



# Tennessee Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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<http://tn.gov/health/topic/pharmacy-board>

## **Board Reiterates That Registrants Shall Have Most Current Edition of the Tennessee Pharmacy Laws ‘Paperback Book’**

During the January 24, 2017 meeting, the Tennessee Board of Pharmacy stated that the “paper law books are required,” referring to the only actual paperback book that is **issued by the Board**. The current book is the orange-colored 2015 edition. The Board opined on this issue earlier in the meeting, only to reverse the decision before the close of business, as it was brought to the Board’s attention that all the information from the actual law book is not published on the Board website. Therefore, a **complete** electronic copy is not available, and the most current physical book is required. To order, click [here](#) for an order form or visit the [About](#) section of the Board’s website.

## **Counseling Responsibilities: New Versus Refill Prescriptions**

Board Executive Director Reginald “Reggie” Dilliard continues to update pharmacists on the issue of counseling and the fact that pharmacists continue to be disciplined for violating one of the main functions that “shall” be performed by a pharmacist.

Recall that the word “shall” is defined in the Board rules. Per new Board rules signed in February 2017, Rule 1140-01-.01(38) states the following: “‘Shall’ means that compliance is mandatory.”

The counseling regulation, which is located in Rule [1140-03-.01](#), indicates that a pharmacist shall counsel on all new prescriptions. It is **not** acceptable to simply ask if a patient has any questions on a **new** prescription. Refer to Section [1140-03-.01\(1\)\(e\)](#) for the eight points of counseling and remember to use professional judgment as stated, in part: “Patient counseling shall cover matters, which **in the exercise of the pharmacist’s professional judgement, the pharmacist deems significant . . .**”

A **new medical or new prescription order** may include, but is not limited to, the following:

- ◆ A prescription medication that has never been taken or used before by a patient.
- ◆ A prescription that has been reassigned a new prescription serial number **as refills are no longer available** from the original prescription due to expiration, refill quantity used to completion, or discontinuance by the prescribing practitioner, among other legitimate reasons.
- ◆ A prescription that is in, as an example, Schedule II, such as amphetamine salts, and therefore is always a new prescription.
- ◆ A prescription that is written for a prescription device such as an auto-injector or oxygen concentrator dispensed from the pharmacy.

Be advised that a new prescription **shall** always be counseled face-to-face by the pharmacist unless the patient or caregiver refuses counseling **to the pharmacist**. Furthermore, the pharmacist may still be held in violation if the patient or caregiver refuses, but does **not** do so **face-to-face** to the pharmacist. A refusal to counsel to the pharmacy technician does **not** meet the requirement on a **new** prescription.

Moving on to the **refill** as stated in Rule 1140-03-.01(1)(f), “Upon the receipt of a request for a refill of a medical or prescription order, a pharmacist or a person designated by the pharmacist shall offer **for the pharmacist** to personally counsel the patient or caregiver.” Therefore, counseling as described in (e) may not be required unless deemed necessary by the pharmacist. However, the **offer** for the pharmacist to counsel **is** still required.

## **Pharmacist-in-Charge Position Adds Large Responsibility**

So, you are fresh out of pharmacy school, or maybe you are an established pharmacist and feel the call to move to a position that at times brings additional compensation or benefit, or maybe the current pharmacist-in-charge (PIC) has unexpectedly been disabled or terminated or has moved for a better opportunity. Regardless of the case, it is strongly


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## FDA Issues Final Rule Amending List of Drug Products That May Not Be Compounded

Food and Drug Administration (FDA) issued a final rule amending FDA's list of drug products that may not be compounded under certain sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that allow the marketing of unapproved compounded drugs. Drug products on the list may not be compounded because the drug products have been withdrawn or removed from the market for safety or effectiveness reasons, indicates FDA. The list may be found in the Code of Federal Regulations at Title 21, Section 216.24, at [www.ecfr.gov](http://www.ecfr.gov).

The final rule adds 24 types of drugs to the withdrawn or removed list; modifies the withdrawn or removed list to allow one type of drug product to be compounded under certain circumstances; and clarifies that the withdrawn or removed list applies to sections 503A and 503B of the FD&C Act. The final rule is available at [www.gpo.gov/fdsys/pkg/FR-2016-10-07/pdf/2016-24333.pdf](http://www.gpo.gov/fdsys/pkg/FR-2016-10-07/pdf/2016-24333.pdf). FDA provides more information online at [www.fda.gov/Drugs/DrugSafety/ucm524320.htm](http://www.fda.gov/Drugs/DrugSafety/ucm524320.htm).

