



Tennessee Board of Pharmacy

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Board Issues Cease and Desist to Pharmacy Repackaging Drugs Dispensed From a Separate Pharmacy

During the June 13, 2017 Tennessee Board of Pharmacy meeting, the Board directed Office of General Counsel Attorney Matthew Gibbs to send a **cease and desist letter** to a pharmacy that serviced an assisted living facility. The pharmacist was reported as repackaging another pharmacy's dispensed medications, already delivered to the site. Board Executive Director Reggie Dilliard and Board President Dr Kevin Eidson referred to Board Rule [1140-03-.08](#) and indicated that the repackaging pharmacist would be unable to follow the regulation since repackaging was not performed from the dispensing pharmacy practice site. Dr Eidson indicated the following information from the rule, as stated in part: "The pharmacy practice site shall have proper facilities, qualified personnel, effectual operational practices, suitable packaging material, and adequate control procedures to assure that the purity, integrity, safety, and effectiveness of the prescription drug or device or related material are not affected by such repackaging." Board Vice President Dr Mike Dickenson made a motion to send a cease and desist notice and a letter of warning to the pharmacy and pharmacist-in-charge (PIC). Seconded by Board Member Dr Debra Wilson, the motion passed.

Board Increases Key Violation Civil Penalty to Amount of Days in Possession for Egregious Circumstances

During its July 12, 2017 meeting, the Board opined on the continual violation of employees, other than pharmacists, having possession of a key to the pharmacy. Refer to Board Rule [1140-01-.13\(3\)\(g\)](#), which states in part:

Keys or other access devices to the physical barriers shall be subject to the following standards.

1. Only pharmacists practicing at the pharmacy and pharmacists authorized by the pharmacist in charge shall be in possession of any keys or other access devices.
2. The pharmacist in charge shall place a key or other access device in a sealed device or vault

in a secured place outside of the department, unless the pharmacy practice utilizes an electronic access device which is capable of restricting and preventing unauthorized access into the pharmacy. The key or access device may be used to allow emergency entrance to the department. A written or electronic record of persons accessing the pharmacy department using the key or other access device must be maintained on the premises of that pharmacy practice site for a period of 2 years.

Board Member Dr Katy Wright made a motion for discipline of reprimand to the PIC, with a \$100 civil penalty per day up to a \$1,000 cap for every day that a non-pharmacist possessed a key to the pharmacy. Board Member Dr Will Bunch seconded the motion, and it was passed.

Board Member Dr Rissa Pryse indicated to the Board that a pharmacy technician found with the key access should also be disciplined. Office of General Counsel Attorney Matthew Gibbs indicated that he would look at the rules and revisit if applicable.

Automated Dispensing Machine Fee Is Now Due (Application Form Available)

Per Board Rules [1140-04-.15\(7\)\(a\)](#) and [1140-14-.12\(1\)](#), as stated in part: "Each pharmacy holding an active license with the Tennessee Board of Pharmacy and using automated dispensing systems shall register each automated dispensing system with the Tennessee Board of Pharmacy." As indicated in Rule [1140-01-.10\(17\)](#), the fee is currently \$300. An additional controlled substance (CS) modifier fee may be required as well. For a paper form application (pdf), click [here](#).

Note that in the Applications section on the Board website, under the heading "Facility License Information," there is a link to the login page for online applications. However, the online application for the automated dispensing machine license may not yet be available as of this *Newsletter's* posting, even though it is listed. When hovering your computer's mouse/pointer over the selection, there are actually two links that appear as one link until the pointer hovers over "PH," as follows: [Automated Dispensing Machine Application Form](#)

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WHO Launches Global Patient Safety Challenge on Medication Safety

To reduce severe, avoidable medication-associated harm in all countries by 50% over the next five years, the World Health Organization (WHO) has launched a worldwide initiative, the Global Patient Safety Challenge on Medication Safety. Medication errors cause at least one death every day and injure approximately 1.3 million people every year in the United States. In addition, low- and middle-income countries are estimated to have similar rates of medication-related adverse events as high-income countries.

The Global Patient Safety Challenge on Medication Safety aims to make improvements in each stage of the medication use process including prescribing, dispensing, administering, monitoring, and use. WHO intends to provide guidance and develop strategies, in addition to plans and tools to ensure that the medication process has the safety of patients at its core in all health care facilities.

Previous WHO Global Safety Challenges have included the Clean Care is Safer Care challenge on hand hygiene in 2005 and the Safe Surgery Saves Lives challenge in 2008. Additional information is available in the WHO press release available at <http://who.int/mediacentre/news/releases/2017/medication-related-errors/en>.

