June 2015

# Tennessee Board of Pharmacy News

*Published to promote compliance of pharmacy and drug law*

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*http://health.state.tn.us/Boards/Pharmacy/index.shtml*

## Professional Privilege Tax Due June 1

The Tennessee Department of Revenue (TDOR) reminds pharmacists that the professional privilege tax was due June 1, 2015. The $400 professional privilege tax is an annual tax imposed on certain professionals who hold an active Tennessee license or registration on the June 1 due date, regardless of whether the person practices his or her profession in Tennessee. Professionals who are subject to the tax may file and pay it online. The TDOR is also happy to answer taxpayer questions, and can be reached through the new online help application, Revenue Help. This application allows taxpayers to search and find answers to their questions, or submit requests electronically.

## Errors at Pharmacy Input May Cause CSMD Integrity to Be Questioned

Increasingly, prescribers are filing complaints against pharmacies that enter incorrect prescriber information into the Controlled Substance Monitoring Database (CSMD). When a patient's prescription has the incorrect prescriber or Drug Enforcement Administration (DEA) number linked to the patient prescription, it is an error that **may be disciplined by the Tennessee Board of Pharmacy.** "The effect of inaccurate data reported to the CSMD causes questions about the integrity and accuracy of the information received," stated Reggie Dilliard, Board executive director. "This possibly discourages the use or actions based on that information."

Common mistakes occur due to prescribers with the same or similar names, former or multiple residents' DEA numbers, and DEA resident modifier numbers. It is imperative for pharmacy personnel to obtain the correct prescriber information and check that the prescribers and DEA numbers match completely from receipt of the prescription through the computer input process.

## Board Member Partners With Local Prescribers in Collaboration Efforts to Manage Patient Care and Spot 'Red Flags'

When discussing how he handles the dispensing of pain medication and the use of "red flags" to verify if a prescription is legitimate, past president and current Board Member Jason Kizer, PharmD, states that he decided to start reaching out to local prescribers and their office staff. He encouraged open lines of communication to discuss the chronic pain management guidelines (referring to the Tennessee Clinical Practice Guidelines for Outpatient Management of Chronic Non-Malignant Pain) and the prescriber/pharmacist's corresponding responsibility. These guidelines may be found at *http://health.state.tn.us/Downloads/ChronicPainGuidelines.pdf*.

As stated in Title 21 Code of Federal Regulations (CFR) §1306.04:

> (a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a **corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription** within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Kizer said that he decided to simply meet with his local prescribers, walk through the guidelines, and collaborate with the staff as to what plan would be put in place for patients if the current therapy was outside of those guidelines. "The key to this process is simply to communicate with the prescribers and their staff to discuss a plan for those particular patients," Kizer said. "I encourage all pharmacists to start that dialogue. This is the first time that I can remember when I felt like I was starting to see a difference in pain management." As an example, Kizer stated that he consults with the prescriber if two short-acting opioids are prescribed together, and he asks

*continued on page 4*

## FDA's New Database Simplifies Searching for Guidance Documents

Food and Drug Administration (FDA) has released a new database that houses most FDA guidance documents for regulatory professionals. The guidance documents for nearly all FDA-regulated professions and industries are available in a searchable database that allows users to enter keywords that update automatically as they are typed. Search results may also be narrowed by product, date, document type, and other terms. The database also indicates whether there is an open comment period and the deadline for submitting comments.

The database can be accessed at *www.fda.gov/RegulatoryInformation/Guidances/default.htm*.

## 2014-2015 Targeted Medication Safety Best Practices for Hospitals

*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.*

The purpose of the Targeted Medication Safety Best Practices (TMSBP) for Hospitals is to identify, inspire, and mobilize widespread, national adoption of consensus-based best practices on specific medication safety issues that continue to cause fatal and harmful errors in patients despite repeated warnings in ISMP publications. These best practices are realistic practices, already adopted by many organizations, upon which hospitals can focus their medication safety efforts. The best practices are applicable to all types of hospitals including, but not limited to, critical access hospitals, cancer hospitals, and children's hospitals. They may also be applicable to other health care settings, as well as non-inpatient areas of hospitals and hospital systems. These best practices have been reviewed by an external expert advisory panel and approved by the ISMP Board of Trustees. Related issues of the *ISMP Medication Safety Alert!* are referenced after each best practice.

