March 2019

Tennessee Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Board Notice: The May Tennessee Board of Pharmacy meeting dates have changed to May 8 and 9.

Board Office Reminds Registrants of New Laws Effective January 1

Already into the first quarter of 2019, the Board office is reminding registrants of laws that became effective January 1, 2019.

Refer to the September 2018 *Tennessee Board of Pharmacy Newsletter* for specifics regarding Public Chapter (PC) 1039, which establishes rules on the partial fill of opioids where applicable and ICD-10 codes that are mandatory when applicable; and PC 1007, which establishes rules on the partial fill of Schedule II controlled substances (CS) on request by the patient or prescribing practitioner as applicable. Refer to the December 2018 *Newsletter* regarding PC 675, which establishes rules that any registrant handling opioids must inform employees of the means to report suspected abuse or diversion.

Board Office Staff Delivers the Take-Home Message

Board staff reminds registrants of the following regulations.

What should be readily retrievable for the Board investigator during an inspection?

Investigators are finding that many pharmacy managers are keeping a compliance binder or box for investigator review. Provided it is kept up to date, this is a great way to move the inspection along in an expedient manner. Those items include, but are not limited to:

- The most recent biennial Drug Enforcement Administration (DEA) CS inventory. (Check to see if the dosage form is included with each drug in the inventory documentation, ie, tablet, capsule, liquid, injection. See Code of Federal Regulations (CFR) 1304.11 for requirements.) Remember to separate the Schedule II biennial inventory list from the Schedule III through Schedule V list. Investigators continue to find that the inventory record is reported but not separated. Investigators also continue to find this inventory record without the designation of "before beginning of day" or "after end of day," or in cases of 24-hour pharmacies, without a time completed. For a proper count, no CS should be dispensed until the inventory is completed so that the numbers are accurate. Do not forget to sign and date these reports.
- Control of the CS inventory at all times. If DEA or Board investigators perform an audit and the counts are off significantly, that is a problem. It is strongly suggested to run random audits throughout the year on different CS medications, especially the high volume/high theft drugs. Refer to page four of the December 2014 *Newsletter* for a sample of an audit worksheet.
- A technician registry (This is simply a typed or written list of the pharmacy technicians and should not include interns or pharmacists.)
- Technician affidavits: Investigators continually are being told that the affidavit is in the employee file, which is locked in a filing cabinet and unavailable for review.
- Schedule II invoices filed separately from all other invoices and Schedule III through Schedule V invoices separated from non-controlled invoices or marked as required, if filing together.
- Prescription records should be either readily retrievable by electronic means, if applicable, or if stored, readily retrievable and in order as hard copies.
- Prescription directions (often written as "sig") that are followed as written in strict conformity by the prescribing practitioner. As an example, an investigator observed a prescription recorded as 1 PO Q4-6H PRNP, which was put into the computer and printed on the prescription label for oxycodone/APAP tablets as, "Take one tablet every four to six hours." Obviously, this is an error, but even more disturbing is that it gives the direction to stay on a schedule of opioid use instead of **as needed** for the pain.

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National Pharmacy Compliance News

March 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.

Final Guidance Documents Address FDA Policies Related to DSCSA

To help ensure that prescription drug products are identified and traced properly as they move through the supply chain in compliance with federal law, Food and Drug Administration (FDA) issued two final guidance documents related to the Drug Supply Chain Security Act (DSCSA). Released on September 19, 2018, the following final guidance documents will help ensure there are no disruptions in the supply chain as manufacturers and repackagers include a product identifier on the package or case.

- *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy* addresses industry-wide readiness for implementation of the new requirements aimed at enhancing the security of the drug supply chain. As the agency continues to work with stakeholders to ensure proper implementation of the law, this guidance document specifies FDA's one-year delay in enforcing the manufacturers' requirement to include a product identifier on the package or case of products to November 27, 2018.
- *Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier* outlines the circumstances in which packages and cases of product that were in the supply chain before the November 2018 product identifier requirement are considered grandfathered. The grandfathering policy describes the circumstances under which products already in the supply chain can remain in distribution without being relabeled with a product identifier.

