter.*

- Pharmacy Benefits Manager (PBM) Anti-Gag Clause (Public Chapter 838)
- Partial Fill of CS (Including Schedule IIs) (Public Chapter 1007)
- Gabapentin Scheduled by Tennessee as Schedule V (Public Chapter 1040)
- TN Together Opioid Reform regarding dispenser check of the Controlled Substance Monitoring Database (CSMD) and more (Public Chapter 1039)

TPRN Provides Assistance to Pharmacy Registrants

If you need help or know an associate who does, please contact Dr Baeteena Black, Tennessee Pharmacists Recovery Network (TPRN) program director, by phone at 615/256-3023 or by email at bblack@tnpharm.org.

Information (including the reporting form) is located at the Tennessee Pharmacists Association website.

Tennessee DEA Office Gives Guidance for Reporting Theft or 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 a DEA Form 106,** available online via the DEA website. If you have questions, please contact DEA. You may also satisfy the Board regulation to report 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 **2018** meeting schedule is listed as follows:

- July 17-18
- September 11-12
- December 3 (one-day meeting only)

Tennessee Board of Pharmacy Members

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Dr Debra Wilson – Vice President
Dr Rissa Pryse – Board Member
Dr Katy Wright – Board Member
Dr James "Adam" Rodgers – Board Member
Dr Kevin Eidson – Board Member
Mrs Lisa Tittle – Public Board Member

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