### Recurrent Issue of Serious Harm

Oral methotrexate for non-oncological indications administered daily instead of weekly or twice weekly is a recurrent issue and one of the six TMSBPs.

ISMP has published this error in seven *ISMP Medication Safety Alert!* issues from 1996 to 2013. Although dosed daily for oncology purposes, it is used weekly or twice weekly to treat a variety of autoimmune diseases (eg, psoriasis, severe rheumatoid arthritis). Error reports point to inadvertent ordering and/or entering as daily instead of weekly or twice weekly, and lack of patient education/understanding of medication dosing schedule. To minimize the risk of error, **Best Practice 2** calls for hospitals to:

a) Use a weekly dosage regimen default for oral methotrexate. If overridden to daily, require a hard stop verification of an appropriate oncologic indication.
b) Provide patient education by a pharmacist for all weekly oral methotrexate discharge orders.

**Question: Does the best practice of a weekly frequency default for oral methotrexate apply to a specialty cancer hospital?**

Answer: The intent of this best practice is to reduce errors when methotrexate is prescribed as a weekly regimen for non-oncologic or oncologic indications. Even when used for oncologic purposes, oral methotrexate is sometimes prescribed as a weekly regimen, not daily. Thus, this best practice applies to all patient care settings, including specialty cancer hospitals.

### Teaching Points (Both Verbal and Written)

- Explain the weekly dosing schedule.
- Explain that taking extra doses is dangerous.
- Have the patient repeat back the instructions.
- Provide the patient with the free ISMP high-alert medication consumer leaflet on methotrexate (found at *www.ismp.org/AHRQ/default.asp)*.

To read all of the best practices, visit *www.ismp.org/Tools/BestPractices/default.asp.*

## ACPE Releases Updated Definition of CPE and Guidance on CPD

The Accreditation Council for Pharmacy Education (ACPE) has released two documents that provide guidance and support for continuing pharmacy education (CPE) and continuing professional development (CPD). The two documents, approved by the ACPE board of directors, are described below.

- The revised *Definition of Continuing Education for the Profession of Pharmacy* defines the quality of CPE required by ACPE and the competencies required for CPE activity content. The *Definition* document will assist providers of CPE in planning activities that will be applicable to the professional development of pharmacists and certified pharmacy technicians.
- The *Guidance on Continuing Professional Development (CPD) for the Profession of Pharmacy* incorporates feedback from a broad survey of the pharmacy profession that was conducted in July 2014. The *Guidance* document provides details on the learning activities that may contribute to the professional development of both pharmacists and pharmacy technicians beyond CPE, and also "provides a process for pharmacists and pharmacy technicians to meet and maintain defined competencies in areas relevant to their respective professional responsibilities."

Additional information, including links to the documents, is available in a press release on the ACPE website at *www.acpe-accredit.org/pdf/ACPEAdvancesCPE-CPDforPharmacists.pdf*.

## Hospira Issues Recall for Multiple Lots of Ketorolac Tromethamine Injection Due to Potential Contamination

Hospira, Inc, of Lake Forest, IL, has issued a voluntary recall of ketorolac tromethamine injection, USP in the United States and Singapore due to potential particulate matter. The presence of particulate was confirmed through a customer report of visible floating particulate that was identified as calcium-ketorolac crystals. If in-

jected, medications contaminated with particulate matter may cause localized inflammation, allergic reaction, granuloma formation, or microembolic effects. Multiple lots are impacted by this recall and are listed in a press release posted to the FDA website at *www.fda.gov/Safety/Recalls/ucm433857.htm*. The lots were distributed from February 2013 to December 2014 in the US. To date, there have been no cases of adverse events associated with this medication. Adverse reactions may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

## FDA Warns of Counterfeit Cialis Tablets Entering the US

Potentially dangerous, counterfeit versions of Cialis® 20 mg tablets were intercepted in the mail before reaching a US consumer, warns FDA. Laboratory analysis of the counterfeit product showed that it contained multiple active ingredients that could lead to adverse effects or harm if used, indicates an FDA Drug Safety Announcement. The agency reminds US consumers to only buy prescription medications from state-licensed pharmacies located in the US. FDA notes that it cannot confirm that the manufacturing, quality, storage, and handling of products ordered from unlicensed websites follow US standards because the products are from an unknown source.

