December 2014

Tennessee Board of Pharmacy News

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Board Policy Explains Compliance of Medication Take-Back Program If DEA Regulations Are Strictly Followed

Recent changes in federal regulations allow licensed retail pharmacies, hospital pharmacies, manufacturers, wholesalers, distributors, and reverse distributors with a valid Drug Enforcement Administration (DEA) registration to accept returns of unused legend drugs from end users. These registrants may do so by modifying their DEA registration to serve as collectors of unused legend drugs, and by further complying with all DEA regulations pertaining to this activity.

Therefore, any retail pharmacy, hospital pharmacy, manufacturer, wholesaler, distributor, or reverse distributor that is licensed by the Tennessee Board of Pharmacy and complies with all applicable DEA regulations pertaining to drug disposal **may** accept returns of unused legend drugs **pursuant to DEA rules.**

If DEA regulations are not strictly followed, regulation will revert to the current Board rule as stated: "Board of Pharmacy Rule 1140-03-.03(8) prohibits pharmacy practice sites, pharmacists, pharmacist interns, technicians, or any other place involved in the compounding and dispensing of prescription drugs and devices (except institutional pharmacies pursuant to Rule 1140-04-.10) from accepting returns of any order that has been taken from the premises of that pharmacy practice site or any other place of business."

DEA resources pertaining to drug disposal, including a complete text of the applicable DEA rules, are available at *www.deadiversion.usdoj.gov/drug_disposal.*

Please contact the Board with any questions about this policy.

Tennessee Department of Health Ebola Information Line Is Now Available

Tennessee's toll-free Ebola information line, 1-877/857-2945, is now open 10 AM to 5 PM, Monday through Friday. Hours for the information line will be increased in length and will be available seven days a week in the near future.

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 the following months in 2014 are listed below. The complete health-related boards disciplinary reports may be found at *http://health.state.tn.us/boards/disciplinary.htm.*

January 2014	**License/ Registration Number**
Julie Rae Amos, RT, Mt Juliet, TN	41186
Monika Everette Covington, RT, Memphis, TN	40385
Reva Delaine Henry, RT, Rising Fawn, GA	17689
Courtney Leanne Leach, RT, Jacksboro, TN	38705
C. Keith Ledbetter, DPh, Livingston, TN	1388
Melissa Canada Macrae, RT, Memphis	42404
Jeffery Dewitt Underwood, DPh, Ooltewah, TN	25032
March 2014	
Neil Montgomery Cameron, DPh, Plantation, FL	33428
Robert B. Kilpatrick, DPh, Manchester, TN	8194
May 2014	
Barry Cadden, DPh, Framingham, MA	22971
Kendria R. Johnson, RT, Memphis	34150
Derek A. Leach, RT, Nashville, TN	41735
Shanelle M. Sutton, RT, Nashville	44442
Jesse E. Thompson, DPh, Nashville (Restricted License)	29706
Tyler Blake Zazzi, RT, Franklin, TN	40509
July 2014	
Corder's Community Pharmacy, Inc, Smyrna, TN	5304
Susan Gayle Cost-Hoaglin, RT, Cordova, TN	16304
Kimberly H. Hawkins, DPh, Chattanooga, TN	5881
Crystal Marie Hunt, RT, Dickson, TN	32890
Richard H. Maynard, DPh, Mt Juliet	5233
Theresa Ann Santana, RT, Lebanon, TN	19600

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DEA Reschedules Hydrocodone Combination Products as Schedule II

Drug Enforcement Administration (DEA) has published its final rule rescheduling hydrocodone combination products from Schedule III to Schedule II in the *Federal Register.* The change imposes Schedule II regulatory controls and sanctions on anyone handling hydrocodone combination products, effective October 6, 2014. DEA first published the proposed rules in March 2014 in response to a Food and Drug Administration (FDA) recommendation. DEA received almost 600 public comments regarding the proposed rules after they were published, with a small majority of the commenters supporting the change, DEA notes in a press release, which is available at *www.justice.gov/dea/divisions/hq/2014/hq082114.shtml.*

The announcement is available on the *Federal Register* website at *https://federalregister.gov/articles/2014/08/22/2014-19922/schedules-of-controlled-substances-rescheduling-of-hydrocodone-combination-products-from-schedule.*

The mL-Only Standard for Liquid Dosing Gathers Steam

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. *E-mail: ismpinfo@ismp.org.*

ISMP first reported on the confusion of teaspoonfuls and milliliters (mL) in its newsletter in 2000, and in 2009, issued a call for practitioners to move to sole use of the metric system for measuring over-the-counter and prescription oral liquid doses, but mix-ups have continued to result in the serious injury of children and adults. Use of the metric system alone when prescribing, dispensing, and administering medications would prevent mix-ups because there would only be one method used to communicate and measure doses.