## Selected Medication Risks to Manage in 2017

 *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).*

Some medication safety risks are painfully apparent in an organization, while many others lie dormant in the system until an error or adverse event draws attention to them. ISMP thought it would be useful to describe selected medication safety risks for organizations to manage in 2017 that might otherwise fall off the radar screen.

### Environmental Factors, Workflow, and Staffing Patterns – Poor Quality Lighting

Lighting is a crucial aspect of the physical environment that has been linked to medication safety.<sup>1</sup> Poor quality lighting has often impaired the highly visual tasks associated with medication use, thus leading to medication errors. Examples include tubing misconnections due to low lighting in a patient's room, infusion pumps that have been misprogrammed because of dim backlighting on the screens, and product selection errors in the pharmacy and patient care units caused by low lighting under a pharmacy hood or shadows around an automated dispensing cabinet (ADC).

Despite existing guidelines for lighting in health care, it has been a challenge to implement optimal lighting conditions for prescribing, dispensing, and administering medications. Recent literature reviews found that little system-wide action has been

taken to increase staff awareness of the problem or improve the lighting.<sup>1,2</sup> This is largely because the tasks associated with medication use are varied and carried out under diverse physical conditions and in differing locations, and because there are differences in an individual's light requirements based on visual acuity and age. With an ever-increasing population of older health care providers, eye fatigue from computer work and task complexity, small font sizes on medication labels, poor background contrast, and glare or shadows have taken their toll on visual accuracy.<sup>1,2</sup>

Proper illumination improves both the accuracy and efficiency of medication-related tasks. Fluorescent cool white lamps or compact fluorescent lamps should be used in areas where critical tasks are performed, including on mobile medication carts, near ADCs, and in patients' rooms for nighttime administration of medications.<sup>3,4</sup> Administration of medications at night under low lighting to avoid disturbing the patient is an unsafe practice and should be avoided. Adjustable 50-watt high-intensity task lights are recommended when difficult-to-read prescriptions and product labels are encountered.<sup>4</sup> Illumination levels for computer order entry areas should be at least 75 foot-candles (fc), while 100-150 fc are needed when interpreting handwritten orders.<sup>4</sup> Medication preparation areas, medication verification areas, and patient counseling areas should have illumination levels between 90-150 fc.<sup>4</sup> Medication rooms should provide illumination at 100 fc.<sup>4</sup> Lighting levels should be increased if the workforce has an average age above 45 years. A magnifying glass and task light together can also significantly improve accuracy<sup>3</sup> and should be used on mobile medication carts (including those used with bar code medication verification systems)<sup>4</sup> and near ADCs.

### References:

1. Chaudhury H, Mahmood A, Valente M. The effect of environmental design on reducing nursing errors and increasing efficiency in acute care settings: a review and analysis of the literature. *Environ Behav.* 2009;41(6):755-786.
2. Graves K. *Nurses' Decision Making Processes About Lighting During Medication Administration* [dissertation]. Denton: Texas Woman's University College of Nursing; 2014.
3. Grasha AF. Psychosocial factors, workload, and risk of medication errors. *US Pharm.* 2002;27(4):HS32-52.
4. United States Pharmacopeial Convention. Chapter <1066> Physical environments that promote safe medication use. *Revision Bulletin.* October 1, 2010;2-6. [www.ismp.org/sc?id=1664](http://www.ismp.org/sc?id=1664).

### DEA to Decrease Manufacturing Amount of Opioid Controlled Substances in 2017

Drug Enforcement Administration (DEA) is reducing the amount of almost every Schedule II opiate and opioid medication that may be manufactured in 2017 by 25% or more. Other medicines were reduced by more, such as hydrocodone, which will be 66% of last year's level, indicates the DEA news release. DEA notes that demand for these opioid medicines has declined based on sales data from IMS Health, a company that provides insurance companies with data on prescriptions written and prescription medications sold in the United States.

The aggregate production quota (APQ) established by the final order is the total amount of a controlled substance (CS) necessary to meet the estimated medical, scientific, research, industrial, and export needs for the year and for the maintenance

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

of reserve stocks. The 2017 APQ has been reduced for oxycodone, hydrocodone, fentanyl, hydromorphone, morphine, and other such medications. Much of this reduction is attributed to the elimination of a 25% buffer that was added to the APQ annually in 2013 through 2016 to guard against shortages. The purpose of quotas is to provide an adequate and uninterrupted supply for legitimate medical need of the types of Schedule I and II CS that have a potential for abuse, while limiting the amounts available to prevent diversion.