The final guidance documents can be found at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm621095.htm.*

First FDA-Approved Drug Containing Extract From Cannabis Plant to Be Placed in Schedule V

On September 27, 2018, the United States Department of Justice and Drug Enforcement Administration (DEA) announced that Epidiolex® – which contains cannabidiol, a chemical constituent of the cannabis plant, and is the first FDA-approved drug to contain a purified extract from the plant – is being placed in Schedule V of the Controlled Substances Act. FDA approved Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older on June 25, 2018. Additional information is available in the announcement at *www.dea.gov/press-releases/2018/09/27/fda-approved-drug-epidiolex-placed-schedule-v-controlled-substance-act.*

ASHP Guidelines Provide Recommendations for Preventing Patient Harm From Medication Errors

New guidelines from the American Society of Health-System Pharmacists (ASHP) describe opportunities for pharmacists on interprofessional teams to prevent errors across the continuum of care in hospitals and health systems. The "ASHP Guidelines on Preventing Medication Errors in Hospitals" are intended to apply to the acute care setting because of the special collaborative processes established in this setting. However, these guidelines may be applicable to practice settings outside of the acute care setting, especially in health systems.

Further, the ASHP press release notes that the guidelines address numerous areas in the medication-use process where errors may occur, including: patient admission; selection and procurement; storage; ordering, transcribing, and reviewing; preparation; dispensing; administration; monitoring; evaluation; and patient discharge. Published in the October 1, 2018 issue of the *American Journal of Health-System Pharmacy,* the guidelines are available at *www.ajhp.org/content/75/19/1493.* ASHP's October 2, 2018 press release can be found in the News section at *www.ashp.org.*

FDA's Final Guidance Documents Address Compounding and Repackaging of Radiopharmaceuticals

On September 26, 2018, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities.* In this final guidance for industry, FDA sets forth its policy regarding compounding and repackaging of radiopharmaceuticals for human use by entities that are registered with FDA as outsourcing facilities. This guidance describes how FDA generally intends to apply section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to radiopharmaceuticals compounded by outsourcing facilities.

In addition, this guidance describes the conditions under which FDA generally does not intend to take action for violations of certain provisions of the FD&C Act when an outsourcing facility repackages radiopharmaceuticals, according to the *Federal Register* notice at *www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20901.pdf.*

At the same time, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities.* This guidance sets forth FDA's policy regarding compounding and repackaging of radiopharmaceuticals for human use by state-licensed nuclear pharmacies, federal facilities, and other entities that hold a radioactive materials license for medical use issued by the Nuclear Regulatory Commission or by an Agreement State. Because such radiopharmaceuticals are not eligible for exemptions from provisions of the FD&C Act related to the production of drugs, FDA is issuing this guidance to describe the conditions under which it generally does not intend to take action for violations of certain provisions of the FD&C Act when these entities compound or repackage radiopharmaceuticals. More details are available in the *Federal Register* notice at *www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20902.pdf.*

Pharmacy Toolkit Encourages Conversations With Patients About Prescription Opioids

In collaboration with its pharmacy partners and several state pharmacy associations, Allied Against Opioid Abuse (AAOA) developed a Pharmacy Toolkit to help pharmacists engage and educate patients about the safe use, storage, and disposal of pain medicines. The AAOA Pharmacy Toolkit includes resources to help pharmacists raise awareness among patients about their rights, risks, and responsibilities associated with prescription opioids. These resources include: a pharmacy display, patient handout, patient engagement guide, tips for talking with patients and caregivers, prescriber engagement guide, safe storage and disposal training, and social graphics. To learn more about the Pharmacy Toolkit and to obtain these resources, visit AAOA's website at *https://againstopioidabuse.org.*

Biosimilars Added to FIP's Policy on Pharmacists' Right to Substitute a Medication

To account for the emergence of biological medicines and their biosimilars onto the medical landscape, the International Pharmaceutical Federation (FIP) has added biosimilars to its policy on pharmacists' right to substitute one medicine for another. The revised Statement of Policy titled "Pharmacist's authority in pharmaceutical product selection: therapeutic interchange and substitution" includes the core principles of the original statement and the following:

- generic substitution is recommended as part of the pharmacist's dispensing role;
- pharmacists should be provided with bioavailability data by regulatory authorities and manufacturers; and
- a medicine should only be substituted with a product containing a different active ingredient in agreement with the prescriber.

