March 2021

Tennessee Board of Pharmacy News

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Pharmacists Question CS Electronic Prescriptions Requirement

The Tennessee Board of Pharmacy Executive Director Reginald "Reggie" Dilliard, DPh, continues to receive questions regarding Tennessee Code Annotated 63-1-160, which requires Tennessee prescribing practitioners to electronically prescribe controlled substances (CS) to pharmacies. **However,** the statute lists several exemptions, including a prescriber's ability to obtain a waiver.

Provided all other aspects of the prescription are valid, **the pharmacist may fill the prescription.** Dr Dilliard relayed the message that the pharmacist **is not** responsible for verifying if a prescribing practitioner has a waiver or is otherwise exempt, as indicated in section (e) of the statute:

> (e) A pharmacist who receives a written, oral, or faxed prescription is not required to verify with the health care prescriber that the prescription properly falls under one (1) of the exceptions from the requirement to electronically prescribe in subsection (d). Pharmacists may continue to dispense medications from otherwise valid written, oral, or fax prescriptions that are consistent with §53-11-308.

The pharmacist **is** responsible for verifying the validity of all other aspects of the prescription as has always been the direction/regulation of the Board.

Board Discusses Key Issues at December 2020 Meeting

Multi-Dose Packaging Not Returnable to Pharmacy

At the December 1, 2020 virtual Board meeting, multi-dose packaging was discussed as placing more than one drug product in the same package, eg, bubble or unit container. Members interpreted that in conjunction with Board Rule 1140-14-.08 – also mirrored in Board Rule 1140-04-.10(1) – the Board does **not** consider multi-dose packaging to ". . . meet all federal and state board standards for product integrity . . . " Therefore, a multi-dose package shall not be allowed for return to the pharmacy.

Pharmacy Technicians Administering Vaccines

The Board indicated that it does not plan to take disciplinary action against registrants who strictly follow the United States Department of Health and Human Services (HHS) Public Readiness and Emergency Preparedness Act (PREP Act) as it relates to pharmacy technicians administering coronavirus disease 2019 (COVID-19) vaccines and childhood vaccines. The declarations and amendments may be found here. It may be prudent to scroll down to the HHS Guidance for additional information.

The Board reminds registrants to follow proper training discussed in the PREP Act and have documentation readily retrievable for Board investigators to review. The Board decided to discuss a possibility of additional rules regarding this issue once the pandemic has ceased. Note that the PREP Act allows for "childhood" vaccines to be administered by a pharmacy technician and therefore, a shingles inoculation, as an example, **may not** be considered as such.

FDA Compounded Drug Interstate Distribution MOU Discussion

The Board continues to discuss the memorandum of understanding (MOU) offered by Food and Drug Administration (FDA) regarding interstate commerce with compounded medications. According to the September 2020 issue of the National Association of Boards of Pharmacy Foundation® *National Pharmacy Compliance News,* "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."

If the Board denies the MOU, then only 5% of compounded product would be allowed for distribution. Discussion revealed that the MOU requires the Board to report physician-compounded medications dispensed interstate, which is not regulated by the Board. Members opined on the tremendous burden that may be added to investigator duties to obtain this data for all registrants who may compound medications.

Board Executive Director Reggie Dilliard explained that the National Association of Boards of Pharmacy® (NABP®)

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National Pharmacy Compliance News

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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 Publishes New Version of Pharmacist's Manual

The latest version of the *Pharmacist's Manual: An Informational Outline of the Controlled Substances Act* has been released by Drug Enforcement Administration's (DEA's) Diversion Control Division. The guide is provided to assist pharmacists in understanding the Federal Controlled Substances Act and its regulations as they pertain to the pharmacy profession. This edition has been updated to include information on the Secure and Responsible Drug Disposal Act of 2010, the Comprehensive Addiction and Recovery Act of 2016, and the SUPPORT for Patients and Communities Act of 2018, and replaces all versions of the guidance previously issued by the agency. The new *Pharmacist's Manual* can be accessed by visiting the DEA website.

