September 2018

# Tennessee Board of Pharmacy News

*Published to promote compliance of pharmacy and drug law*

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*https://www.tn.gov/health/health-program-areas/health-professional-boards/pharmacy-board.html*

## TN Together

As of July 1, 2018, pharmacists dispensing across and into Tennessee from outside of the state have joined in and followed the TN Together Plan to help combat the opioid crisis. Tennessee Board of Pharmacy Executive Director Reggie Dilliard continues to answer questions on a daily basis and encourages registrants to contact him, his staff, and investigators as additional questions or concerns arise after reviewing the information and links listed below. Dr Dilliard may be reached at reginald.dilliard@tn.gov or 615/741-2403. The Board office main phone line to reach staff and investigators is 615/741-2718.

The plan took effect regarding the following public chapters. *(Note that parts of the legislation, such as partial fill and the submission of ICD-10 codes to the controlled substance database, will go into effect January 1, 2019, to give computer software specialists time for updates to comply).*

- TN Together Opioid Reform regarding dispenser check of the Controlled Substance Monitoring Database (CSMD) and more (Public Chapter 1039)
- Question and Answer regarding TN Together Opioid Reform legislation including opioid limits and tramadol designation
- Partial Fill of Controlled Substances (Including Schedule IIs) (Public Chapter 1007)
- Gabapentin Scheduled by Tennessee as Schedule V (Public Chapter 1040)

## Other Public Chapter Legislation Is Reported From TDH

Patrick Powell, liaison to Commissioner John Dreyzehner's office at the Tennessee Department of Health (TDH), presented an updated public chapter report to the Board regarding legislation that may directly and indirectly affect Board registrants. Once updated on the website, registrants may click here for more legislative information.

Public Chapter 638

This chapter prohibits health care prescribers and their employees, agents, or independent contractors from in-person solicitation, telemarketing, or telephonic solicitation of victims within 30 days of an accident or disaster for the purpose of marketing services of the healing arts related to the accident or disaster. There are specific exceptions laid out in the chapter.

This act took effect July 1, 2018.

Public Chapter 675

This act requires TDH to accept allegations of opioid abuse or diversion and for TDH to publicize a means of reporting allegations.

Any entity that prescribes, dispenses, **or** handles opioids is required to provide information to employees about reporting suspected opioid abuse/diversion. That notice is to either be provided individually to the employee in writing and documented by the employer **or** by posting a sign in a conspicuous, non-public area of minimum height and width stating: "NOTICE: PLEASE REPORT ANY SUSPECTED ABUSE OR DIVERSION OF OPIOIDS, OR ANY OTHER IMPROPER BEHAVIOR WITH RESPECT TO OPIOIDS, TO THE DEPARTMENT OF HEALTH'S COMPLAINT INTAKE LINE: 800-852-2187."

Whistleblower protections are also established. An individual who makes a report in good faith may not be terminated or suffer adverse licensure action solely based on the report. The individual is also immune from any civil liability related to a good faith report.

This act takes effect January 1, 2019.

Public Chapter 744

This statute allows a licensing entity the discretion to not suspend/deny/revoke a license in cases where the licensee has defaulted or become delinquent on student loans **if** a medical hardship significantly contributed to the default or delinquency.

This act takes effect January 1, 2019.

Public Chapters 745 and 793

These public chapters work together to create and implement the "Fresh Start Act." Licensing authorities are prohibited from denying an application or renewal for a license/certificate/registration due to a prior criminal conviction that does not directly relate to the applicable occupation.

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# National Pharmacy Compliance News

**September 2018**

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 Launches New Tool to Help Distributors Make Informed Decisions About Customers

In February 2018, Drug Enforcement Administration (DEA) launched a new tool to assist drug manufacturers and distributors with their regulatory obligations under the Controlled Substances Act. The agency added a new feature to its Automation of Reports and Consolidated Orders System (ARCOS) Online Reporting System, a comprehensive drug reporting system that monitors the flow of controlled substances (CS) from their point of manufacture through commercial distribution channels to the point of sale at the dispensing/retail level. This newly added function will allow the more than 1,500 DEA-registered manufacturers and distributors to view the number of registrants who have sold a particular CS to a prospective customer in the last six months.

