



# Tennessee Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## **Board Office Gives Statement Regarding the Transfer of Schedule III, IV, and V CS**

Tennessee Board of Pharmacy staff has become aware in recent days that some pharmacies have heard, or have been told, that federal law prohibits a pharmacy from transferring a Schedule III, IV, or V controlled substance (CS) prescription that was placed on file at the pharmacy, but never filled. The asserted basis is Title 21, Code of Federal Regulations (CFR), Section 1306.25, which discusses transfers of these prescriptions for “refill purposes.” Notwithstanding, the Board has never taken the position that such transfers will subject a pharmacy to discipline. Nor is Board staff aware of any Drug Enforcement Administration (DEA) action taken against a pharmacy for transferring a valid Schedule III, IV, or V prescription to the pharmacy of the patient’s choice for purposes of initial fill. If personnel at DEA issue formal policy guidance stating an intent to enforce the Controlled Substance Act in a way that would prohibit such transfers, Board staff will advise pharmacists accordingly.

## **Professional Privilege Tax Is Due**

The professional privilege tax is an annual privilege tax imposed on persons holding, on the due date of June 1, an active Tennessee license or registration to practice certain professions. This tax is imposed without regard to whether the profession is actually practiced in the state of Tennessee (Tennessee Code Annotated Section 67-4-1701). Visit the [Tennessee Tax Payer Access Point](#) web page for more information.

## **Board Updated Rules Are Now in Effect**

As registrants may already be aware, the most current Board rules are now available online and in effect. However, be advised that the orange-colored 2015 *Tennessee Pharmacy Laws* physical hard copy book is still required (see the [March 2017 Tennessee Board of Pharmacy Newsletter](#) for additional explanations on this regulation). Registrants are advised to review all updated rules.

New Board Rule 1140-14 has been included specifically for long-term care (LTC) pharmacy practice sites. Furthermore, the rules for institutional and LTC pharmacy practice have been revised when using automated dispensing systems. The regulation requires all automated dispensing devices at each address to be listed and maintained with a specific location noted for each device (eg, third floor east nurse’s station). The Board expects that this list will be available for investigators during inspections or other

Board business. The Board is currently discussing clarifications (nomenclature) of this rule update and will disseminate the information once the final guidance has been completed. The biennial fee is \$300 for each address where each system of devices is located. The application form is currently being constructed.

Furthermore, a few of the many other updates include collaborative pharmacy practice (1140-03-.17), peer assistance (1140-01-.10), non-allowance of financial incentives (eg, coupons for prescription transfer) (1140-02-.01(18)), drug take-back provisions (1140-03-.03(8)), pilot program applications (1140-01-.16), fees (1140-01-.10), and CS monitoring database reporting (1140-11-.05 (report each business day)). To view all the rules in detail, visit the Board website and navigate to the “Statutes and Rules” tab or click [here](#).

## **Board Investigator Shares Latest Statistics Regarding Drug Diversion**

As required in Board Rule 1140-03-.09, “The pharmacist in charge shall immediately report to the board any robbery, embezzlement, theft, burglary, or fire or disaster resulting in a loss of prescription drugs, or controlled substances or medical devices or related materials. The report shall include a list, including amounts, of such prescription drugs or controlled substances or medical devices or related materials lost or damaged.”

According to Dr Terry Grinder, investigator for the Board, statistics were tracked for the year-to-date of April 24, 2016, to year-to-date of April 24, 2017. The results are as follows:

	Armed Robberies	Break-ins	Technician Pilferage	Nurse Pilferage	Lost in Transit by Contract Courier
Year-to-Date April 24, 2016	10	5	17	10	23
Year-to-Date April 24, 2017	5	9	17	13	32

## **Board Gives Policy Statement Regarding Drug Quantity Limits of Medication Stored in LTC Automated Dispensing Systems**

During the April 12, 2017 Board meeting, members discussed quantity limits for the updated rule regarding automated dispensing

*continued on page 4*

## DEA Changes Registration Renewal Process

As of January 2017, Drug Enforcement Administration (DEA) will no longer send its second renewal notification by mail. Instead, an electronic reminder to renew will be sent to the email address associated with the DEA registration.

In addition, DEA will retain its current policy and procedures with respect to renewal and reinstatement of registration. The policy is described below.

