MARCH 2022

TENNESSEE BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

Tennessee Board of Pharmacy Welcomes New Executive Director

Lucy Shell, PharmD, DPh, is the new director of the Tennessee Board of Pharmacy.

Lucy comes to the Board after serving as the director of pharmacy practice initiatives for the Tennessee Pharmacists Association (TPA). As part of that role and her recent interim position as executive director for TPA, Lucy has had the opportunity to work on many different initiatives that impact the profession of pharmacy and how it is regulated. She has been heavily involved with the legislative and regulatory process, serving as the association's lobbyist in 2021, and helping develop comments on pending rules before the Board of Pharmacy. Lucy also practiced as a pharmacist at CVS Health for five years.

It is this experience and her skill set that will allow her to lead the Board in cultivating relationships with key constituency groups, working with external stakeholders, adhering to regulatory matters, and facilitating relationships with state pharmacy schools, making her a wonderful addition to the Division of Health Licensure and the Board.

Lastly, the Board wants to offer its sincere appreciation to Dr Terry Grinder for all his work while serving as interim director.

Policy Suspending Live CE for Board Registrants Has Expired

The policy suspending in-person/live continuing education (CE) requirements expired on December 31, 2021. Therefore, as of January 1, 2022, any CE credits/hours taken in calendar year 2022 must be obtained as required by each individual profession's rules. Hours obtained prior to January 1, 2022, according to the previous policy, will be permitted for the 2021/2022 audit cycle.

Notice of New CSMD Rule Regarding Chapters 1140-11 and 1145-01 Is Revealed

The Controlled Substance Monitoring Database (CSMD) rules have not been amended since before the passage of the Tennessee Prescription Safety Act of 2016, which resulted in significant changes to the statutory scheme. The current CSMD rules may be found in the Pharmacy Rules and Regulations.

Several of these rules apply to prescribers rather than pharmacies. The rule amendment will pull those rules that deal primarily with prescribers out of Chapter 1140 (Pharmacy) and place them in a newly created Chapter 1145 (Commissioner's CSMD Rules).

The rule amendment also increases the list of mandatory fields for pharmacy and prescriber dispenser reporting information to the CSMD. These fields are consistent with the June 2017 version of the Telecommunications Format for Controlled Substances established by the American Society for Automation in Pharmacy. The current rules use the 2009 version of that format. Pharmacies and prescriber dispensers will have until July 1, 2022, to become compliant with the increased number of data fields. Other changes are made to update the rule due to the changes outlined above (changes in numbering, removal of definitions of terms no longer used in the rules, and formatting changes).

Finally, a new rule is created that explicitly allows for the sharing of patient-level opioid overdose data through the CSMD. The Tennessee Department of Health is working to complete enhanced prescriber report cards (EPRs), which will pull data from the CSMD as well as opioid overdose data. The EPRs will be provided to practitioners through the CSMD.

Please note that the changes to these sections became effective **January 26, 2022.** Also provided is the link to the changes here.

Electronic Prescription Waiver Request for Providers Is Available on the Board Website for Year 2022

During the coronavirus disease 2019 pandemic, a waiver was offered to providers for the year 2021 for those who were not prepared to send prescriptions electronically and did not meet the exceptions to the statute. A waiver for the year 2022 is also offered and may be found here. Registrants may wish to read the explanation in the statute in its entirety regarding the responsibility of the pharmacist dispensing prescriptions that are not sent electronically. See (11)(e) in Tennessee Code Annotated (TCA) §63-1-160, noted in the next article specifically. For additional questions, registrants may wish to consult an attorney regarding this topic as well as any federal regulations that may supersede state regulation.

Exceptions to Mandatory Electronic Prescription Writing Are Listed

TCA §63-1-160. Prescription for Schedule II controlled substance — Electronic prescription for Schedule II, III, IV, or V controlled substance — Exceptions.

(a) As used in this section, "electronic prescription" means a written prescription that is generated on an electronic application and is transmitted in accordance with 21 CFR Part 1311.

(b) All written, printed, or electronic prescription orders for a Schedule II controlled substance must contain all information otherwise required by law. The healthcare prescriber must sign the written, printed, or electronic prescription order on the day it is issued. Nothing in this section prevents a healthcare prescriber from issuing a verbal prescription order.

(c) Subject to subsection (d), on or after January 1, 2021, any prescription for a Schedule II, III, IV, or V controlled substance issued by a prescriber who is authorized by law to prescribe the drug must be issued as an electronic prescription from the person issuing the prescription to a pharmacy. The name, address, and telephone number of the collaborating physician of an advanced practice registered nurse or physician assistant must be included on electronic prescriptions issued by an advance practice registered nurse or physician assistant.

(d) Subsection (c) does not apply to prescriptions:

(1) Issued by veterinarians;

(2) Issued in circumstances where electronic prescribing is not available due to technological or electrical failure, as set forth in rule;

(3) Issued by a health care prescriber to be dispensed by a pharmacy located outside the state, as set forth in rule;

(4) Issued when the health care prescriber and dispenser are the same entity;

(5) Issued while including elements that are not supported by the most recently implemented version of the National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard;

(6) Issued by a health care prescriber for a drug that the federal food and drug administration (FDA) requires the prescription to contain certain elements that are not able to be accomplished with electronic prescribing;

(7) Issued by a health care prescriber allowing for the dispensing of a non-patient-specific prescription pursuant to a standing order, approved protocol for drug therapy, collaborative pharmacy practice agreement in response to a public health emergency, or in other circumstances where the health care prescriber may issue a non-patient-specific prescription;

(8) Issued by a health care prescriber prescribing a drug under a research protocol;

(9) Issued by a health care prescriber who has received a waiver or a renewed waiver for a specified period determined by the commissioner of health, not to exceed one (1) year without renewal by the commissioner, from the requirement to use electronic prescribing, pursuant to a process established in rule by the commissioner, due to economic hardship, technological limitations that are not reasonably within the control of the health care prescriber, or other exceptional circumstance demonstrated by the health care prescriber;

(10) Issued by a health care prescriber under circumstances where, notwithstanding the health care prescriber's present ability to make an electronic prescription as required by this subsection (a), the health care prescriber reasonably determines that it would be impractical for the patient to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the patient's medical condition;

(11) Issued by a health care prescriber who issues fifty (50) or fewer prescriptions for Schedule II controlled substances per year.