The health care industry is beginning to acknowledge the risk of confusion when using non-metric measurements, especially with oral liquid medications. The National Council for Prescription Drug Programs (NCPDP) just released a white paper entitled *NCPDP Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications,* which is available at *www.ismp.org/sc?id=337.* The white paper supports mL as the standard unit of liquid measure used on prescription container labels for oral liquid medications. It also calls for dosing devices with numeric graduations, and for units that correspond to the container labeling to be easily and universally available, such as including a device each time oral liquid prescription medications are dispensed. NCPDP also reiterates that dose amounts should always use leading zeroes before the decimal point for amounts less than one, and should not use trailing zeroes after a decimal point on labels for oral liquid medications.

The white paper comes as welcome news and is well-aligned with the *ISMP 2014-15 Targeted Medication Safety Best Practices for Hospitals,* Best Practice 5, which calls for organizations to use oral liquid dosing devices (oral syringes/cups/droppers) that only display the metric scale. The white paper also comes at a time when the Centers for Disease Control and Prevention, ISMP, the Consumer Healthcare Products Association, the United States FDA, the US Metric Association, and the American Academy of Pediatrics have initiatives in place that will help guide health care organizations to commit to metric measurements.

ISMP recommends the following actions to help prevent errors:

- Use only metric units, not teaspoon or other non-metric measurements, for all patient instructions, including those listed in prescribing and pharmacy computer systems. This should cover directions incorporated into computer system mnemonics, speed codes, or any defaults used to generate prescriptions and prescription labels.
- Take steps to ensure patients have an appropriate device to measure oral liquid volumes in milliliters.
- Coach patients on how to use and clean measuring devices; use the "teach back" approach and ask patients or caregivers to demonstrate their understanding.

DEA Classifies Tramadol a Controlled Substance

Under a final rule published in the *Federal Register*, the pain reliever tramadol is now classified as a Schedule IV controlled substance. As of August 18, 2014, DEA requires manufacturers to print the "C-IV" designation on all labels that contain 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl) cyclohexanol (tramadol), including its salts, isomers, and salts of isomers. The agency notes that every "DEA registrant who possesses any quantity of tramadol on the effective date of this final rule must take an inventory of all stocks of tramadol on hand as of August 18, 2014, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11 (a) and (d)." In addition, all "prescriptions for tramadol

or products containing tramadol must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR part 1306 and subpart C of 21 CFR part 1311 as of August 18, 2014."

The announcement is available on the *Federal Register* website at *www.federalregister.gov/articles/2014/07/02/2014-15548/schedules-of-controlled-substances-placement-of-tramadol-into-schedule-iv*.

FDA Lowers Recommended Starting Dose for Lunesta Due to Risk of Morning Impairment

FDA has lowered the recommended starting dose of the sleep drug Lunesta® (eszopiclone) from 2 mg to 1 mg. Patients who are currently taking 2 mg and 3 mg doses of eszopiclone should contact their health care provider to ask for instructions on how to continue to take their medication safely at a dose that is best for them, FDA advises. The dose change came after findings from a study of 91 healthy adults found that the medication was associated with impairment to driving skills, memory, and coordination for as long as 11 hours after the drug is taken, FDA notes.

More information is available in an FDA news release at *www.fda.gov/newsevents/newsroom/pressannouncements/ucm397453.htm*.

Lidocaine Should Not Be Used to Treat Teething Pain in Children, FDA Warns

FDA is recommending that prescription oral viscous lidocaine 2% solution should not be used to treat infants and children with teething pain, and is now requiring a new boxed warning to be added to the drug label to highlight this information. Oral viscous lidocaine solution is not approved to treat teething pain, and use in infants and young children can cause serious harm, including death, indicates FDA in a June 2014 Safety Announcement. FDA advises health care providers not to prescribe or recommend this product for teething pain. FDA is also requiring the "Warnings" and "Dosage and Administration" sections of the drug label to describe the risk of severe adverse events and to include additional instructions for dosing when the drug is prescribed for approved uses.

In 2014, FDA reviewed 22 case reports of serious adverse reactions, including deaths, in infants and young children who were either given lidocaine for treatment of mouth pain, or who accidentally ingested the medication.

More information is available in the safety announcement on FDA's website at *www.fda.gov/Drugs/DrugSafety/ucm402240.htm*.

FDA Reiterates Warning Against Using NuVision Pharmacy Products

Health care providers should not use or distribute compounded drugs marketed as sterile produced by Downing Labs, LLC, of Dallas, TX, also known as NuVision Pharmacy, warns FDA. Inspection results issued on July 16, 2014, indicate that FDA observed unsanitary conditions resulting in a lack of sterility assurance of sterile drug products produced by the company, which may put patients at risk, FDA notes in the safety announcement. "The inspection revealed sterility failures in 19 lots of drug products intended to be sterile, endotoxin failures in three lots of drug products, and inadequate or no investigation of these failures," states FDA in the announcement.

