June 2013

Tennessee Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

227 French Landing, Suite 300 • Nashville, TN 37243
http://health.state.tn.us/Boards/Pharmacy/index.shtml

September Tennessee Board of Pharmacy Meeting Moved to August

Due to the Tennessee Board of Pharmacy office moving to a new location in September, the Board has changed the September 10-11, 2013 meeting date to **August 28-29, 2013.** The meetings generally start at 9 AM.

The Tennessee Department of Health is Seeking an Executive-Level Pharmacy Board Director in Its Nashville Office

All applicants must be a pharmacist licensed in Tennessee for a period of at least five years. Responsibilities:

1. Consultant in matters related to the practice of pharmacy, including state and federal legislation;
2. Management of Board of Pharmacy;
3. Supervision of employees;
4. Studies and research;
5. Board representative at meetings and activities; and
6. Licensure regulatory duties.

Send résumé to Tennessee Department of Health, Division of Health Licensure and Regulation, 220 Athens Way, Suite 104, Plaza 1, Metro Center, Nashville, TN 37243, ATTN: Assistant Commissioner.

The state of Tennessee is an equal opportunity, equal access, affirmative action employer.

DEA Relays Information on Split Bill of Controlled Substances

A recent discussion with Drug Enforcement Administration (DEA) confirmed that pharmacists are advised to only use and record one prescription serial number (prescription number) when dispensing Schedule II controlled substance prescriptions. Therefore, if the computer system will not allow for only one prescription number to be used on a bill split between insurance and cash, the prescription will need to be filled for the one amount. To fill the additional amount, another completed prescription order will need to be obtained for that amount from the prescribing practitioner.

State Legislature Approves Tamper-Resistant Paper to Be Printed by Prescriber

Effective April 1, 2013, prescribing practitioners are permitted to print their own tamper-resistant paper as amended in the Public Chapter 74. Tennessee Code Annotated (TCA) 53-10-401(a) states in part

> . . . All prescriptions written or printed by practitioners authorized to write prescriptions in this state shall be written on either tamper-resistant prescription paper or **printed utilizing a technology that results in a tamper-resistant prescription that meets the current centers for medicare and medicaid services guidance . . .**

Therefore, pharmacists are advised to check with prescribing practitioners before declining to fill prescriptions that appear to be written or typed on a new format of tamper-resistant paper. The amended statute may be viewed in full at *www.tn.gov/sos/acts/108/pub/pc0074.pdf.*

Statute Amended Regarding Compounding

As stated in Public Chapter 266, TCA 63-10-204(4), the definition of "compounding" includes the following new language:

(D) For use in a licensed prescribing practitioner's office for administration to the prescribing practitioner's patient or patients when the product is not commercially available upon receipt of an order from the prescriber;

(E) For use in a health care facility for administration to a patient or patients receiving treatment or services provided by the facility when the product is not commercially available upon receipt of an order from an authorized licensed medical practitioner of the facility;

(F) For use by emergency medical services for administration to a patient or patients receiving services from them under authorized medical control when the product is not commercially available upon receipt of an order from a licensed prescriber authorized to provide medical control; or

(G) For use by a licensed veterinarian for administration to their non-human patient or patients or for dispensing to non-human patients in the course of the practice of veterinary medicine upon receipt of an order from a veterinarian when the product is not commercially available.

In TCA 63-10-204(12), the definition of "dispense" now reads as follows:

> . . . "Dispense" means preparing, packaging, compounding or labeling for delivery and actual delivery of a prescription drug, nonprescription drug or device in the course of professional practice to a patient or the patient's agent, **to include a licensed health care practitioner or a health care facility providing services or treatment to the patient or patients,** by or pursuant to the lawful order of a prescriber . . .

TCA 63-10-216 adds this section as follows:

(a) Prior to initial licensure in this state as a compounding pharmacy, a pharmacy located outside of this state

continued on page 4

FDA Issues New Guidelines for Sleep Aids Containing Zolpidem

Food and Drug Administration (FDA) has issued new dosing recommendations for sleep aids containing zolpidem. The new recommendations are based upon new data that shows that when taken at night, blood levels of zolpidem remain high enough in the morning to impair activities that require alertness, such as driving. The new guidelines halve the dosage for women because the new data showed that their bodies take longer to eliminate the drug.

FDA urges drug manufacturers and health care providers to follow the new dosing instructions, which apply to brand name and generic drugs containing zolpidem:

- Ambien®, Edluar™, and Zolpimist®: 5 mg for women, 5 mg or 10 mg for men
- Ambien CR®: 6.25 mg for women, 6.25 mg or 12.5 mg for men

Additionally, manufacturers of these drugs have been instructed to follow the new guidelines and print new patient information drug labels containing the new recommendations.