DEA regulations require distributors to both "know their customer" and to develop a system to identify and report suspicious orders. Manufacturers and distributors have asked DEA for assistance in fulfilling these obligations and have requested ARCOS information to help them determine if new customers are purchasing excessive quantities of CS. This new tool will provide valuable information for distributors to consider as part of their assessment. More details are available in a news release at *www.dea.gov/divisions/hq/2018/hq021418.shtml.*

## PTCB Launches Certified Compounded Sterile Preparation Technician Program

In January 2018, the Pharmacy Technician Certification Board (PTCB) launched the PTCB Certified Compounded Sterile Preparation Technician (CSPT) Program. To be eligible to apply, a technician must:

- Be a PTCB certified pharmacy technician (CPhT) in good standing; and
- Have completed either a PTCB-recognized sterile compounding education/training program and one year of continuous full-time compounded sterile preparation work experience, or three years of continuous full-time compounded sterile preparation work experience.

To earn CSPT Certification, eligible CPhTs are required to pass the CSPT Exam and submit competency attestation documentation from a qualified supervisor. The two-hour, 75-question CSPT Exam covers hazardous and nonhazardous compounded sterile products in the four domains of:

- Medications and components (17%);
- Facilities and equipment (22%);
- Sterile compounding procedures (53%); and
- Handling, packaging, storage, and disposal (8%).

The purpose of the Attestation Form is to document the candidate's completion of required training and certain skill and competency assessments in such areas as aseptic technique, equipment cleaning, and use of personal protective equipment. More details about the CSPT Program are available on PTCB's website at *www.ptcb.org.*

## DEA Enables Mid-level Practitioners to Prescribe and Dispense Buprenorphine

In January 2018, DEA announced a deregulatory measure that will make it easier for residents of underserved areas to receive treatment for opioid addiction. Nurse practitioners and physician assistants can now become Drug Addiction Treatment Act-Waived qualifying practitioners, which gives them authority to prescribe and dispense the opioid maintenance drug buprenorphine from their offices. This final rule took effect January 22, 2018. More details about DEA's amendments are available in a Federal Register notice titled "Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder" (Document Number: 2018-01173).

## New CDC Training Offers CPE on Antibiotic Stewardship

The Centers for Disease Control and Prevention's (CDC's) Office of Antibiotic Stewardship is offering free continuing education opportunities for health care professionals. Focused on judicious antibiotic prescribing and antibiotic resistance, the online training is offered in four sections, each with multiple modules. Section 1 of the "CDC Training on Antibiotic Stewardship" is open now and can be accessed at *www.train.org/cdctrain/course/1075730/compilation.* Additional sections will be released throughout 2018. More information and resources about CDC's national effort to help fight antibiotic resistance and improve antibiotic prescribing and use are available on CDC's website at *www.cdc.gov/antibiotic-use/index.html.* CDC is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). This program meets the criteria for 0.258 CEUs of CPE credit. The ACPE Universal Activity Number is 0387-0000-18-031-H05-P.

## Walmart to Provide Free Solution to Dispose of Medications With Schedule II Prescriptions

In partnership with Walmart, DisposeRx will provide a safe and easy way to neutralize unused, unwanted, or expired prescription opioids. DisposeRx developed a powdered product, also called DisposeRx, that permanently dissolves when

mixed with water and sequesters excess opioids and other drugs in a stiff, biodegradable gel that can be safely thrown in the trash. Walmart will provide a free packet of DisposeRx with every new Schedule II prescription filled at its 4,700 pharmacies nationwide. "This partnership with DisposeRx is an exciting opportunity for Walmart to protect the safety of its customers and public health. Unwanted or expired prescription medications left inside consumers' medicine cabinets can be an easy source for those seeking to misuse or abuse a prescription drug," said Pharmacy Clinical Services Manager for WalMart Health and Wellness and NABP Past President Jeanne D. Waggener, RPh, DPh. "We're not just making it easy for patients to safely dispose of their medications, but we're also helping prevent abuse before it starts." Additional information is provided in a January 17, 2018 news release titled "Walmart Launches Groundbreaking Disposal Solution to Aid in Fight Against Opioid Abuse and Misuse."

## ASHP Research and Education Foundation Predicts Trends to Affect Pharmacy in 2018

In the 2018 Pharmacy Forecast: Strategic Planning Advice for Pharmacy Departments in Hospitals and Health Systems, the American Society of Health-System Pharmacists (ASHP) Research and Education Foundation provides guidance on eight topics that will challenge pharmacy practice leaders in hospitals and health systems. Published in the January 15, 2018 issue of American Journal of Health-System Pharmacy, the new report focuses on the following areas:

- Therapeutic innovation;
- Data, analytics, and technology;
- Business of pharmacy;
- Pharmacy and health-system leadership;
- Advanced pharmacy technician roles;
- Population health management;
- Public health imperatives; and
- Coping with uncertainty and chaos.

