

June 2016

News



# Tennessee Board of Pharmacy

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## **Professional Privilege Tax Due Now (June 1, 2016)**

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 (TCA), Section 67-4-1701). Visit <https://apps.tn.gov/privtx> for information.

## **New Tennessee Board of Pharmacy Law Book Now Available**

The new law book is available for purchase from the Tennessee Board of Pharmacy office for \$20, which includes shipping and handling. To purchase, please visit the Board's [website](#) and click on "2015 Law Books (limited supply)" located under the subheading "Featured Links."

## **Legislation Affecting Pharmacy in 2016**

**Public Chapter (PC) 1002: Prescribing practitioners and pharmacists are required to check the database.** Enacts the "Tennessee Prescription Safety Act of 2016," which revises regulation of controlled substances (CS) primarily by means of procedures involving the CS database. Pharmacists may be particularly interested in TCA 53-10-310(e). This section explains that health care practitioners, except where exempted, **(of which pharmacists are included per specific definition "for this section")** shall check the database for human patients for initial dispensing and then at least once yearly thereafter for the defined CS, also noted in this statute. Signed into law April 27, 2016.

**PC 596:** Authorizes the chief medical officer of the Tennessee Department of Health to implement a statewide collaborative pharmacy practice agreement for opioid antagonist therapy with pharmacists. Signed into law March 10, 2016.

**PC 942:** Permits a pharmacist to provide hormonal contraceptives, as defined in the PC according to a valid collaborative pharmacy practice agreement that contains a "[non-patient-specific] prescriptive order and standardized procedures developed and executed by one (1) or more authorized prescribers." Signed into law April 27, 2016.

**PC 656:** Permits a pharmacist to dispense medication in a quantity that varies from the prescription **under certain circumstances**, provided that the units dispensed do not exceed a 90-day supply. Signed into law March 29, 2016.

**This PC does not supersede the current regulation for the dispensing of opioids or benzodiazepines as stated in TCA 53-11-308(e): "No prescription for any opioids or benzodiazepines may be dispensed in quantities greater than a thirty-day supply."**

**PC 805:** Authorizes certain entities to stock epinephrine auto-injectors on their premises; authorizes employees, agents, and laypersons to provide or administer an epinephrine auto-injector under certain circumstances. Furthermore, it allows **pharmacists to dispense an epinephrine auto-injector to the authorized entity** pursuant to a prescription authorized by a health care prescriber as defined in this section (see TCA 68-140-501(5)). Signed into law April 14, 2016.

**PC 801:** Authorizes law enforcement officers to administer epinephrine in emergency situations if the officer's law enforcement agency has adopted a protocol governing the administration of epinephrine; authorizes physicians to prescribe epinephrine to a law enforcement agency for use by officers in emergency situations. **It allows for a pharmacist to dispense the epinephrine auto-injector in the name of the law enforcement agency** pursuant to a prescription authorized by a health care prescriber. Signed into law April 14, 2016.

**PC 773:** Extends the Board two years to June 30, 2018; requires the Board to appear before the Government Operations Joint Evaluation Committee on Education,

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## **FDA Approves Naloxone Nasal Spray to Prevent Opioid Overdose Deaths**

Food and Drug Administration (FDA) has approved Narcan® Nasal Spray (also known as naloxone), a life-saving medication that can stop or reverse the effects of an opioid overdose. Prior to this approval, naloxone was only approved in injectable forms, most commonly delivered by syringe or auto-injector, explains FDA in a news release.

Narcan Nasal Spray does not require assembly and delivers a consistent, measured dose when used as directed. This prescription product can be used on adults or children and is easily administered by anyone, even those without medical training. The drug is sprayed into one nostril while the patient is lying on his or her back, which can be repeated if necessary. However, it is important to note that it is not a substitute for immediate medical care, and the person administering Narcan Nasal Spray should seek further immediate medical attention on the patient's behalf. The use of Narcan Nasal Spray in patients who are opioid dependent may result in severe opioid withdrawal characterized by body aches, diarrhea, increased heart rate (tachycardia), fever, runny nose, sneezing, goose bumps (piloerection), sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure. Narcan Nasal Spray is distributed by Adapt Pharma, Inc, of Radnor, PA. The FDA news release is available at [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm473505.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm473505.htm).