Time to End VinCRIStine Syringe Administration

This column was prepared by the Institute for Safe Medication Practices (ISMP), an ECRI affiliate. Have you experienced a medication error or close call? Report such incidents in confidence to ISMP's National Medication Errors Reporting Program online at www.ismp.org or by email to ismpinfo@ismp.org to activate an alert system that reaches manufacturers, the medical community, and Food and Drug Administration (FDA). To read more about the risk reduction strategies that you can put into practice today, subscribe to the ISMP Medication Safety Alert!® newsletters at www.ismp.org.

At the request of FDA, Pfizer has revised the prescribing information and product packaging for vin**CRIS**tine sulfate injection. Importantly, they have removed wording from the vin**CRIS**tine package insert that described direct intravenous (IV) injection of vin**CRIS**tine via a syringe. FDA recommended this revision at the request of ISMP, the National Comprehensive Cancer Network, and The Joint Commission.

The WARNINGS section of the package insert now states, "To reduce the potential for fatal medication errors due to incorrect route of administration, vin**CRIS**tine sulfate injection should be diluted in a flexible plastic container and prominently labeled as indicated 'FOR INTRAVENOUS USE ONLY—FATAL IF GIVEN BY OTHER ROUTES.'" More than 140 deaths are known to have occurred in the United States and globally due to accidental intrathecal injection of the drug via syringe, often when it was mixed up with, or wrongly assumed it was supposed to be given with, another drug meant for intrathecal administration, such as methotrexate. No such cases have been reported with dilution of vin**CRIS**tine in a minibag, due to physical differences in the packaging and the need for an administration set.

Unfortunately, some practice sites are still using syringes to administer IV vin**CRIS**tine. Based on data collected in response to the *ISMP Medication Safety Self Assessment for High Alert Medications* between September 2017 and March 2018 from 442 US hospitals, nearly 20% of respondents still used syringes at least part of the time, including 13% who always used syringes to administer IV vin**CRIS**tine. Thus, the risk of accidental intrathecal injection still exists in the US and globally.

Dispensing vin**CRIS**tine and other vinca alkaloids in a minibag of compatible solution, and not in a syringe, was among the very first *ISMP Targeted Medication Safety Best Practices for Hospitals,* which were launched in 2014[1]. Then, in March 2019, ISMP called on the FDA to eliminate all mention of syringe administration from official vin**CRIS**tine labeling.[2]

ISMP has frequently referred to wrong route administration of vin**CRIS**tine and vinca alkaloids as the "most serious of all medication errors." Patients experience tremendous pain and are often aware of their impending death, which typically occurs within days or weeks. There is no effective reversal once the mistake is made. Even with the labeling change, there is nothing to stop health care practitioners from administering vin**CRIS**tine via syringe (except if they can only get the drug dispensed in a minibag). We hope that every hospital and health system will investigate exactly how vin**CRIS**tine is being administered at any site that uses the drug. It is time to end the practice of syringe administration by making it a requirement for all vin**CRIS**tine doses to be diluted in a minibag.

References

1. *www.ismp.org/guidelines/best-practices-hospitals*
2. *www.ismp.org/resources/ismp-calls-fda-no-more-syringes-vinca-alkaloids*

What Pharmacists Need to Know About Biosimilar and Interchangeable Biological Products

This column was prepared by FDA, an agency within the US Department of Health and Human Services, that protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines, and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

Biological products are a diverse category of products and are generally large, complex molecules. These products may be produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell, and are often more difficult to characterize than small molecule drugs. There are many types of biological products approved for use in the US, including therapeutic proteins (eg, filgrastim), monoclonal

antibodies (eg, adalimumab), and vaccines (eg, influenza and tetanus).

Section 351(k) of the Public Health Service Act (PHS Act) provides an abbreviated licensure pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference product, which can help provide more affordable treatment options for patients. For example, on March 23, 2020, FDA-approved insulin products were transitioned to regulation as biological products under the PHS Act, which means that transitioned insulin products are open to competition from future biosimilars, including interchangeable biosimilars.

Key Terms for Biosimilar and Interchangeable Products

- **Biosimilar Product:** A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an FDA-approved reference product.
- **Interchangeable Product:** An interchangeable product is a biosimilar that meets additional approval requirements and may be substituted for the reference product without the intervention of the prescribing health care provider.
- **Reference Product:** A reference product is the single biological product, already approved by FDA, against which a proposed biosimilar or interchangeable product is compared.