The recommended doses of Intermezzo®, a lower dose zolpidem product approved for middle-of-the-night awakenings, are not changing. At the time of Intermezzo's approval in November 2011, the label already recommended a lower dosage for women than for men. Additional details are available in an FDA Drug Safety Communication, available at *www.fda.gov/Drugs/DrugSafety/ucm334033.htm.*

What is the National Medication Error Rate? What Standards Are Available for Benchmarking?

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency 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 is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

A national or other regional medication error rate does not exist. It is not possible to establish a national medication error rate or set a benchmark for medication error rates. Each pharmacy organization is different. The rates that are tracked are a measure of the number of **reports** at a given organization, not the actual number of **events** or the quality of the care given. Most systems for measuring medication errors rely on voluntary reporting of errors and near-miss events. Studies have shown that even in good systems, voluntary reporting only captures the "tip of the iceberg." For this reason, counting **reported** errors yields limited information about how safe a pharmacy actually is. It is very possible that a pharmacy organization with a good reporting system, and thus what appears to be a high error "rate," may have a safer system.

The National Coordinating Council for Medication Error Reporting and Prevention published a statement refuting the use of medication error rates. The statement, which is posted on the council's Web site (*www.nccmerp.org*), states the "Use of medication error rates to compare health care organizations is of no value." The council has taken this position for the following reasons:

- Differences in **culture** among health care organizations can lead to significant differences in the level of reporting of medication errors.
- Differences in the **definition** of a medication error among health care organizations can lead to significant differences in the reporting and classification of medication errors.
- Differences in the **patient populations** served by various health care organizations can lead to significant differences in the number and severity of medication errors occurring among organizations.
- Differences in the **type(s) of reporting and detection systems** for medication errors among health care organizations can lead to significant differences in the number of medication errors recorded.

According to the statement, the council believes that there are no acceptable incidence rates for medication errors. The goal of every health care organization should be to continually improve systems to prevent harm to patients due to medication errors. Pharmacies should monitor actual and potential medication errors that occur within their organization, and investigate the root cause of errors with the goal of identifying ways to improve the medication-use system to prevent future errors and potential patient harm. The value of medication error reporting and other data gathering strategies is to provide the information that allows an organization to identify weaknesses in its medication-use system and to apply lessons learned to improve the system. The sheer number of error reports is less important than the quality of the information collected in the reports, the organization's analysis of the information, and its actions to improve the system to prevent harm to patients.

It is more important to create the open environment that encourages the reporting of errors and near errors than to develop less meaningful comparative error rates.

ISMP Launches Program to Track Vaccine Errors

ISMP has launched a National Vaccine Error Reporting Program (VERP) that allows health care providers to confidentially report vaccine administration errors and near misses. Health care providers from all practice settings, including pharmacies and physicians' offices, are encouraged to report all mistakes related to vaccines, regardless of whether any harm resulted from the incident. The program will help ISMP "better quantify the sources of errors and advocate for vaccine name, labeling, device, information, and other needed product changes to ensure patient safety," stated Michael Cohen, ISMP president. The ISMP VERP was designed with the assistance of the California Department of Public Health and with input from experts in the field, indicates ISMP. Reports sent to the ISMP VERP will be shared with FDA and forwarded to the vaccine manufacturer when applicable. ISMP also plans to work with the Centers for Disease Control and Prevention on information received to address vaccine-related safety. VERP can be accessed at *http://verp.ismp.org/.*

Providers Should Ensure Only Diluted Forms of Acetic Acid Are Used, ISMP Warns

ISMP has issued a National Alert Network (NAN) notice advising that health care organizations should take immediate steps to ensure that only diluted acetic acid solutions are used in patient care. ISMP advises that the use and purchase of glacial acetic acid, the most concentrated form of acetic acid available, should be eliminated. Several cases of severe burns, scarring, and other permanent damage to skin or mucous membranes due to the inadvertent application of glacial acetic acid have been reported to the National Medication Errors Reporting Program operated by ISMP. ISMP provides the following steps for preventing further such events:

- Remove glacial acetic acid, which has no use in its current form in clinical medicine, from the pharmacy and replace with vinegar (5% solution) or commercially available diluted acetic acid 0.25% (for irrigation) or 2% (for otic use).
- Restrict purchasing so that pharmacy staff is purchasing acetic acid for all procedural areas.
- Restrict choices for purchasing so that glacial acetic acid is not selected by mistake.
- Ensure the correct strength is ordered.
- Educate staff about the differences between glacial acetic acid and diluted forms of acetic acid.
- Order 5% as "vinegar," which reduces the potential for confusion with glacial acetic acid.
- Verify the product by requiring an independent double-check of acetic acid solutions before dispensing or applying the product.