- ◆ If a renewal application is submitted in a timely manner prior to expiration, the registrant may continue operations, authorized by the registration, beyond the expiration date until final action is taken on the application.
- ◆ DEA allows the reinstatement of an expired registration for one calendar month after the expiration date. If the registration is not renewed within that calendar month, an application for a new DEA registration will be required.
- ◆ Regardless of whether a registration is reinstated within the calendar month after expiration, federal law prohibits the handling of controlled substances or List 1 chemicals for any period of time under an expired registration.

Additional information is available on the DEA website at [www.deadiversion.usdoj.gov/drugreg/index.html](http://www.deadiversion.usdoj.gov/drugreg/index.html).

## ISMP Medication Safety Self Assessment for Community/Ambulatory Pharmacy

 *This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting [www.ismp.org](http://www.ismp.org). ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at [www.ismp.org](http://www.ismp.org). Email: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

Pharmacists in community and ambulatory settings can now access a newly revised tool that will help them review and improve their medication safety practices. The 2017 Institute for Safe Medication Practices (ISMP) Medication Safety Self Assessment® for Community/Ambulatory Pharmacy is designed to help pharmacies evaluate their current systems, proactively identify opportunities for improvement, and track their efforts over time.

An advisory panel of experts helped ISMP update items from the 2001 community/ambulatory self-assessment as well as add items to address new practices and processes, including the pharmacist's evolving role in immunization administration. New research findings about error prevention and emerging technologies previously not widely adopted are also covered.

The self-assessment contains items that address the use of medications in the clinical setting, many of which are on the

ISMP list of high-alert medications. Many of the items included represent system improvements and safeguards that ISMP has recommended in response to analysis of medication errors reported to the ISMP Medication Errors Reporting Program, problems identified during on-site consultations with health care organizations, and guidelines in medical literature.

The self-assessment is divided into 10 key elements that most significantly influence safe medication use. Each element is defined by one or more core characteristics of a safe pharmacy system that further define a safe medication use system. Each core characteristic contains individual self-assessment items to help evaluate success with achieving each core characteristic.

ISMP recommends that each pharmacy site convene its own team of staff members (ie, pharmacist(s), technician(s), and student pharmacist(s)) to complete this comprehensive assessment and use the information as part of its ongoing safety and quality improvement efforts. An online form has been provided to help participants organize and score their responses. **Important:** The self-assessment should be completed in its entirety by staff and managers who work within the pharmacy, not by off-site managers on behalf of the pharmacy.

When the self-assessment is completed, respondents can generate reports showing how their pharmacy answered each item and how they scored on each as a percentage of the maximum possible score. The pharmacy can then use its scores to identify and prioritize opportunities for its safety plan of action.

ISMP is not a regulatory or standards-setting organization. As such, the self-assessment characteristics represent ideal practices and are not purported to represent a minimum standard of practice. Some of the self-assessment criteria represent innovative practices and system enhancements that are not widely available in pharmacies today. However, the value of these practices in reducing errors is grounded in expert analysis of medication errors, scientific research, or strong evidence of their ability to reduce errors.

To view, download, and print the PDF of the assessment, which includes the introduction, instructions for use, self-assessment items, and definitions, visit <https://www.ismp.org/Survey/NewMssacap/Index.asp>.

## CDC Publishes Resource to Foster Use of JCPP Pharmacists' Patient Care Process

A publication intended to encourage the use of the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists' Patient Care Process was released by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention. In *Using the Pharmacists' Patient Care Process to Manage High Blood Pressure: A Resource Guide for Pharmacists*, CDC calls on pharmacists and other health care providers to implement the Pharmacists' Patient Care Process model to reduce heart disease and stroke in the United States. Pharmacists can have a positive effect on population health by providing patient care services and participating in collaborative practice agreements and continuing education (CE) programs, notes the CDC publication. The publication is available at [www.cdc.gov/dhbsp/pubs/docs/pharmacist-resource-guide.pdf](http://www.cdc.gov/dhbsp/pubs/docs/pharmacist-resource-guide.pdf).

News to a particular state or jurisdiction can only be ascertained  
such state or jurisdiction.

The National Association of Boards of Pharmacy® (NABP®) is a member of JCPP and endorses the Pharmacists' Patient Care Process. In its September 2015 newsletter (page 167), NABP discusses integrating the JCPP Pharmacists' Patient Care Process to improve medication outcomes and promote consistency in patient care service delivery. Additional information about JCPP is available at <https://jcphp.net>.