## **Selected Medication Safety Risks to Manage in 2016**



*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).*

It is a nearly impossible task to list all the risks associated with medication use that could lead to harmful medication

errors. So where do health care professionals start to improve medication safety? Most people frequently resort to playing “whack-a-mole,” addressing risks only after they pop up and become visible after an adverse event.

Listed below are two serious medication safety risks that might fall off the radar screen unless an adverse event happens to draw attention to them. Additional serious risks will be published in future issues of the National Association of Boards of Pharmacy® *National Pharmacy Compliance News*.  
**Patient Information – Placing Orders on the Wrong Patient's Electronic Health Record**

A potentially hidden vulnerability that can lead to serious errors is placing orders on the wrong patient's electronic health record. A recent study published in the *Journal of the American Medical Informatics Association* identified and quantified close calls that would have resulted in wrong-patient errors. According to this study, about 14 wrong-patient electronic orders are placed every day in a large hospital system with approximately 1,500 beds, or about 68 wrong-patient errors per 100,000 medication orders. By this measure, one in 37 hospitalized patients will have an order placed for them that was intended for another patient.<sup>1</sup>

These errors are sometimes due to juxtaposition but more often caused by interruptions and having more than one patient's electronic health record open.

Multiple studies have demonstrated ways to reduce these events. Requiring verification of the patient's identity has reduced errors by 16% to 30%, and requiring re-entry of the patient's identification has reduced errors by 41%.<sup>1,2</sup> Prompting clinicians for an indication when certain medications are ordered without an indication on the patient's problem list has intercepted errors at a rate of 0.25 per 1,000 alerts.<sup>3</sup> In one study, most emergency department (ED) staff (81%) felt a room number watermark on the patient's electronic health record would eliminate most wrong-patient orders in the ED.<sup>4</sup>

## **Communication About Drug Therapy – Confusing the Available Concentration as the Patient's Dose on Electronic Records**

Another risk deals with how home medications appear on computer screens. For example, a physician accidentally ordered 100 units of Lantus® (insulin glargine) instead of the correct dose of six units because the list of medications used at home displayed the concentration right next to the drug name on the first line, and the patient's dose below it on the second line: “Insulin glargine (Lantus) 100 units/mL,” followed on the next line with “6 units subcutaneous daily every evening.”

Now that insulin is available in 100 units/mL, 200 units/mL, 300 units/mL, and 500 units/mL concentrations, the risk



of receiving an overdose of insulin is high if the presentation of the order lists the product's concentration before the patient's dose. ISMP's recommendation is to list the drug name, patient-specific dose, and directions for use on the first line of the electronic medication administration record and patient medication lists, and the available concentration and any directions on how to measure the patient's dose below it.

#### References

1. Adelman JS, Kalkut GE, Schechter CB, et al. Understanding and preventing wrong-patient electronic orders: a randomized controlled trial. *J Am Med Inform Assoc.* 2013; 20(2):305-310.
2. Green RA, Hripcsak G, Salmasian H, et al. Intercepting wrong-patient orders in computerized provider order entry system. *Ann Emerg Med.* 2015; 65(6):679-686.
3. Galanter W, Falck S, Burns M, Laragh M, Lambert BL. Indication-based prescribing prevents wrong-patient medication errors in computerized provider order entry (CPOE). *J Am Med Inform Assoc.* 2013; 20(3):477-481.
4. Yamamoto LG. Reducing emergency department charting and ordering errors with a room number watermark on the electronic medical record display. *Hawaii J Med Public Health.* 2014; 73(10):322-328.

### **FDA Provides Training Videos on MedWatch Resources and Breakthrough Therapy**

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the January 2016 Drug Info Rounds video, "MedWatch Tips and Tools," pharmacists discuss reporting adverse events to FDA's MedWatch Safety Information and Adverse Event Reporting Program and the resources available for health care professionals to report safety information. In the December 2015 Drug Info Rounds video, "Breakthrough Therapy," pharmacists discuss the breakthrough therapy designation program, which is intended to expedite the development and review of drugs for serious or life-threatening conditions. Drug Info Rounds is 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](http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm).