Information on the cases reported and common reasons for the cases are included in the NAN alert, which is available on the ISMP Web site at *www.ismp.org/NAN/files/20130121.pdf.*

New FDA Training Video

FDA Drug Info Rounds, a series of online training videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest Drug Info Rounds video, pharmacists discuss how FDA Drug Safety Communications let health care providers, patients, and consumers know about newly observed potential risks of FDA-approved drugs. Drug Info Rounds videos are developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information and are available on the FDA Web site at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

Progress Made in Implementing Recommendations Intended to Prevent Acetaminophen Overdose

Compelling progress has been made by stakeholders seeking to address the public health issue of acetaminophen overdose, indicates a white paper published by the National Council for Prescription Drug Programs (NCPDP). In 2011, NCPDP made recommendations that the health care industry take actions to support the safe use of acetaminophen, including recommending that pharmacies produce prescription labels with the complete spelling of acetaminophen and eliminating use of abbreviations such as "acet" or "APAP." Previous to that, in July 2010, the National Association of Boards of Pharmacy® (NABP®) recommended that "state boards of pharmacy prohibit the use of the abbreviation 'APAP' on prescription labels, and require that 'acetaminophen' be spelled out to assist in preventing the well-recognized danger of acetaminophen induced hepatotoxicity." The recommendation was based on established policy and a letter, sent by FDA to state boards of pharmacy, regarding the pharmacist's role in educating patients about acetaminophen induced hepatotoxicity caused by unintentional overdose. The recommendation was also consistent with the report of the NABP Task Force on Uniform Prescription Labeling Requirements, which made recommendations to encourage use of prescription labels that are organized in a patient-centered manner. NCPDP reports that pharmacy retailers "estimated to collectively represent more than half of the prescriptions dispensed in 2011, have either implemented or committed to a phased implementation" of the recommendation to use the complete spelling of acetaminophen on prescription labels. "This update to our white paper provides additional guidance for those industry stakeholders who have not yet implemented the new pharmacy labeling practices for acetaminophen-containing medicines," states Lee Ann Stember, president, NCPDP. The updated white paper is accompanied by a bulletin (PDF), available at *www.ncpdp.org/pdf/wp/NCPDPAcetaminophenInfoBulletin_PharmacyStakeholders.pdf,* developed for pharmacists that summarizes some of NCPDP's key recommendations regarding acetaminophen. In addition, the white paper, available for download at *www.ncpdp.org/ind_WP.aspx,* includes a list of resources for pharmacists to use in educating staff and pharmacy staff to use in educating patients (see Appendix D of the white paper). More information is available in an NCPDP news release available at *www.ncpdp.org/press/013113_NCPDP_Acetaminophen%20WP_FINAL.pdf.*

Pharmacists Rated High for Honesty and Ethical Standards in Gallup's 2012 Poll

Pharmacists ranked as the second most trusted profession in the 2012 Gallup Poll that asked consumers to rate 22 professions according to their honesty and ethical standards. Pharmacists were ranked as very high or high in this category by 75% of those surveyed, with nurses ranking first at 85%, and medical doctors third at 70%. Additional information on the results of the 2012 poll is available on the Gallup Web site at *www.gallup.com/poll/159035/congress-retains-low-honesty-rating.aspx*.

continued from page 1

must have an inspection by the regulatory or licensing agency of the state in which the pharmacy practice site is physically located. Out-of-state pharmacy practice sites must provide a copy of the most recent inspection by the regulatory or licensing agency of the state in which the pharmacy practice site is physically located, which must have been within the previous twelve (12) months. Prior to renewal of its license in this state, an out-of-state pharmacy practice site must provide the most recent inspection by the regulatory or licensing agency of the state in which the pharmacy practice site is physically located or equivalent regulatory entity, and which must have been within the previous twelve (12) months. The board of pharmacy shall have the right to require additional information before issuing or renewing a pharmacy license to insure compliance with applicable laws of this state and any rules and policies of the board.

(b) Any compounding pharmacy having an active Tennessee license shall notify the board within fourteen (14) business days of receipt of any order or decision by a regulatory agency, other than the Tennessee board of pharmacy, imposing any disciplinary action, including any warning, on the pharmacy.

(c) Any pharmacies engaged in sterile compounding must comply with relevant United States Pharmacopeia (USP) guidelines as adopted by the board by rule or policy.