### **FDA Issues Final Guidance on Repackaging Drugs by Pharmacies and Registered Outsourcing Facilities**

In January 2017, Food and Drug Administration (FDA) issued a final guidance for industry titled, "Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities." This guidance describes the conditions under which FDA does not intend to take action for violations of certain provisions of the Federal Food, Drug, and Cosmetic Act when a state-licensed pharmacy, a federal facility, or an outsourcing facility repackages certain human drug products. The guidance is available at [www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM434174.pdf](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM434174.pdf).

Electronic or written comments may be submitted at any time for this final guidance following the instructions provided in the *Federal Register*, which can be found at [www.federalregister.gov/documents/2017/01/13/2017-00723/repackaging-of-certain-human-drug-products-by-pharmacies-and-outsourcing-facilities-final-guidance](http://www.federalregister.gov/documents/2017/01/13/2017-00723/repackaging-of-certain-human-drug-products-by-pharmacies-and-outsourcing-facilities-final-guidance).

### **CriticalPoint Launches QP503A Certification Program for Sterile Compounding in 2017**

In 2017, CriticalPoint, LLC, launched its QP503A certification program for sterile compounding personnel. Specifically, CriticalPoint is offering the QP503A Certification and the QP503A Master Certification, which may be earned after obtaining the basic QP503A Certification. Participants will gain vital knowledge and skills to successfully plan, develop, and operate a 503A pharmacy sterile compounding operation.

The QP503A Certification involves a didactic program of home study, live training, and practicum activities accompanied by required objective personnel and cognitive testing. The QP503A Master Certification requires participants to demonstrate their ability to apply their QP503A Certification training in actual work settings and produce measurable changes in sterile compounding processes resulting in improved patient safety.

Additional details about these programs and the certification requirements are available online at [www.criticalpoint.info/wp-content/uploads/CriticalPoint-QP503A-Certification.pdf](http://www.criticalpoint.info/wp-content/uploads/CriticalPoint-QP503A-Certification.pdf).

### **PTCB Suspends Implementation of Planned 2020 Accredited Education Requirement for Pharmacy Technicians**

The Pharmacy Technician Certification Board (PTCB) is suspending the implementation of the accredited education requirement for pharmacy technicians. In 2013, PTCB announced that the requirement would take effect in 2020, but PTCB has "determined that additional deliberation and research are needed

to address stakeholder input, develop supporting policy, and conduct further study of technician roles," said Larry Wagenknecht, BPharm, chair of the PTCB Board of Governors, and chief executive officer of the Michigan Pharmacists Association, in a news release. The role of pharmacy technicians is evolving, and PTCB is taking steps to support the pharmacy community.

PTCB recently completed a job analysis study to collect data on current roles and responsibilities of pharmacy technicians across all practice settings to update PTCB's Pharmacy Technician Certification Exam and is in the process of developing advanced certification programs. In addition, PTCB hosted an invitational conference in February 2017 where pharmacy leaders and stakeholders examined entry-level standards and provided information to help determine future plans for implementing PTCB program changes.

PTCB's news release is available at [www.ptcb.org](http://www.ptcb.org) in the News Room section.

### **ASOP Global Spreads Awareness About Illegal Online Drug Sellers and Counterfeit Medications**

Alliance for Safe Online Pharmacies (ASOP Global) partnered with several nonprofit organizations, including NABP, to launch a campaign to raise awareness of illegal online drug sellers and counterfeit medications. The campaign encourages dialogue among health care providers and patients regarding where patients purchase their medications, especially if patients are buying them online.

After offering the CE course "Internet Drug Sellers: What Providers Need to Know" to over 1,000 health care providers, ASOP Global found that less than 10% of providers reported they were "very aware" counterfeit prescription drugs are being sold on the internet and only 1.4% said they regularly discuss the risks of illegal internet drug sellers with patients. ASOP Global Executive Director Libby Baney said, "After completing the course, however, there was a ten-fold increase in the expected frequency in which providers planned to discuss the risks associated with buying prescription medicines online with their patients and what they can do to avoid physical and financial harm."

For more information about the campaign, visit [www.BuySafeRx.pharmacy](http://www.BuySafeRx.pharmacy).