Additional details may be found in the DEA news release available at [www.dea.gov/divisions/hq/2016/hq100416.shtml](http://www.dea.gov/divisions/hq/2016/hq100416.shtml) and in the final order available at <https://www.gpo.gov/fdsys/pkg/FR-2016-10-05/pdf/2016-23988.pdf>.

### **New CDC Brochure Offers Pharmacists Tips for Addressing Prescription Opioid Abuse and Overdose**

Centers for Disease Control and Prevention (CDC) released a brochure encouraging pharmacists, who are an essential part of the health care team, to help prevent opioid abuse and overdose. The brochure, “Pharmacists: On the Front Lines,” offers tips for communicating with patients who are receiving opioid therapy. In addition, the brochure offers tips on how to identify forged prescriptions and urges pharmacists to maintain collaborative working relationships with prescribers to improve patient outcomes. The brochure is available at [www.cdc.gov/drugoverdose/pdf/pharmacists\\_brochure-a.pdf](http://www.cdc.gov/drugoverdose/pdf/pharmacists_brochure-a.pdf).

### **FDA Requires Boxed Warnings and Patient-Focused Medication Guides Indicating Serious Risks Related to Combined Use of Certain Opioid Medications and Benzodiazepines**

FDA is requiring class-wide drug labeling changes to inform health care providers and patients of the serious risks associated with the combined use of certain opioid medications and benzodiazepines. Specifically, after an extensive review of the latest scientific evidence, FDA is requiring boxed warnings and patient-focused Medication Guides for prescription opioid analgesics, opioid-containing cough products, and benzodiazepines that provide information about the serious risks associated with using these medications at the same time. Risks include extreme sleepiness, respiratory depression, coma, and death.

FDA’s news release indicates the changes are part of the agency’s Opioids Action Plan, which focuses on policies aimed at reversing the prescription opioid abuse epidemic while providing patients in pain with access to effective and appropriate pain management. The public health crisis is evident through the significant rise of preventable overdose and death associated with the concurrent use of two drug classes, indicates FDA Commissioner Robert Califf, MD, in the press release, available at [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm).

### **FDA’s Division of Drug Information Offers CE Webinars for Students and Clinicians**

FDA’s Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information 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 drug shortages and prescription drug promotion. The webinars and presentation slides can be accessed on FDA’s website at [www.fda.gov/DDIWebinars](http://www.fda.gov/DDIWebinars).

### **FDA Approves Labeling Changes for All Prescription Testosterone Products**

In October 2016, FDA approved class-wide labeling changes for all prescription testosterone products regarding the risks associated with abuse and dependence of the drug. The changes include adding a new warning as well as updating the Abuse and Dependence section to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other anabolic androgenic steroids (AAS). The Anabolic Steroids Control Act of 1990 placed AAS, including testosterone, in Schedule III of the Controlled Substances Act.

Prescription testosterone products are FDA-approved as hormone replacement therapy for men who have low testosterone due to certain medical conditions. However, testosterone and other AAS are abused by adults and adolescents, including athletes and body builders, notes FDA. FDA indicates the new warning will “alert prescribers to the abuse potential of testosterone and the serious adverse outcomes, especially those related to heart and mental health that have been reported in association with testosterone/AAS abuse.” In addition, new labeling information in the Warning and Precautions section advises prescribers of the importance of measuring serum testosterone concentration if abuse is suspected.

FDA explains that abuse of testosterone, usually at doses higher than those typically prescribed and usually in conjunction with other AAS, is associated with serious safety risks affecting the heart, brain, liver, mental health, and endocrine system. Reported serious adverse outcomes include heart attack, heart failure, stroke, depression, hostility, aggression, liver toxicity, and male infertility. Individuals abusing high doses of testosterone have also reported withdrawal symptoms, such as depression, fatigue, irritability, loss of appetite, decreased libido, and insomnia. The FDA announcement is available at [www.fda.gov/Drugs/DrugSafety/ucm526206.htm](http://www.fda.gov/Drugs/DrugSafety/ucm526206.htm).