Continuous Quality Improvement and Patient Safety Organizations

 *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. 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. Email: ismpinfo@ismp.org.*

Data from the ISMP Medication Errors Reporting Program reveals that medication-related problems are repetitive in nature. An incident of misuse in one setting is likely to repeat itself in another. Most importantly, the system changes that are necessary to prevent errors are similar, and a growing body of literature is available to guide these efforts. Tragically, too many organizations and individual providers do not believe similar incidents could happen to them. They fail to use information about errors occurring elsewhere as a roadmap for improvement in their own organization or practice. It is not until a serious error hits home that aggressive prevention efforts are implemented. With so much evidence-based information about error prevention at hand, there is little excuse for reacting to errors after they happen instead of preventing them.

The development and implementation of continuous quality improvement (CQI) efforts should be the highest priority in all pharmacies. Such efforts must be aimed specifically at preventing

well-known and repetitive dispensing errors. Pharmacies should seek out medication safety information and use it proactively to prevent medication errors. At the same time, safety issues recognized internally and/or reported by patients should be documented and analyzed, with a process to determine the best strategies to prevent future problems and methods to ensure implementation. An annual survey to assess consumer perceptions of the quality of pharmaceutical products and professional services could supply additional information upon which to base improvement strategies. For more information on CQI programs, visit Section 7 of Model Rules for the Practice of Pharmacy in *The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*.

Informational tools like the *ISMP Medication Safety Alert!* publication, or ISMP's *Quarterly Action Agenda*, which is a readily available list of medication problems compiled from the nation's reporting programs, can be a backbone of any CQI effort. The very purpose of the ISMP Medication Errors Reporting Program – indeed the purpose of any type of safety reporting program and the expert recommendations that stem from it – is to guide the implementation of quality improvement initiatives by practitioners and organizations.

It is important that certain information from the CQI proceedings and records of review be protected from discovery. Patient safety organizations (PSO) are organizations that share the goal of improving the quality and safety of health care delivery. Patient Safety Work Product (PSWP) is the information protected by the privilege and confidentiality protections of the Patient Safety Act and Patient Safety Rule. PSOs serve as independent, external experts who can collect, analyze, and aggregate PSWP locally, regionally, and nationally to develop insights into the underlying causes of patient safety events, thus improving quality by identifying and reducing the risks and hazards associated with patient care. Communications with PSOs are protected to allay fears of increased risk of liability because of collection and analysis of patient safety events.

For more information on PSOs, visit <https://www.pso.ahrq.gov/faq>.

NCPDP Releases Guide to Ensure Patients Get Their Medications During a Disaster

The National Council for Prescription Drug Programs (NCPDP) released the *NCPDP Emergency Preparedness Information* guide to assist pharmacists and other health care providers during a declared emergency. Prepared by the NCPDP Emergency Preparedness Committee, the guide provides resource information for eligibility and claims processing affecting displaced individuals. The guide is available at www.ncdp.org/NCPDP/media/pdf/NCPDPEmergencyPreparednessInformation_v1_4.pdf. Additional information for pharmacists about emergency preparedness is available on the NCPDP website at www.ncdp.org/Resources/Emergency-Preparedness.

FDA Warns of Illnesses and Deaths in Pets Exposed to Fluorouracil

Food and Drug Administration (FDA) is alerting pharmacists that patients' pets are at risk of illness and death when exposed to the topical cancer medication fluorouracil cream USP 5% (5-FU) that is intended for use in people. Fluorouracil may also be marketed under the brand names Carac®, Efudex®, and

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

Fluoroplex®. Very small amounts could be dangerous to household pets; thus, patients should use care when applying and storing the medication. FDA has received reports of five dogs that became ill and died after accidentally ingesting the topical cream, notes a Center for Veterinary Medicine Update available at www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm537434.htm.

Although FDA has not received any reports involving cats to date, cats are also expected to be extremely sensitive to fluorouracil cream. For instance, if an owner applies fluorouracil cream to an afflicted area and touches his or her cat, the cat may accidentally ingest the medication when grooming itself and suffer adverse events.

FDA advises that pharmacists who fill these prescriptions should advise patients with pets to prevent exposing their pet to the medication. Adverse events may be reported to FDA using the Form FDA 1932a, which may be obtained at www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm.

FDA Revises Final Guidance Documents on Bulk Drug Substances Used in Compounding

In January 2017, FDA issued revised versions of two final guidance documents regarding the use of bulk drug substances in compounding.

- ◆ Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act
- ◆ Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act

FDA clarified that the policies described in the guidances do not apply to inactive ingredients. Inactive ingredients are not included in the definition of a “bulk drug substance” and can be used in compounding without appearing on the bulk drug substances lists developed under sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act, if all applicable conditions are met.

As indicated on its website at www.fda.gov/Drugs/DrugSafety/ucm502075.htm, FDA will also provide regular updates to the categories of bulk drug substances described in the guidances. FDA previously stated that it would not evaluate new nominations for placement in one of the three categories until after it completed its review of substances already nominated with adequate supporting information.