In 2013, the agency issued several similar warnings following NuVision's refusal to recall all sterile products. In April 2013, NuVision recalled methylcobalamin injection and lyophilized injection products, citing concerns about sterility in the wake of adverse event reports. Health care providers and consumers may report adverse events or quality problems associated with NuVision products to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Additional information is available in the safety announcement, available on FDA's website at *www.fda.gov/Drugs/DrugSafety/ucm405940.htm*.

JCPP Releases New Patient-Care Document to Promote Consistency

The Joint Commission of Pharmacy Practitioners (JCPP) has released a resource document aimed at promoting consistency in the pharmacists' process of patient care service delivery. "Pharmacists' Patient Care Process" was developed by examining key source documents on pharmaceutical care and medication therapy management. The document describes the process in five parts: collect, assess, plan, implement, and follow-up.

JCPP brings together the chief executive officers and elected officers of national pharmacy associations, including the National Association of Boards of Pharmacy®, to create a forum for discussion and opportunity for collaborative work on issues and priorities of pharmacy practice.

The document can be downloaded online at *www.pharmacist.com/sites/default/files/JCPP_Pharmacists_Patient_Care_Process.pdf*.

CPE Credit Offered for FDA Course on Misleading Prescription Drug Promotion

To raise awareness about the risks associated with false or misleading prescription medication marketing, FDA, in partnership with Medscape, is offering an online, one-hour continuing education course through its Bad Ad Program. Pharmacists may receive continuing pharmacy education (CPE) credit by taking this course. Learning objectives, faculty information, and other information is available on the course's website at *www.sigmatech.com/BadAd*. There is no registration fee for the course. Upon completion, pharmacists will receive one Accreditation Council for Pharmacy Education-accredited CPE hour (0.1 continuing education unit).

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September 2014	
Anna Ellis, RT, Knoxville, TN	41508
David Arthur Lenard, DPh, Hendersonville, TN	21722
Mitzi Pratt, RT, Morristown, TN	15945
Michael Paul Randolph, DPh, Knoxville	37119
Robin Terrero, DPh, Cleveland, TN/Georgetown, TN	5073
Wellness Store Compounding Pharmacy, Cleveland	3223
Jennifer Lee White, RT, Hohenwald, TN	23335
November 2014	
Melissa Ann Duncan, RT, Tazewell, TN	18866
Johnathan Wayne Grim, DPh, Jonesborough, TN	22278

Help Is Available for Impaired Pharmacists

Health care professionals, including pharmacists, are at risk for chemical dependency for reasons including greater stress and burnout, as well as easier access to drugs. Impairment creates major problems, not just for personal lives and careers, but in the potential harm that can be inflicted upon the patients who trust their health and lives to the dependability of the pharmacist's services. Recognizing this, and in genuine concern for both the impaired professional and the integrity of the profession, the Tennessee Pharmacists Association has a vigorous program to provide assistance to impaired colleagues.

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 e-mail at bblack@tnpharm.org.

Informational links (including the reporting form) are located at *www.tnpharm.org/member-center/tn-pharmacists-recovery-network.*

Complete Audits Advised as Diversion Continues in Pharmacies

Pharmacists are realizing that it is much more difficult to obtain an accurate loss count for controlled substances (CS) and other high-risk diverted medications when simply following the DEA Code of Federal Regulations (CFR), which only requires an inventory every two years (biennial inventory). Even then, the audit only requires a count, and does not require that the pharmacy reconcile a surplus or loss of medication. Therefore, it is advised to at least pick the most highly dispensed CS in the pharmacy and audit those items more frequently.

When auditing, it is important to remember to run a drug usage report correctly. If the audit was performed on January 2, 2014, after the end of the day, do not forget to run the usage report from January 3, 2014 (beginning of the day) to the current time. Also, remember to count invoice orders from **all** wholesalers/distributors. Do not forget to account for any previous losses/thefts or returns for destruction in the count, or it will certainly cause an inaccuracy. One possible guide has been provided for review as follows:

Drug Name	Beginning Inventory	(+) Ordered	(=) Total to Pull From Stock	(-) Dispensed	(-) Reverse Distributor (-) Previous Loss (-) Previous Theft (-) Destroyed	(=) What Should Be on Hand	(-) Ending Physical Inventory	Difference +/-

If the count is off considerably, it may be prudent to contact the wholesaler/distributor for a complete order during the audited time period, as invoices may be misplaced, lost, or even stolen to help hide the diversion. Also, it may be helpful to request the documentation with the medications listed together as opposed to by date ordered.

For additional information or questions, feel free to contact the Board office or an area pharmacy investigator. By following these steps, the pharmacist may greatly curtail the diversion of controlled and other high-theft medications.