To help consumers identify these counterfeit medications, FDA provides guidelines in the safety announcement. For example, these counterfeits list "AUSTR81137" on the front of the bottle and lack a National Drug Code number. Other possible identifiers include misspellings and unusual colors on the label, and a manufacturer listed as "112 Wharf Road, WEST RYDE, NSW 2114" on the side of the bottle.

To date, FDA is not aware of any adverse events associated with these counterfeit medications; however, consumers are encouraged to talk to a health care provider about their condition and options for treatment if a counterfeit product was received.

The National Association of Boards of Pharmacy® (NABP®) has reviewed more than 10,900 websites selling prescription drugs to patients in the US and found that nearly 97% are operating out of compliance with pharmacy laws and practice standards established to protect the public health. To help consumers in the US find the safest sources for purchasing medications online, NABP developed the Verified Internet Pharmacy Practice Sites® (VIPPS®) program. NABP encourages consumers to look for the VIPPS Seal and to check NABP's list of accredited sites on the AWAR$_X$E® Prescription Drug Safety Program website. In addition, consumers may soon watch for pharmacy sites using the newly launched .pharmacy Top-Level Domain; sites in the domain (with a website address ending in .pharmacy) will be reviewed by NABP and approved only if they are legitimate online pharmacies or pharmacy resources adhering to applicable pharmacy laws and best practices.

Additional details on the counterfeit Cialis are available in a Drug Safety Announcement posted to the FDA website at *www.fda.gov/Drugs/DrugSafety/ucm431071.htm*. More information on VIPPS and other NABP programs is available in the Programs section of the NABP website, *www.nabp.net*.

## New FDA Drug Info Rounds Training Videos Review Drug Disposal and REMS

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. The latest Drug Info Rounds videos are as follows.

- In "Disposal of Unused Medicines," pharmacists discuss how consumers can safely dispose of expired or unused medications to prevent abuse or misuse and accidental poisoning.
- In "REMS," pharmacists discuss the many components of Risk Evaluation and Mitigation Strategies (REMS) and how they can help manage a drug product with known or potential serious risks.

Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. These videos and previous Drug Info Rounds resources are available on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm*.

## FDA Issues New Drug Labeling Rules to Benefit Pregnant, Breastfeeding Women

FDA announced new prescription drug labeling requirements that will clarify how medications might affect women who are pregnant or breastfeeding and men and women of reproductive potential. The final "Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling Rule" removes the previously used pregnancy letter categories – A, B, C, D, and X – and places information into three main categories:

- **Pregnancy:** Labor and delivery guidelines now fall under this category, which also now includes information for pregnancy exposure registries. Such registries track data on the effects of certain approved medications on pregnant and breastfeeding women.
- **Lactation:** Previously labeled "Nursing Mothers," this category provides information such as how much drug is secreted through breast milk and the potential effects on a breastfed infant.
- **Females and Males of Reproductive Potential:** This is a new category that includes information on how a certain medication might affect pregnancy testing, contraception, and infertility.

The new labeling changes go into effect on June 30, 2015. Over-the-counter medication labels will not be affected. The new rules are available for download through the *Federal Register* at *https://s3.amazonaws.com/public-inspection.federalregister.gov/2014-28241.pdf*.

## FDA Approves Zohydro ER With Abuse-Deterrent Properties

In February 2015, FDA approved a new formulation of Zohydro® ER with abuse-deterrent properties. The new formulation uses a technology that allows the drug to maintain its release properties when used as intended, according to a press release from Zogenix. The abuse-deterrent system, known as BeadTek, incorporates "pharmaceutical excipients" that create a viscous gel when the medication is crushed and dissolved in a liquid or solvent, thus making the product more difficult to abuse through methods that involve crushing, breaking, or dissolving the drug. In early 2014, Zohydro ER became the first extended-release, single-ingredient hydrocodone product to receive approval for use in the US. Approval of the drug came under criticism, with some organizations arguing that the potential for addiction, abuse, and misuse could outweigh therapeutic benefits, in part because the drug lacked abuse-deterrent properties. Zogenix indicates that transition to the new abuse-deterrent formulation will take place in second quarter 2015.

Additional information on the new formulation is provided in a press release available on the Zogenix website at *http://ir.zogenix.com/phoenix.zhtml?c=220862&p=irol-newsArticle&cat=news&id=2012326*.

*continued from page 1*

for the rationale for this action along with the therapeutic plan to resolve the issue. Kizer tracks patient drug usage by way of the drug regimen review and the CSMD, while also checking for increased morphine equivalents.