Now, the guidances state that FDA will determine after submissions are received whether new nominations, including renominations of substances with additional supporting information, have sufficient information for FDA to review them. After making that determination, FDA will place nominated substances in the appropriate category on FDA’s website. FDA intends to update the categories with any new nominations the first business day of each month. This revised policy will further minimize unnecessary disruptions to patient treatment while FDA develops the lists of bulk drug substances for use in compounding.

The guidances are available online at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf and www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469122.pdf.

APhA Resource Guide Applies JCPP Pharmacists’ Patient Care Process to Immunization Services

The American Pharmacists Association (APhA) published a resource guide that applies the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists’ Patient Care Process to pharmacy-based immunization services. The components of the Pharmacists’ Patient Care Process to collect, assess, plan, implement, and follow-up should be implemented as routine practice along with the National Vaccine Advisory Committee Standards for Adult Immunization Practice, as noted in the resource guide, *Applying the Pharmacists’ Patient Care Process to Immunization Services*. “[P]harmacists and other vaccine providers need to strive to constantly improve collaboration, communication, and documentation,” indicates the APhA guide. For more information, visit the APhA Immunization Center at www.pharmacist.com/immunization-center.

CPE Training on Older Adult Fall Prevention Available Online

Developed in collaboration with the Centers for Disease Control and Prevention (CDC) and the APhA, the Stopping Elderly Accidents, Deaths, and Injuries (STEADI) initiative is offering continuing pharmacy education (CPE) training for pharmacists to prevent falls in adults 65 and older. The training will provide strategies to help pharmacists screen older adults for fall risk, conduct medication review and management, and offer patient education. To participate in the free online training, “STEADI: The Pharmacist’s Role in Older Adult Fall Prevention,” visit the CDC website at www.cdc.gov/steadi/training.html for more information.

New FDA Drug Info Rounds Training Video Addresses the Combat Methamphetamine Epidemic Act

Drug Info Rounds, a series of online videos by FDA, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the latest Drug Info Rounds video, “Combat Methamphetamine Epidemic Act,” pharmacists discuss the legal requirements for the sale of over-the-counter drug products that contain pseudoephedrine. Drug Info Rounds was developed with contributions from pharmacists in FDA’s Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.

FDA Presents Series of CE Webinars for Students and Clinicians

FDA’s Division of Drug Information in the CDER presents a series of continuing education (CE) webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of FDA’s role in medication error prevention and prescription drug labeling. The webinars and presentation slides can be accessed on FDA’s website at www.fda.gov/DDIWebinars.

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(PH). The “(PH)” link will navigate to the paper form. For additional help, please contact the Board office at 615/741-2718 and choose the option for pharmacy license applications.

Board of Pharmacy Legislative Update 2017

Legislation that may affect the Board is listed below. To review each public chapter in its entirety, click on the highlighted links.

Public Chapter (PC) 392: This legislation authorizes the Tennessee Department of Health, in cooperation with the Board, to establish a prescription drug donation repository program, under which a person or organization may donate prescription drugs and supplies for use by an eligible nonprofit organization. The law requires these nonprofit organizations to report data to the Department about the number of donors, donations, types of prescriptions, and other data. The law allows donated drugs to be dispensed at no cost if they are in their original sealed packaging, are inspected by a pharmacist, and are prescribed by a health care practitioner and dispensed by a pharmacist. Additionally, the law provides for limited civil and criminal liability for matters related to the donation, acceptance, or dispensing of drugs pursuant to this repository program. Finally, the law allows the Department of Health, in consultation with the Board, to promulgate rules to effectuate the purposes of this part. This act will take effect on January 1, 2018.

PC 268: This law specifies that any person licensed by the Board and holding a valid wholesaler license will be considered to be licensed as a drug distributor until such a time when the Board can promulgate rules to implement the third-party logistics provider licensing process. This act took effect on May 4, 2017.

PC 112: This legislation requires the commissioners of the Department of Health and the Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS) to produce guidelines on nonresidential buprenorphine treatment by January 1, 2018, and to annually update those guidelines. The commissioner of TDMHSAS shall submit these guidelines to the Board, who shall review the guidelines and determine how they should be used by the Board’s licensees as well as post them on the Board’s website. This act took effect on April 7, 2017.

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](#).

Registrants may now update their profile on the Board website. Click [here](#) to sign up for an online account or to update a profile.

Help Is Available for Impaired Pharmacists Through the TPRN

If you need help or know an associate who does, please contact Dr Baeteena Black, Tennessee Pharmacists Recovery Network (TPRN) program director, by phone at 615/256-3023 or by email at bblack@tnpharm.org.

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

Link for Disciplinary Action

Monthly disciplinary action information is available by clicking [here](#). This web page also contains specific registrant verification as well as the option to receive a monthly disciplinary email report.

Tennessee DEA Office Gives Guidance for Reporting Theft or Loss

Per Title 21, Code of Federal Regulations, 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 a DEA Form 106**, available 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.

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:

- ◆ 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

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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