### **Reading Medicine Labels Helps Reduce Acetaminophen Overdoses**

The Acetaminophen Awareness Coalition (AAC) reminds pharmacists and other health care providers to encourage patients to properly read medicine labels to avoid unintentional acetaminophen overdoses. The coalition also encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use.

AAC's "Know Your Dose" campaign reminds patients to take these four steps to avoid acetaminophen overdose:

- (1) Always read and follow the medicine label.
- (2) Know if their medicines contain acetaminophen.
- (3) Take only one medicine at a time that contains acetaminophen.
- (4) Ask their health care provider about any questions.

Additionally, pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website at [www.knowyourdose.org](http://www.knowyourdose.org).

### **Over-the-Counter Children's Medicine Recalled Due to Incorrect Dose Markings**

In January 2016, Perrigo Company voluntarily recalled two lots of children's guaifenesin grape liquid cough medicine (100 mg/5 mL) and three lots of children's guaifenesin DM cherry liquid cough medicine (100 mg guaifenesin and 5 mg dextromethorphan HBr/5 mL) sold in 4 oz bottles. The recall was initiated because some packages contain an oral dosing cup with incorrect dose markings. The affected products were sold by distributors nationwide and distributed through retail stores. The recalled lots and store brands are available in the Perrigo press release posted on the company's website, [www.perrigo.com](http://www.perrigo.com), under "Investors." To date, the company has not received reports of overdose. Distributors and retailers that have the affected lots should stop distribution and return the product using the information provided in the press release.

Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at [www.fda.gov/MedWatch](http://www.fda.gov/MedWatch).

### **FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians**

FDA's Division of Drug Information, CDER, presents a series of continuing education 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. Past topics have included "Introduction to FDA's MedWatch Adverse Reporting Program" and "An Overview of the FDA's Breakthrough Therapy Designation Program." Upcoming webinars, previous webinars, and presentation slides can be accessed on FDA's website at [www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm](http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm).



Health and General Welfare no later than November 18, 2016, to provide an update on the Board's progress in addressing the findings set forth in the October 2015 performance audit report issued by the Division of State Audit. Signed into law April 12, 2016. (There is also [additional information](#) not yet updated to the PC.)

**PC 564:** Extends the state TennCare Pharmacy Advisory Committee four years to June 30, 2020. Signed into law March 2, 2016.

**PC 546:** Extends the Controlled Substance Monitoring Database Advisory Committee two years to June 30, 2018; requires the advisory committee to appear before the Government Operations Joint Evaluation Committee on Education, Health and General Welfare no later than November 18, 2016, to provide an update on the advisory committee's progress in addressing the findings set forth in the October 2015 performance audit report issued by the Division of State Audit. Signed into law March 2, 2016.

**PC 763:** Permits licensees whose licenses from a health-related board have expired to obtain reinstatement on the basis of a plan developed by the Department of Health for periodic payment of past due renewal fees and unattained continuing education (CE) instead of the current requirement of payment of all past due fees before reinstatement. Signed into law April 19, 2016.

**PC 952:** Supersedes rules of the Tennessee Board of Medical Examiners to permit the prescription, order, sale, or other distribution of the drug lisdexamfetamine dimesylate for any currently accepted medical use in the United States. Signed into law April 27, 2016.

## **Board Office Review of Facsimile (Fax) Versus Electronic Prescription Regulation**

Have you ever been confused about the differences in state and federal regulations regarding the validity of facsimile and electronic prescriptions? If so, you are probably not alone! Dr William Bunch, current Board president, approved the addition of the following information that may be helpful in understanding guidance for this confusing issue.

- ◆ A CS fax must have a **manually written** signature via Drug Enforcement Administration (DEA) regulation, even if prepared via electronic means, as stated in the DEA [General Questions and Answers](#).
- ◆ An **electronic prescription for CS** must have an electronic signature as defined by the [Code of Federal Regulations](#) and may only be filled if accepted through the DEA-approved vendor software that meets all the requirements from prescriber computer to pharmacy computer.