The following Board Rule applies to Kizer's rationale. Board Rule 1140-03-.01 states, in part:

(3) **Drug Regimen Review.** (a) A pharmacist shall be responsible for a reasonable review of a patient's record prior to dispensing each medical or prescription order. The review shall include evaluating the medical and prescription order for: 1. over-utilization or under-utilization; 2. therapeutic duplication; 3. drug-disease contraindication; 4. drug-drug interactions; 5. incorrect drug dosage or duration of drug treatment; 6. drug-allergy interactions; 7. clinical abuse/misuse. (b) Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the problem.

(4) **Implementation of Pharmaceutical Care.** (a) As a necessary health care provider, pharmacists **shall** carry out, in addition to the responsibilities in paragraphs (1) through (3) of this rule, those professional acts, professional decisions and professional services necessary to maintain a patient's pharmacy-related care and to implement and accomplish the medical and prescription orders of licensed practitioners, including but not limited to: 1. Developing relationships with licensed practitioners to enable the pharmacist to accomplish comprehensive management of a patient's pharmacy related care and to enhance a patient's wellness, quality of life and optimize outcomes; and 2. Communicating to the health care provider any knowledge of unexpected or adverse response to drug therapy, or resolving unexpected or adverse response.

## Board Reemphasizes Review of 'Red Flags' When Deciding to Dispense CS Prescriptions

As mentioned in the September 2014 edition of the *Tennessee Board of Pharmacy Newsletter,* pharmacists are advised to review the following red flags before deciding to fill any controlled substance (CS) prescriptions. This list includes, but is not limited to, patients who receive the same combination of prescriptions (eg, oxycodone/alprazolam/carisoprodol cocktail); receive the same strength of CS; pay cash for their prescriptions; present with the same diagnosis; drive long distances to visit prescribing practitioners and fill prescriptions; visit the pharmacy in groups, each with the same prescriptions from the same physician; bring prescriptions resulting in therapeutic conflicts; and request constant, early refills. Multiple red flags may be a reason to deny the fill. For more information, visit *www.nabp.net/system/rich/rich_files/rich_files/000/000/567/original/tn092014.pdf* for the full article in the September 2014 Board *Newsletter* about Executive Director Reggie Dilliard discussing CS prescriptions and red flags.

## When Reporting Theft or Loss, Electronic DEA Form 106 Is a Two-Step Process

In the March 2015 issue of the Board *Newsletter,* located at *www.nabp.net/system/rich/rich_files/rich_files/000/000/861/original/tn032015r.pdf,* the reporting of theft or significant loss was discussed. To further clarify reporting to DEA as stated in Title 21 CFR §1301.76(b), in part, "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete, and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft." The complete CFR may be viewed at *www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_76.htm.*

Therefore, it is advised to overnight a written notification to the Field Division Office with a confirmation of receipt and include a copy of the completed DEA Form 106. Contact information may be found at *www.deadiversion.usdoj.gov/offices_n_dirs/fielddiv/atlanta.htm#tn.*

## Board Reports Revoked/Surrendered/Suspended Licenses and Registrations

All registrants who have had a license or registration revoked, surrendered, or suspended due to Board disciplinary action in January and March 2015 are listed below. The complete disciplinary action report may be found at *http://health.state.tn.us/boards/disciplinary.htm.*

**Registered technicians (pharmacy registration/license number is in parenthesis) include the following:** Amber Bleeck/suspended (30663), Lavonda Booker/suspended (22303), Tonya Lee Branner/voluntarily surrendered (32867), Barry Gaines/suspended (14590), Aymbur Graham/revoked (43418), Mary Hamby/voluntarily suspended (13626), Heather Higgs/suspended (44517), Shannon Jones/suspended (38019), Derek Ross Kirby/revoked (20482), Ashley Morton/revoked (34769), Paige I. Nappier/suspended (46265), Felicia Parker/suspended (41456), Andrew Savage/revoked (40887), Lashay Latrice Sharp/voluntarily surrendered (20567), Kayla Stedam/suspended (47104), Katherine Cantrell/revoked (48762), Narecus M. Cox/revoked (45412), Amanda Paige Maddox/revoked (19570), Meikai D. Mapp/revoked (46363), Wanda Rena Musgrave/revoked (46960), Amanda Reynolds/revoked (48034), and Rachel E. Webb/revoked (44777).