### **New Interactive Map Tracks Pharmacist Vaccination Laws**

A new resource – an interactive 50-state map tracking pharmacist vaccination laws between 1990 and 2016 – was published by The Policy Surveillance Program, A LawAtlas Project. The map, which is available at <http://lawatlas.org/datasets/pharmacist-vaccination>, explores laws that give pharmacists authority to administer vaccines and establish requirements for third-party vaccination authorization, patient age restrictions, and specific vaccination practice requirements, such as training, reporting, record keeping, notification, malpractice insurance, and emergency exceptions. The Policy Surveillance Program is administered by Temple University Beasley School of Law.

continued from page 1

systems that was in question from the institutional emergency kit regulation, commonly known as the “tackle box” rule. Dr Julie Frazier, a former Board member, noted that it is very difficult to drive across town in even a local area such as Nashville, TN. She commented that patient care is hindered due to the current limits, and many patients are now being admitted to LTC facilities due to additional issues such as cardiac and orthopedic rehabilitation.

Dr Kevin Eidson, Board president, replied that it would be good patient care to allow the limits to be set by the pharmacist-in-charge (PIC) with collaboration of facility management. Dr Debra Wilson agreed. She made a motion to approve a policy statement indicating that, for the purposes of an LTC facility using an automated dispensing system, each facility will have a policy determined by the PIC in collaboration with the medical director or other manager in charge of the facility, to determine the adequate amount of drugs to be stored in the automated dispensing machine (device) at that facility. The motion passed.

### **Board Welcomes New Public Member**

If working side-by-side with fellow employees of the Tennessee Department of Health brings knowledge and experience for a position, then new Public Member Lisa Tittle certainly has the “time in” for it!

As a state of Tennessee employee, Mrs Tittle has tallied 30 years of service! She officially retired in June 2008, but continued to return and help the state on interim duties in the financial department. Her knowledge of the Department of Health includes the legislative, budget, and fiscal process. She is current in her understanding of the Board’s directive to follow the requirements to be self-sufficient, required by the state of Tennessee.

When she is not driving from her hometown of Hendersonville, TN, to deliberate on Board business, Mrs Tittle serves as the financial administrator for the law firm of Downard and Associates.

In her spare time, Mrs Tittle continues to be a member of the Tennessee End of Life Partnership, where she worked previously as the program coordinator, providing administrative duties. Two of her tasks included the application process for educational grants to conduct End of Life Care Workshops across the state for health care professionals and setting up workshop programs. The Board is very familiar with Mrs Tittle’s experience from her previous presentations for its fiscal year and looks forward to her expertise and consumer opinion.

### **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 [tntheforloss@usdoj.gov](mailto:tntheforloss@usdoj.gov). Registrants must still complete a **DEA Form 106** and may do so online via the [DEA website](#). If you have questions, please contact DEA Diversion Investigator James N. Stevens at 615/736-7343. You may also satisfy the Board regulation to report by sending a copy to Dr Terry Grinder at [terry.grinder@tn.gov](mailto:terry.grinder@tn.gov).

### **Help Is Available for Impaired Pharmacists Through the Tennessee Pharmacists Recovery Network**

If you need help or know an associate who does, please contact Dr Baeteena Black, Tennessee Pharmacists Recovery Network

program director, by phone at 615/256-3023 or by email at [bblack@tnpharm.org](mailto:bblack@tnpharm.org).

Information (including the reporting form) is located at the Tennessee Pharmacists Recovery Network [website](#).

### **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. 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 **2017** meeting schedule is listed as follows:

- ◆ June 13-14
- ◆ July 11-12
- ◆ September 12-13
- ◆ November 14-15

The **2018** meeting schedule is listed as follows:

- ◆ January 30-31
- ◆ March 13-14
- ◆ May 1-2
- ◆ July 17-18
- ◆ September 11-12
- ◆ November 27-28

### **Mandatory Practitioner Profiles**

The Board reminds licensees that the Mandatory Practitioner Profile Questionnaire for Licensed Health Care Providers must be completed and updated as information changes. To obtain a copy of the Mandatory Practitioner Profile Questionnaire, click [here](#).

Completed/updated profiles should be submitted by mail to the Tennessee Department of Health, in care of the address provided as part of the questionnaire instructions.

### **Tennessee Board of Pharmacy Members**

Dr Kevin Eidson – President  
Dr Mike Dickenson – Vice President  
Dr Debra Wilson – Board Member  
Dr Rissa Pryse – Board Member  
Dr Katy Wright – Board Member  
Dr William J. Bunch – Board Member  
Mrs Lisa Tittle – Public Board Member

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Page 4 – June 2017

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