According to FIP's October 2, 2018 press release, the use of generic names is still encouraged, but the revised statement gives focus to the use of international nonproprietary names. The full Statement of Policy and press release are available at *www.fip.org* in their respective sections.

FDA Offers CE Course on Reducing Hypoglycemic Events in Patients With Type 2 Diabetes

FDA is offering a free, one-hour continuing education (CE) course for health care providers (physicians, pharmacists, nurses, and others) about the reduction of hypoglycemic events in patients with Type 2 diabetes. The course, *Leveraging Health Literacy and Patient Preferences to Reduce Hypoglycemic Events in Patients with Type 2 Diabetes,* will describe the prevalence of hypoglycemic events and identify risk factors leading to an event. Available for credit through October 31, 2020, this course will introduce methods of assessing health literacy and numeracy of patients and caregivers; review effective ways to incorporate patient preferences into care plans; and list action steps to reduce the likelihood of a hypoglycemic event for high-risk patients. To participate in this CE course, visit *http://fdapasediabetes.e-paga.com.*

The FDA Center for Drug Evaluation and Research (CDER) is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). This program meets the criteria for one contact hour (0.1 CEU) of CPE credit. The ACPE Universal Activity Number for this knowledge-based activity is 0453-9999-17-449-H01-P. Further, FDA's CDERLearn in the CDER offers a variety of learning opportunities, which can be found at *www.fda.gov/Training/ForHealthProfessionals/ucm545645.htm.*

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- A dispensing log that documents all refills as being true and correct should be signed by each pharmacist working that day, or a signed report that attests to the same should be on file for review.
- Do not forget your Combat Methamphetamine Epidemic Act responsibilities if you are selling pseudoephedrine over the counter. Investigators are finding expired certifications, which are required to be renewed annually.

Sterile Compounding Corner

Investigators continue to see violations regarding aseptic technique. The following are important reminders to ensure compliance.

- Keep your head out of the flow hood. Unlike biological safety cabinets (BSCs), which are much harder to get one's head and torso into, laminar airflow work systems are generally open and allow for much easier access to the deck and "first air." Investigators continually observe compounding staff breaking the plane while preparing a compounding sterile preparation (CSP) or when cleaning toward the back of the primary engineering control (PEC). Some issues arise from not being tall enough or not having long enough arms to easily reach these areas. However, leaning in is not acceptable. A cleanable step stool or chair may be helpful. An extended handle handwiper may also be used, if needed and maintained properly, to reach the back areas. Managers are encouraged to video their personnel cleaning the PEC and preparing CSPs. In this manner, the employee can observe from a side view how far he or she is leaning in and how much of the head/body is also literally inside the PEC. A picture or video is truly worth a thousand words.
- Proper gloving is essential to aseptic technique. This action includes a sterile, powder-free glove that has enough elasticity, strength, and length at the bottom of the glove to properly cover the hand and hold tightly around the wrist and over the sleeve. Investigators continue to find ill-fitting gloves that roll at the bottom, which makes it very difficult to don these gloves. This type of glove could cause a failure with exposure to bare skin or a fold in the glove that harbors a bioburden since the sterile alcohol may not get to the part of the glove underneath the fold. Be sure to note the instructional illustrations on the cover of the package of gloves that show how to don them properly.
- Cleaning behind the PEC is required. Older design teams installed BSCs and other non-movable PECs against a wall that is too difficult to reach to clean appropriately. Either the PEC must be built as part of the room so that the walls are all cleanable, or other measures must be taken to get the back wall cleaned when scheduled. If building the PEC into the wall hinders flow or causes other mechanical issues, then the PEC must be moved out from the wall, or the room will have to be redesigned to meet the requirement.
- Current United States Pharmacopeia (USP) Chapter <797> guidelines do not require a smoke study to be videoed when one is performed. However, a video shows that the proper air flow occurs and helps to prove that the equipment is not hindering flow, etc.
- Media Fills, **which must be placed in an incubator,** are very useful in determining proper aseptic technique. USP Chapter <797> indicates that the most difficult process should be used for the media fill challenge. Therefore, if an automated compounding device, such as a repeater pump or total parenteral nutrition machine is utilized, this may be the more difficult challenge. If compounding a high-risk preparation, the high-risk procedure with sterilization will most likely be the most difficult challenge.
- Spraying items with sterile isopropyl alcohol (sIPA) and moving the items into the PEC is not acceptable. Without wiping the vial or other apparatus, the bottom and sides are not being sanitized. Also, the proper dwell/contact time must be utilized before moving the items into the PEC.
- Quick, "boogie 'till you just can't boogie no more," types of movements may be fun on the dance floor, but they are not best practice in a cleanroom environment. The use of slow and steady movements will help decrease turbulence.
- Many of us were taught to get the trash out of the PEC and keep it clutter free. However, the in-and-out movement has been studied, and now best practice is indicated as working from one side to the other, leaving the syringe and other wrappers to the side of the direct compounding area, but inside the PEC until the preparation is complete. Make sure the trash does not impede first air, and note the following procedure:
  - ◊ Have all product for the preparation loaded inside the PEC at one time or as few times as possible. **First air must not be impeded. Dynamic testing during PEC certification is a suggested time to prove the greatest load of a CSP to meet particle counts and all other requirements.**
  - ◊ Keep your hands inside the PEC as much as possible while making the preparation.
  - ◊ Throw the trash away once the product is completed.
  - ◊ The less movement in-and-out, the better.