**Registered pharmacists and pharmacies include the following:** James Catron, DPh/voluntarily surrendered (10999); Mark McGill, DPh/voluntarily retired (25926); Robin Terrero, DPh/voluntarily surrendered (5073); Wellness Store Compounding Pharmacy/voluntarily surrendered (3223); Ashley Nicole Corder, DPh/revoked (36987); and Corder's Community Pharmacy/revoked (5304).

## Board Rule Amendments Become Effective This Summer

If you are a student planning to obtain licensure in Tennessee, this first rule amendment may be of great interest to you!

*continued on page 5*

*continued from page 4*

The Board is happy to announce that as of June 22, 2015, the following language will take effect regarding intern hours as stated below to possibly expedite the licensure process. (Additional amendments are also included.)

1140-01-.04 PHARMACY INTERNSHIP

(1) An applicant for an initial pharmacist license by examination must show, on affidavit forms prescribed by the board, that the applicant has acquired a minimum of one thousand seven hundred (1,700) hours of pharmacy internship (practical pharmacy experience) under the instruction of a pharmacist in good standing, subject to all of the following conditions.

(a) The one thousand seven hundred (1,700) hours must be acquired after enrollment in a recognized college or school of pharmacy; one thousand seven hundred (1,700) of these hours must be acquired in pharmacy programs or demonstration projects structured by the college or school of pharmacy.

(b) Pharmacy internship may be acquired in another state, provided that the preceptor's qualifications are certified by the appropriate authorities of such state.

(c) Foreign pharmacy graduates shall complete five hundred (500) hours of pharmacy internship in Tennessee within a period of six (6) consecutive months.

Moving on to other amendments, two definitions will be added to Board Rule 1140-01-.01:

(23) "Outsourcing facility" means a facility engaged in the compounding of sterile drugs which has elected to register as an outsourcing facility with the U.S. Food and Drug Administration and which complies with all relevant federal laws and regulations.

(24) "Oxygen supplier" means any person who sells, delivers, distributes or wholesales medical gases which require a prescription or medical order prior to administration, dispensing or delivery and which are considered legend drugs pursuant to the federal Food, Drug, and Cosmetic Act to any person residing in this state

It is advised to review the completed Board Rules 1140-01 and 1140-9, which was also amended, once the amendments have been completed, as not all changes have been included in this *Newsletter.* The web link is *www.state.tn.us/sos/rules/1140/1140.htm.*

## Board Amends Quarterly Reporting of Sterile Products

On July 7, 2014, the Board approved the amendment to Rule 1140-07-.02(4) to add the words **"high risk or batch sterile products."** Therefore, the current rule is stated as follows.

(4) Any licensed pharmacy which compounds sterile products, except hospital pharmacies compounding for inpatients of a hospital, shall submit to the Board of Pharmacy, on a quarterly basis, a report listing the quantity of high risk or batch sterile products, as defined by USP standards, compounded and dispensed during the previous quarterly period and any other information as required by USP standards.

(a) Quarterly reports submitted pursuant to this paragraph shall be submitted by the 15th day of the month following the end of each calendar quarter.

(b) In any calendar year where any one of the above dates fall on a weekend or official state holiday, all quarterly reports due on that date shall be submitted on the following business day.

Reports may be mailed to the Board (665 Mainstream Drive, Nashville, TN 37243) or emailed to Dr Terry Grinder at terry.grinder@tn.gov.

## Tennessee Board of Pharmacy Meeting Dates

The Tennessee Board of Pharmacy extends an open invitation for all pharmacists, as well as the general public, to attend its public meetings in Nashville, TN. The following dates are scheduled for 2015 (Address is 665 Mainstream Drive, Nashville, TN 37243):

- July 28-30
- September 1-2
- November 3-4

The meetings are currently scheduled to start at 9 AM on the first day, and at 8 AM on the second day, unless otherwise stated. It is advised to check the Board website, as meeting dates and times can be subject to change.

## Tennessee Board of Pharmacy Members

Dr Nina Smothers – President

Dr William J. Bunch – Vice President

Dr Mike Dickenson – Board Member

Dr Kevin Eidson – Board Member

Dr Debra Wilson – Board Member

Dr Jason S. Kizer – Board Member

Ms Joyce McDaniel – Public Board Member



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