(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.

(f) The commissioner of health shall refer individual health care prescribers who violate this section to the health care prescriber's licensing board, and for such violation in this section, the health care prescriber is subject to penalties under §63-1-134.

(g) Any health-related board under §68-1-101(a)(8) that is affected by this section, shall report to the general assembly by January 1, 2019, on issues related to the implementation of this section.

News From the January 12, 2022 Board Meeting

Board Elections for the New Year Are Completed

Congratulations to Dr Adam Rodgers, president, and Dr Melissa McCall, vice president, who were unanimously voted in by the Board.

Board President Gives Appreciation to Past President Wright for a Difficult Year

Board President Adam Rodgers conveyed a heartfelt message recognizing Dr Katy Wright for her leadership and guidance over the past year. He indicated that her dedication to making patient safety the top priority in this state has been unwavering, despite a year of constant change in the field of health care.

"Dr Wright," Adam relayed, "I want to personally thank you for all you have given and continue to give to both the profession and most importantly, the citizens of Tennessee."

Board Approves USP Policy Statement Allowing Pharmacies to Use Proposed/Revised Standards

The Board opined on policy to allow Tennessee pharmacies to plan for future United States Pharmacopeia (USP) regulations. Dr Katy Wright, the Board member who volunteered to work on the compounding committee, explained that this policy will allow pharmacies to choose the current version of USP or move to the proposed/revised version. She clarified that pharmacy management will have to choose one version or the other and cannot "cherry pick" parts of each to fit their needs. The Board policy statement can be found on the Board website, and is stated as follows:

> The Board interprets "applicable USP standards" under Official Compilation of the Rules and Regulations of the State of Tennessee 1140-07-.02 to mean a pharmacy engaged in prescription drug compounding under either: (1) the active proposed / revised version of

a USP chapter or (2) the currently official chapter and version of the USP compendium. The Board shall evaluate the compounding practices under the version of the USP chapter chosen by the pharmacy. ADOPTED BY THE TENNESSEE BOARD OF PHARMACY ON January 12, 2022

The Board's compounding rule 1140-07 was discussed as well and will be made available for public comment.

Board Interprets Injectable Vaccine Administration Regarding Off-site Practice

During a discussion regarding the ability for a pharmacist to administer vaccines at a location other than a pharmacy practice site, the Board interpreted that a prescription order, written for an injectable vaccine, may be administered without being considered part of the dispensing process. Registrants are reminded to follow all state and federal regulations regarding injectable vaccines and may wish to seek legal counsel if needed.

Sterile Compounding Corner

Investigators remind registrants who participate in sterile compounding of the following Board rule 1140-07-.02 in part.

Compounding Records:

. . . (5) Any licensed pharmacy which compounds and dispenses sterile products shall provide at a minimum upon request of the Board of Pharmacy the following information for any sterile drug product compounded, dispensed, traded, sold, or otherwise distributed:

(a) Name, strength, and dosage form;

(b) Quantity compounded, dispensed, traded, sold, or otherwise distributed during the preceding quarterly period;

(c) All components and an accurate statement of the weight or measure of each component;

(d) The beyond-use date;

(e) Storage requirements;

(f) Labels and labeling with appropriate beyond-use date and instructions for storage and use.

(6) Any licensed pharmacy which compounds and dispenses sterile products must ensure that the following information is on file at the practice site and readily accessible for sterile products:

(a) Documentation of the name and strength of all drug products compounded over the past two (2) years;

(b) The sources and lot numbers of the components used in those drug products;

(c) The total number of dosage units compounded over the past two (2) years;

(d) The name of the person who prepared the drug product;

(e) The name of the pharmacist who approved the drug product;

(f) The name of the practitioner or the name of the patient or healthcare entity who received the compounded drug product;

(g) The results of any sampling, testing or other quantitative evaluation conducted for the purposes of quality control for any sterile compounded products, as defined by chapter 1140-01, compounded over the past two (2) years.

Tennessee Pharmacy Recovery Network

If you need help with addiction 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.

Disciplinary Actions

For disciplinary actions taken against registrants licensed with the health-related boards, click here.

Report Theft or Significant Loss

Per Title 21, Code of Federal Regulations, Section 1301.76(b), registrants must notify their local Drug Enforcement Administration (DEA) office, in writing, of the theft or significant loss of controlled substances 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. 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 9 AM. It is advised to check for schedule changes on the Board website under the Meeting Schedule tab.

The 2022 meeting schedule is as follows:

- May 10-11
- July 12-13
- September 13-14
- November 8-9

Tennessee Board of Pharmacy Members

- Dr Adam Rodgers, President
- Dr Melissa McCall, Vice President
- Dr Richard Breeden, Board Member
- Dr Shanea McKinney, Board Member
- Dr Rissa Pryse, Board Member
- Dr Katy Wright, Board Member
- Weakley County Mayor Jake Bynum, Consumer Member

National Pharmacy Compliance News Now Available!

Visit NABP's website for the latest regulatory updates and news from FDA, USP, NABP, and more.

Read National News

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