New Licensees: Do Not Forget the DEA Opening Inventory

For **new** businesses/licensees that require the need for a DEA license, it is advised to review CFR 1304.11(b). Visit the following link for the complete regulation: *www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_11.htm*. This requirement encompasses all Board registrants, including pharmacies, manufacturers/wholesaler/distributors (M/W/Ds), dog handlers, and researchers. Without this opening inventory, DEA agents may find the registrant in violation. **Many times, the opening inventory may be zero, and is documented as such.**

Also note that if M/W/Ds wish to store any non-CS in the cage or safe with CS due to a higher rate of theft (eg, pseudoephedrine, sildenafil), a request must be sent to DEA for permission to do so. **It is advised to keep the return written approval documentation from DEA** available for Board investigator and DEA agent review.

Investigators Find Technician Registry, Affidavit, and Certified Technician Certificates Many Times Unavailable in Pharmacies

Two of the top five violations Board investigators experience while inspecting pharmacies include the lack of being able to retrieve the technician registry and affidavit. When asked for this documentation, many pharmacists have no idea what these items are or that there is even a requirement to keep these documents.

The technician registry is simply a list of all pharmacy technicians. It is stated in Board Rule 1140-03-.14(10): "The pharmacist in charge shall maintain a current registry of individuals employed at the pharmacy practice site **performing the functions of a pharmacy technician."**

Therefore, all pharmacy technicians, including the probationary employees working within the 90-day window of registration or working as students enrolled in a formal pharmacy technician training program as part of their academic curriculum, should be added to the registry. Pharmacy students/interns should not be added. If an employee is **not** registered as a technician with the Board, and works only as a cashier or in another non-pharmacy technician role, such as delivery to a patient's home, he or she is **not** required to be added to the registry.

Lastly, **certified pharmacy technicians** are required to display certification certificates at the pharmacy practice site as indicated in Board Rule 1140-02-.02(10).

As for the affidavit, refer to Tennessee Board Rule 1140-02-.02(1)(a), which states that the applicant shall submit an affidavit from his or her employer attesting that the applicant has read and understands the statutes and regulations pertaining to the practice of pharmacy in Tennessee. **(A copy of this affidavit shall be retained at the place of employment.)**

To obtain copies of the affidavit, simply visit the Board website or visit the following link: *http://health.state.tn.us/boards/Pharmacy/PDFs/PH-4013.pdf*.

Extender Violation Realized During Board Inspections

By Cole Phillips, 2015 PharmD Candidate, Lipscomb University

During recent routine inspections of pharmacies, investigators reported that many registrants are not aware of the Control Substance Monitoring Database (CSMD) rule regarding the health care practitioner extender.

Extenders (eg, pharmacy technicians/interns) are under the impression that they may use their pharmacist's information to access the database. However, each individual extender must have **his or her own access** information to use the CSMD.

According to Board Rule 1140-11-.02(2):

> Information sent to, contained in, and reported from the database in any format shall be made available only as provided for in T.C.A. § 53-10-306 and to the following persons in accordance with this chapter:
>
> . . . (f) A healthcare practitioner extender, who is acting under the direction and supervision of a prescriber or dispenser, and only to the extent the information relates specifically to a current or bona fide prospective patient to whom the prescriber or dispenser has prescribed or dispensed, or considering prescribing or dispensing any controlled substance. **Each authorized individual under this paragraph shall have a separate identifiable authentication for access,** and the prescriber or dispenser shall cancel the healthcare practitioner extender's access to the database upon the end of the agency relationship.

Once registered, the extender status can be granted by following prompts on the database. Any issues regarding extender status may be handled by contacting the CSMD office at CSMD.admin@tn.gov or 615/253-1305.

Public Chapter 1011 Moves Reporting Requirement for CSMD to Each Business Day

Note: The effective update for reporting each day starts January 1, **2016.**

> AN ACT to amend Tennessee Code Annotated, Title 53, Chapter 10, relative to the controlled substance database.
>
> BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:
>
> SECTION 1. Tennessee Code Annotated, Section 53-10-305(b)(2), is amended by deleting the language "at least once every seven (7) days for all the controlled substances dispensed during the preceding seven-day period" and by substituting instead the language "for each business day but no later than the close of business on the following business day; provided, that a veterinarian shall submit information at least once every seven (7) days and shall not be required to use a computerized system in order to submit required information pursuant to this section".

The complete public chapter may be viewed at *www.tn.gov/sos/acts/108/pub/pc1011.pdf*.

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):

- January 27-28, 2015
- March 10-11, 2015
- May 11-12, 2015
- July 29-30, 2015
- September 1-2, 2015
- November 3-4, 2015

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.

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://health.state.tn.us/boards/Pharmacy/applications.shtml* 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.

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