### **Latest FDA Drug Info Rounds Training Videos Available**

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, “Extortion Scam,” pharmacists discuss steps a potential victim could take if they receive a call from individuals posing as FDA and DEA agents. Drug Info Rounds is developed with contributions from pharmacists in FDA’s 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](http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm).

advised to review past [Board minutes](#), [live streaming videos](#) of Board meetings, and [Board regulations](#) so that you may better understand the PIC responsibilities. The PIC may be found accountable, and many times disciplined by the Board, for actions including negligence of theft or loss of drugs (not auditing controlled substances (CS) consistently), failure of self or of other employees to counsel patients or offer for the pharmacist to counsel patients, lack of a sink with hot running water, lack of a functional refrigerator, lack of or not following standard operating procedures, not following sterile compounding rules and regulations, lack of proper staff training, cleaning, and other required documentation, lack of drug removal due to adulterated/expired drugs found on shelves, and the finding of pharmacy technicians with expired registrations, among other things. Discipline may include, but is not limited to, a letter of instruction, letter of warning, reprimand, probation, suspension, or revocation. These violations become a permanent record in your pharmacist license file. Except for the letter of instruction or warning, other violations will be made available for public view. Costly civil penalties may also be levied by the Board. **Even if you did not directly commit the violation** (eg, failure to counsel or technician registration expired), violations may result against the PIC's license.

Moreover, it is strongly suggested that you read the Board rule specific to the PIC before you accept the position. [Rule 1140-03-.14](#) in part requires that you immediately conduct an inventory of all CS, including damaged but not yet destroyed or other held-for-return medications. If at all possible, the incoming and outgoing PIC shall perform this task and notify the Board with this information by rule. [This form](#) will satisfy the rule once it is sent to the Board. If the outgoing PIC is no longer available, the incoming PIC performs this task and notifies the Board. If a pharmacist is disabled and you are asked to "fill in" as PIC and the time period exceeds 30 days, then you shall conduct a CS inventory at that time. If the disabled or other pharmacist returns, an additional CS inventory is required. If a pharmacy closes, is sold, or is otherwise transferred to different ownership, the PIC shall notify the Board "in writing," which will include the disposition of records, etc. For a detailed list of tasks involved in closing/transferring a pharmacy, [click here](#).

The PIC is responsible for maintaining a technician "registry" (a simple list of all the pharmacy technicians working at that site). The PIC shall be on duty for at least 50% of the time the pharmacy is in operation, but is not required to be on duty more than an average of 40 hours per week. And last but not least, the PIC is responsible for reporting **". . . any situation in which a medical or prescription order has caused serious personal injury or death."**

Remember that the pharmacy investigator staff and director are ready to answer your questions and welcome you to use them as a resource (see page 5 of the [December 2013 Tennessee Board of Pharmacy Newsletter](#) for contact information). As Board Executive Director Reggie Dilliard has repeated from select predecessors, "We would rather

educate you on how to do it correctly as opposed to catch you in violation."

## **January Meeting Results in Board Officers Being Elected for the New Year**

As is customary at the beginning of each calendar year, new Board officers were nominated and elected as follows: Dr Kevin Eidson accepted the president's chair, while Dr Mike Dickenson accepted the nod as vice president for 2017. Before passing the gavel, President Will Bunch had a few last words for the Board. "It has been an honor and a pleasure to serve on this Board in this capacity and I appreciate your trust and patience with me," he said. The Board thanks Dr Bunch for his leadership and congratulates the elected officers on their new positions.

## **Board Members and Staff Bid Farewell to Long-Standing Public Member Joyce McDaniel**

As Ms Joyce McDaniel ended her term as a Board public member, the January meeting minutes reflected that she has served since June 9, 2009.

"The Board has lost a valuable public member in Joyce McDaniel," Executive Director Reggie Dilliard stated. "She has always been able to give us a valuable perspective from the consumer side that is needed and important to the Board's deliberations."

Before giving up the president's chair, Dr Will Bunch voiced his very sincere and heartfelt appreciation for Ms McDaniel. "Joyce has always been the one to plan everything for us," said Dr Bunch. "She has been our caterer, concierge, and event planner." He noted that she will be missed.

## **New Public Member Is Appointed to the Board**

As the January 24, 2017 Board meeting ended, Mrs Lisa Tittle completed her first Tennessee Board of Pharmacy meeting. Before the meeting, Executive Director Reggie Dilliard introduced her via email to the Board members and staff.

"Lisa Tittle has been appointed and has accepted the position of consumer member with our board officially," he said. "Please welcome her and let her know that we appreciate her willingness to serve."

Mrs Tittle was previously known to the Board, as she has worked for the Tennessee Department of Health, answering questions to the Board about the Board's financials. According to Executive Director Reggie Dilliard, she is very knowledgeable about the budget and will be a tremendous resource in understanding each line item. The Board looks forward to her input.

## **Link for Disciplinary Actions**

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 Drug Enforcement Administration (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:

- ◆ March 14-15
- ◆ May 9-10
- ◆ July 11-12

◆ September 12-13

◆ November 14-15

Tentative 2017 dates set for contested hearings include the following:

◆ April 12-13

◆ June 13-14

## **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, 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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