**However, state rules** regarding **non-controlled** prescriptions were explained at the July 2012 Board meeting. The Board discussed Rule 1140-03-.04(2)(a)(2)(iv) and

interpreted that the prescriber's electronic signature was acceptable for all electronically generated prescriptions if the signature met all validation requirements of the definition stated in this rule. Therefore, an electronically generated prescription authenticated in accordance with the rule would be considered acceptable by the Board. Per the rule, "authenticated" means:

. . . proof of claimed identity, such as by biometrics, fingerprints, retinal scans, or hand written signature verification, [etc] at the time the signature is generated and creates the logical manifestation of a signature.

### **Therefore, in Tennessee:**

- ◆ A **non-controlled** prescription may be prepared by electronic means and be faxed without the manual written prescription provided that it has an electronic signature.
- ◆ A **non-controlled** prescription may be prepared and sent by fax provided it has an electronic signature. This type of prescription may also be given to the patient to be taken to the pharmacy.
- ◆ A **non-controlled** prescription may be filled if received as a fax provided that it is valid, legitimate, and was sent as an electronic prescription but the software routed it to the fax. This type of prescription may be given to the patient to be taken to the pharmacy as well.

Regarding all of these possibilities of receiving a prescription into the pharmacy, it must always be reviewed for **validity and legitimacy** before dispensing.

- ◆ It is **valid** if all the requirements are met from regulation.
- ◆ It is **legitimate** if the prescription is written for a sound professional judgment purpose.

Still confused? Board Executive Director Reginald B. "Reggie" Dilliard, DPh, may be reached at reginald.dilliard@tn.gov or 615/741-2403, or you may call the Board office to be routed to your local investigator at 615/741-2718.

## **Clarification for the Sale of PSE by Way of Pharmacist-Generated Prescriptions, Reporting, and Dispensing Regulations**

In the March 9, 2016 Board meeting, Dr Kevin Eidson, current Board vice president, requested that clarification of the pharmacist-generated prescription reporting regulations for the dispensing of pseudoephedrine (PSE) be explained in the June 2016 *Tennessee Board of Pharmacy Newsletter*.

Dr Terry Grinder, Board investigator, with the assistance of intent from former Tennessee Pharmacists Association Executive Director Baeteena Black, indicated that a pharmacist in Tennessee may generate a prescription for

PSE but must adhere to the definition and limits set by the statute as stated in TCA 39-17-431(c)(1).

A pharmacy shall not sell products containing ephedrine or pseudoephedrine base, or their salts, isomers or salts of isomers to the same person in an amount more than: (A) Five and seventy-six hundredths (5.76) grams in any period of thirty (30) consecutive days; or (B) Twenty-eight and eight tenths (28.8) grams in any one-year period.

Furthermore, the pharmacist is exempt from reporting the pharmacist-generated prescription to the National Precursor Log Exchange system, referring to the specific regulation of this same statute (TCA 39-17-431(c)(1)(4)), as follows:

This subsection (c) also shall apply to **pharmacist-generated prescription orders** of the product pursuant to § 63-10-206. The provision of the patient education and counseling as a part of the practice of pharmacy shall be required when any product is issued under this subsection (c).

It is advised to read all sections of the statute, which may be found by visiting the [Board website](#). Under “Statutes,” click on and follow the directions of the LexisNexis Law link.

### **Link for Disciplinary Action**

Information about disciplinary actions is available on the Board’s [License Verification](#) web page.

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

If you need help or know an associate who does, please contact 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).

An information link (including the reporting form) is located at [www.tnpharm.org/member-center/tn-pharmacists-recovery-network](http://www.tnpharm.org/member-center/tn-pharmacists-recovery-network).

### **Board Meeting Schedule**

The Tennessee Board of Pharmacy 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 CE, 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.

Currently, the **2016** meeting schedule is listed as follows: July 26-27, September 20-21, and November 8-9.

### **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, visit <http://tn.gov/health/article/pharmacy-applications> and click on “Mandatory Practitioner Profile Questionnaire (PH-3585).”

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 William J. Bunch – President
- Dr Kevin Eidson – Vice President
- Dr Mike Dickenson – Board Member
- Dr Debra Wilson – Board Member
- Dr Rissa Pryse – Board Member
- Dr Nina Smothers – Board Member
- Ms Joyce McDaniel – Public Board Member