On a final note, investigators continually observe employees spraying their sterile gloves with sIPA and then flapping their hands in the air in a quick, jerky motion, trying to decrease the time it takes to dry the gloves. Once again, this action may cause turbulent air and move particles. Best practice is

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to slow down and continue to rub hands together until dried. The sIPA will dry and should dwell the appropriate amount of time before compounding begins. Slow and steady still wins the race.

Board Members and Staff Welcome Investigators Golden and Beckham to Team Tennessee

With goals to inspect sterile compounding pharmacies in a yearly benchmark, the Board welcomes newly hired investigators Rita Davis Golden and Patricia Beckham, both pharmacists with sterile compounding background experience. (More about Investigator Beckham will be featured in the June *Newsletter*.)

As the featured investigator for this *Newsletter,* Dr Rita Davis Golden has practiced in Tennessee since 1982. She obtained institutional experience in Nashville, TN, with Baptist Hospital, retail experience with Eckerd Drug, sterile compounding experience with Maury Regional Hospital, additional nonsterile/sterile compounding experience with Atrium Pharmacy, and long-term care experience with Network Healthcare in Franklin, TN.

A University of Tennessee College of Pharmacy graduate, Dr Golden's experience includes training at the Professional Compounding Centers of America facility in nonsterile compounding. She has trained pharmacy staff on the QS/1 pharmacy management system and the DocuTrack system, and she also maintained a training manual.

Dr Golden continues to be a member of the Tennessee Pharmacists Association and the Tennessee Society of Long-Term Care Pharmacists.

As an active, attending member of the Church of the City in Franklin, she enjoys volunteering for Kid City and Cracked Pot Sunday school activities. She continues to volunteer at Gentry Educational Foundation where she tutors underprivileged children, GraceWorks Ministries, and Deer Run's Christian retreat.

Residing in Franklin, Dr Golden enjoys spending time with her family, including her two sons and two grandsons.

TPRN Provides Assistance to Pharmacy Registrants

If you need help or know an associate 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.

Tennessee DEA Office Gives Guidance for Reporting Theft or Loss

Per Title 21, CFR, 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. If you have questions, please contact a diversion investigator at 615/736-2559 or Supervisory Diversion Investigator James N. Stevens at 615/736-2112. You shall also satisfy the Board regulation to immediately report theft or loss by sending a copy to Dr Terry Grinder at terry.grinder@tn.gov.

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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:

- March 12-13
- May 8-9
- 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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