The 2018 report is available at *www.ajhp.org/content/75/2/23.*

## USP Encourages Pharmacists to Help Patients Find Quality Dietary Supplements

Recall announcements, enforcement actions, and reports challenging the quality of dietary supplements are problematic issues facing pharmacists who want to ensure that the over-the-counter (OTC) products they are recommending to patients are of good quality. Many consumers purchase OTC dietary supplements and herbal products, often assuming they are regulated like prescription medications. While the law requires pharmaceuticals to meet specific quality standards set by the United States Pharmacopeial Convention (USP), the same requirements do not apply to supplements. For this reason, USP has created quality standards and a verification process specifically for these health products. Brands displaying the USP Verified Mark signal to the public that "what's on their label is what's in the bottle." Health care practitioners can learn more about USP's efforts at *www.usp.org/dietary-supplements-herbal-medicines.*

Further,,USP Dietary Supplement Verification Services are available to manufacturers and brands worldwide. They include Good Manufacturing Practice facility auditing, product quality control and manufacturing product documentation review, and product testing. Manufacturers that are participating in USP's verification program for dietary supplements can be found at *www.usp.org/verification-services/program-participants.*

## New CPE Monitor Subscription Service Makes Licensure Compliance Easier

To help pharmacists easily monitor their CPE compliance, NABP partnered with the Accreditation Council for Pharmacy Education (ACPE) to expand CPE Monitor® by offering a new subscription service. Users can keep their free, Standard version of CPE Monitor or upgrade to the Plus subscription plan. Launched in April 2018, the new Plus plan enables pharmacists to perform a variety of advanced functions beyond the Standard plan, including:

- Verifying how much CPE credit must be earned to satisfy renewal requirements;
- Receiving alerts when a license is nearing the end of a CPE cycle;
- Uploading non-ACPE credits to a licensee's e-Profile;
- Viewing consolidated transcripts for each state license;
- Connecting to My CPD, which allows licensees to maintain their continuing professional development (CPD) in one place; and
- Connecting to the Pharmacists' Learning Assistance Network, where licensees can easily search for ACPE-approved courses.

The Plus subscription is available for an annual, renewable fee of $29.95, regardless of how many licenses a pharmacist has or adds at a later date. It is only available via NABP's new mobile app. Search for NABP e-Profile in Google Play Store (Android) or the App Store (iPhone).

The Standard plan is still available for free and can also be accessed via the app or a desktop by signing in with NABP e-Profile login credentials.

For more information, visit *www.nabp.pharmacy/CPE.*

*CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their CPE credit electronically.*

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The requirements on the licensing authorities are laid out, as well as the exceptions to the law (eg, rebuttable presumption regarding A- and B-level felonies).

These acts took effect July 1, 2018.

### Public Chapter 754

This chapter prevents any board, commission, committee, etc, created by statute from promulgating rules, issuing statements, or issuing intra-agency memoranda that infringe on an entity member's freedom of speech.

Freedom of speech includes, but is not limited to, a member's freedom to express an opinion concerning any matter relating to that governmental entity, excluding matters deemed to be confidential under Tennessee Code Annotated (TCA) 10-7-504.

Violations as determined by a joint evaluation committee may result in recommendations to the general assembly concerning the entity's sunset status, rulemaking authority, and funding.

This act took effect April 18, 2018.

### Public Chapter 883

This act lays the framework for e-prescribing practices in the state and the exceptions from electronic prescriptions. It requires that all Schedule II prescriptions be e-prescribed by January 1, 2020, except under certain circumstances. Any health-related board under TCA 68-1-101(a)(8) that is affected by this act shall report to the general assembly by January 1, 2019, on issues related to the implementation of this section. The commissioner of health is authorized to promulgate rules to effectuate the purposes of this act.

This act took effect May 3, 2018, for rule purposes, and goes into effect January 1, 2019, for all other purposes.

### Public Chapter 901

This act requires that prior to prescribing more than a three-day supply of an opioid or an opioid dosage that exceeds a total of 180 morphine milligram equivalent to a woman of childbearing age (15-44 years old), a prescriber must do the following:

1. Advise of risks associated with opioid use during pregnancy;
2. Counsel patient on effective forms of birth control; and
3. Offer information on availability of free or reduced cost birth control.

These requirements do not apply if the patient was previously informed by prescriber in previous three months or prescriber reasonably believes patient is incapable of becoming pregnant. Requirements may be met with a patient under 18 years of age by informing the parent of the patient.

TDH is to publish guidance to assist prescribers in complying with this act.

This act took effect July 1, 2018.

### Public Chapter 929

This act redefines policy and rule and requires each agency to submit a list of all policies, with certain exceptions, that have been adopted or changed in the previous year to the chairs of the government operations committees on July 1 of each year. The submission shall include a summary of the policy and the justification for adopting a policy instead of a rule.