Are Biosimilars the Same as Generic Drugs?

Biosimilars and generic drugs are versions of brand name drugs and may offer more affordable treatment options to patients. Biosimilars and generics are approved through different abbreviated pathways that avoid duplicating costly clinical trials. But biosimilars are not generics, and there are important differences between them.

For example, the manufacturer of a generic drug must demonstrate, among other things, that the generic contains the same active ingredient as the brand name drug and that the generic is bioequivalent to the brand name drug. By contrast, biosimilar manufacturers must demonstrate that the biosimilar is highly similar to the reference product, except for minor differences in clinically inactive components, and that there are no clinically meaningful differences between the biosimilar and the reference product in terms of safety and effectiveness.

Unlike generics, biosimilars are generally prescribed by brand name by a health care provider, while interchangeables, like generics, may be substituted without the involvement of the prescribing health care provider, depending on state laws.

What is the Purple Book?

The Purple Book database contains information on FDA-licensed (approved) biological products regulated by the Center for Drug Evaluation and Research, including licensed biosimilar and interchangeable products, and their reference products. It also contains information about all FDA-licensed allergenic, cellular, and gene therapy, hematologic, and vaccine products regulated by the Center for Biologics Evaluation and Research .

The Purple Book has simple and advanced search capabilities and some information that you can find includes the proprietary (brand) name and nonproprietary (proper) name of biological products, applicant (company), dosage form, product presentation (eg, autoinjector, vial), route of administration, and strength. The Purple Book also will display FDA-approved interchangeable products and note with which brand product each interchangeable product may be substituted.

Are Therapeutic Equivalence Codes Assigned to Biological Products?

FDA does not assign therapeutic equivalence codes to biological products listed in the Purple Book like it does for small molecule drugs listed in the "Orange Book." The Purple Book provides information about whether a biological product has been determined by FDA to be biosimilar to or interchangeable with a reference product.

Can Interchangeable Products Be Substituted at the Pharmacy?

Many states have laws that address pharmacy-level substitution, including permitting substitution of interchangeable products, and the specific laws vary from state to state.

There are currently no FDA-approved interchangeable products. Once there are, interchangeables, by definition, can be expected to produce the same clinical result as the reference product in any given patient.

Biosimilar and interchangeable products meet FDA's rigorous standards for approval, and patients and health care providers can be assured of the safety and effectiveness of these products, just as they would for the reference product.

Where Can I Find Additional Resources?

- *fda.gov/biosimilars*
- *purplebooksearch.fda.gov*
- *fda.gov/drugs/guidance-compliance-regulatory-information/deemed-be-license-provision-bpci-act*
- *fda.gov/media/135340/download*

Final Insanitary Conditions at Compounding Facilities Guidance Released by FDA

Continuing efforts to protect patients from exposure to poor quality compounded drugs, FDA has published final guidance for compounding facilities regarding insanitary conditions. The final guidance, *Insanitary Conditions at Compounding Facilities Guidance for Industry,* provides recent examples of insanitary conditions that FDA has observed at compounding facilities and details corrective actions that facilities should take when they identify these conditions. The guidance is intended to help compounders identify and prevent such issues at their facilities.

While some compounders work hard to meet quality standards, FDA says its investigators continue to observe poor conditions that impact drug quality and that have the potential to harm patients. These include the presence of dirt, mold, insects, trash, peeling paint, unclean exhaust vents, and dirty high-efficiency particulate air filters.

In response to the draft guidance, FDA states that it has also added recommendations for compounders to use risk management tools to develop appropriate controls to prevent insanitary conditions at facilities. The guidance also addresses the regulatory actions that FDA may take in response to these conditions.

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has constructed a database (currently in a pilot format) for use in receiving the data for FDA. However, Office of General Counsel Attorney for the Board Matthew Gibbs explained that a state statutory change would need to occur for certain data to be shared with NABP and FDA. During the Board meeting held January 26, 2021, members again discussed the issue and voted to move forward with requesting a change in state legislation so that the MOU could be signed if all other issues were resolved.