(d) Any pharmacies engaging in sterile compounding, except hospital pharmacies compounding for inpatients of a hospital, shall report on a quarterly basis to the board the quantity of sterile compounded products dispensed in a defined time period in accordance with policies adopted by the board; provided, however, the executive director of the board may request this information from a hospital pharmacy for cause and the hospital pharmacy shall be required to respond in a timely manner as defined by the executive director of the board.

The Board plans to discuss rules and policies for additional clarification to the statute in the near future.

In regard to federal compounding regulations, be advised to continually monitor United States Code 21 353. The current regulation may be found at the following Web link: *www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm155666.htm.*

'Tennessee' Prescribers Are Not Permitted to Prescribe Benzphetamine

According to Tennessee Board of Medical Examiners Rule 0882-02-.14 (3)(c)(1), **Tennessee** prescribing practitioners shall be held in violation if prescribing benzphetamine (an ingredient in the recently released medication Regimex®). Pharmacists may also be found in violation if dispensing a Tennessee prescriber's prescription for benzphetamine as it would be considered an invalid prescription. This rule does not apply to out-of-state prescribers. The rule in its entirety may be found at the following Web link: *www.state.tn.us/sos/rules/0880/0880-02.20100620.pdf.*

CPSC Agent May Visit Tennessee Pharmacies

If an agent for the Consumer Product Safety Commission (CPSC) appears for inspection, do not be surprised. To enter the premises, the agent should present a US Government photo identification badge and be able to clearly define the scope of his or her authority. To contact the CPSC for additional questions or verification, visit *www.cpsc.gov/en/About-CPSC/Contact-Information/* or call 301/504-7923.

CSMD Committee Approves New Position

Since November 2011, Dr Andrew (Andy) Holt has served as executive director of the Tennessee Board of Pharmacy. Part of the duties of that position included managing the Controlled Substance Monitoring Database (CSMD). As the duties and responsibilities of the CSMD continue to grow, Dr Holt has moved to a newly created position devoting his time entirely to the CSMD. In this new position, Dr Holt will be responsible for guiding and expanding the functionality and usefulness of the database.

Third Term for Grinder as Interim Director

Once again, Dr Terry Grinder, investigator for the Board, has accepted the role of interim executive director for the Board. Dr Grinder is no stranger to the position as he served terms from 2006 to 2007 and 2010. He will continue to run Board operations until a new director is named.

National Healthcareer Association Certified Pharmacy Technician Exam Recognized by the Board

At the May 14, 2013 meeting, the Board recognized National Healthcareer Association's Exam for the Certification of Pharmacy Technicians (ExCPT) as a means to satisfy the state requirement of a certified pharmacy technician as stated pursuant to Tennessee Board of Pharmacy Rule 1140-01-.01(7). Visit the following link for the rule in its entirety: *www.state.tn.us/sos/rules/1140/1140-01.20120403.pdf.*

Currently, only the Pharmacy Technician Certification Board and the ExCPT exams are recognized by the Board.

Board Opinions

At the May 14, 2013 meeting, the Board stated that Tennessee Board of Pharmacy Rule 1140-04-.10 is interpreted to allow pharmacists in an institutional setting to return and use medication that is either in unit-dose packaging **or** unopened commercially prepackaged containers and, ". . . in the professional judgment of the pharmacist in charge or designee, the medications or related materials meet all federal and state board standards for product integrity. . ." Review the following link for the rule in its entirety: *www.state.tn.us/sos/rules/1140/1140-04.pdf.*

At the same meeting, Tennessee Board of Pharmacy Rule 1140-03-.08 in regard to a pharmacy repackaging another pharmacy's medications was discussed. The Board **concluded that it is currently a violation for one pharmacy to repackage another pharmacy's medications.** The Board agreed that the process would be positive for patient safety, but a rule change is needed to legalize this type of activity.

Tennessee Board of Pharmacy Meeting Dates

The Board extends an open invitation for all pharmacists as well as the general public to attend its bimonthly meetings in Nashville. The following dates are scheduled for 2013:

- July 9-10, 2013, Iris/Poplar Room – 227 French Landing
- August 28, 2013, Poplar/Iris Room – 227 French Landing
- August 29, 2013, Iris Room – 227 French Landing
- November 13-14, 2013, Iris Room – 227 French Landing

Please check the Board Web site as these dates can be subject to change. Meetings generally begin at 9 AM.

The *Tennessee Board of Pharmacy News* is published by the Tennessee Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

Buddy Stephens, DPh - Tennessee Board of Pharmacy President and Newsletter Editor

Terry Grinder, DPh - Executive Director and Newsletter Editor

Scott G. Denaburg, BA, PharmD - Investigator and Contributor, Tennessee Board of Pharmacy

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Deborah Zak - Communications Manager