This act also prohibits any policy or rule by any agency that infringes upon an agency member's freedom of speech.

Finally, this act establishes that an agency's appointing authority shall have the sole power to remove a member from a board, committee, etc.

This act took effect July 1, 2018, and applies to policies adopted on or after that date.

### Public Chapter 954

This legislation requires the initial licensure fee for low-income persons to be waived. Low-income individuals, per the statute, are defined as persons who are enrolled in a state or federal public assistance program including, but not limited to, Temporary Assistance for Needy Families, Medicaid, and Supplemental Nutrition Assistance Program. All licensing authorities are required to promulgate rules to effectuate the purposes of this act.

This act takes effect January 1, 2019.

### Public Chapter 978

This act makes a number of revisions to opioid treatment regulations. The definition of nonresidential office-based opiate treatment (OBOT) facility has been changed to encompass more facilities.

The commissioner of mental health is required to revise the rules of OBOTs to be consistent with state and federal law for such facilities to establish certain new protocols.

Rules regarding OBOTs are to be reviewed each even-numbered year and the Department of Mental Health and Substance Abuse Services shall submit the rules for OBOTs to each health-related board that licenses any practitioner authorized by the state to prescribe products for treatment of an opioid use disorder. Each board is required to enforce the rules. Each board is required to post the rules on the board's website. Violation of a rule is grounds for disciplinary action by the board. In addition, the act:

- Makes revisions to the licensing fees of OBOTs.
- Requires revision of the buprenorphine treatment guidelines.
- Requires (subject to 42 Code of Federal Regulations part 2) that dispensing of buprenorphine be subject to CSMD requirements.
- Prohibits dispensing of buprenorphine except by certain individuals/facilities and requires pharmacies/distributors to report to TDH the quantities of buprenorphine that are delivered to OBOTs in the state.
- Makes revisions to the high-volume prescriber list compiled by TDH.

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- Requires the comptroller to complete a study of statistically abnormal prescribing patterns. After the study, TDH shall identify prescribers and shall inquire with the boards of action taken against the prescribers. The board is required to respond within 30 days. Each board is required to report the total number of prescribers disciplined each year, as well as other information. TDH shall report a summary of the data and of the disciplinary actions to the chairs of the health committees.
- Comprises a task force to create minimum disciplinary actions for prescribing practices that are a significant deviation from sound medical judgment. The boards of medical examiners, osteopathic examination, dentistry, podiatric medical examiners, optometry, nursing, and the medical examiners' committee on physician assistants shall select one member each for the task force before September 1, 2018.

This act took effect for rulemaking on May 21, 2018, and took effect July 1, 2018, for all other purposes.

Public Chapter 1015

This legislation lays out the specific requirements of hospitals to notify law enforcement of involuntary commitments as well as the possible penalties for failure to comply. Inspections of hospitals by the Department of Mental Health and TDH shall include a determination of the hospital's compliance with the reporting requirements of this act.

The act also allows a pharmacist the right to provide information to an insured individual regarding the amount of the insured individual's cost share for a prescription drug. Neither a pharmacy nor a pharmacist shall be penalized by a pharmacy benefits manager for discussing such information or selling a lower priced drug if one is available.

This act took effect July 1, 2018.

Public Chapter 1021

This act allows for appeals of contested case hearings to be held in the chancery court nearest the residence of the person contesting the agency action or at that person's discretion, in the chancery court nearest the place the action arose, or in the chancery court of Davidson County. Petitions seeking review must be filed within 60 days after entry of the agency's final order.

This act took effect July 1, 2018.

Public Chapter 1029

This act requires the Board to promulgate rules regarding the Board's oversight of facilities that manufacture, warehouse, and distribute medical devices. Rulemaking shall begin no later than September 1, 2018. The rulemaking process shall include the formation of an advisory committee composed of medical device industry representatives and a representative of the Department of Economic and Community Development. Rules promulgated shall be reviewed every three years for purposes of reviewing advancements of new medical device technologies.

This act took effect July 1, 2018.

Public Chapter 1040

This act revises various provisions of the law regarding controlled substances and their analogues and derivatives, including updating identifications of drugs categorized in Schedules I-V. The act also creates an offense for the sale or offer to sell kratom, unless it is labeled and in its natural form. It is also an offense to distribute, offer for sale, or sell kratom to a person under 21 years of age. It is also an offense to purchase or possess kratom if under 21 years of age.

This act took effect July 1, 2018.

## 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 as follows:

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

The 2019 meeting schedule is as follows:

- January 8-9
- March 12-13
- May 14-15
- July 16-17
- November 10-11



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