Board Office Staff Delivers the Take-Home Message

Board staff reminds registrants of the following regulations:

- Use an invoice to transfer prescription drugs or prescription devices. Investigators continue to find prescriptions with wording such as "For Office Use Only." Because of federal regulations, it is advised to use an invoice instead of a prescription order for office use. If it is a CS, the invoice must follow Drug Enforcement Administration (DEA) regulations as in Code of Federal Regulations (CFR) 1307.
- Verify "Purple Drank" when applicable. Recent reports indicate that promethazine with codeine cough syrup prescriptions are being fraudulently circulated in Tennessee. The Board office strongly recommends scrutiny of these prescriptions to make certain of validity, especially if called in as a verbal or appears to be in excessive amounts.
- Retain records. Board Rule 1140-03-.03(2) stipulates that all records are to be kept for two years (Note that prescriptions must be kept two years from the **last dispensed** prescription). However, for compounded preparations, the 2019 versions **(encouraged but not enforced until US Pharmacopeial Convention (USP) deems official)** of USP Chapter <795> (nonsterile compounding chapter) and USP Chapter <797> (sterile compounding chapter) indicate retention of **three years** for all compounding records (CRs) to be maintained. You may wish to click here to apply for the free download of USP Chapters <795>, <797>, and <800> if needed, while available.
  - ◊ Even if mixing two creams together or a crushed tablet with simple syrup, proper master formulation records (MFRs) and CRs should be kept. As indicted in USP Chapter <795>, it is possible to create an MFR and leave blanks to be filled in for the CR (Refer to Section 7 of USP Chapter <795> and Section 11 for USP Chapter <797>). Remember that proper training documentation must also be kept and readily available for inspections.
- The 2019 version of USP Chapter <797> indicates that incubators must be used when growing media. Sampling in the incubator must be set at 20°-25°C for one set of data and 30°-35°C for the other data to meet the requirements. Therefore, it is strongly encouraged that registrants obtain incubators that will monitor those temperatures before the new regulations take effect.

Fraudsters Use COVID-19 Vaccine Distribution Efforts to Scam Patients

The HHS Office of Inspector General (OIG) is alerting the public about fraud schemes related to COVID-19. Scammers are using telemarketing calls, text messages, social media platforms, and door-to-door visits to perpetrate COVID-19-related scams.

Fraudsters are offering COVID-19 tests, HHS grants, and Medicare prescription cards in exchange for personal details, including Medicare information. However, these services are unapproved and illegitimate. Click here for the complete OIG guidance.

Board Members Elect New President and Vice President

As a new year begins, members voted to accept Dr Katy Wright as president and Dr Adam Rodgers as vice president of the Board for the year 2021.

NADDI Adds Drug Disposal Locator to Website, NABP Continues Disposal Links Info

In 2020, the National Association of Drug Diversion Investigators (NADDI) launched an "Rx Drug Drop Box" locator. Simply navigate to its website, and select a location on the map or scroll down to the appropriate state. NADDI also gives information for acquiring drop boxes and other helpful ideas for your patients about discarding medications. Helpful links may be found here. Of note, NABP continues to add new drug disposal locations to its consumer website with helpful links and other information on drug disposal.

Report Theft or Significant 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 by visiting the DEA website. Registrants 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. Questions? Contact a DEA diversion investigator.

- **West Tennessee Office:** Memphis Office/Attn: Diversion Group
  50 North Front Street, Suite 500
  Memphis, TN 38103

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- **Middle Tennessee Office: (Note New Location)**
  Attn: Diversion Group
  457 McNally Drive,
  Nashville, TN 37211
- **East Tennessee Office:** Knoxville Office/Attn: Diversion Group
  624 Reliability Circle,
  Knoxville, TN 37932

Board Meeting Schedule

The Board extends an open invitation for all registrants and the general public to attend the public meetings at 665 Mainstream Drive, Nashville, TN 37243. **Currently, meetings are conducted using WebEx.** It is advised to **check for schedule changes** on the Board website under the Meeting Schedule tab.

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

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

Tennessee Board of Pharmacy Members

- Dr Katy Wright – President
- Dr Adam Rodgers – Vice President
- Dr Melissa McCall – Board Member
- Dr Richard Breeden – Board Member
- Dr Shanea Mckinney – Board Member
- Dr Rissa Pryse – Board Member
- Mr Jake Bynum – Public Member

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