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Tennessee Board of Pharmacy News

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Board Term Ends for Dr 'Buddy'; Wilson Appointed as New Member

As it is time again for the changing of the guard, Dr Charles "Buddy" Stephens has fulfilled his six-year obligation to the Tennessee Board of Pharmacy and relinquished his seat. Fellow Board members expressed their appreciation to Stephens for using his previous experiences and adding "just the right touch of common sense" to Board discussion and interpretation of Board rule.

Using his practice knowledge as a long-term care pharmacist and as a former inspector for the Tennessee Department of Health, Office of Health Care Facilities, Stephens worked with diligence to stay educated on the most current interpretations of other entities and their regulations, including Drug Enforcement Administration (DEA), Food and Drug Administration, and the Centers for Medicare & Medicaid Services. He unselfishly interpreted current rules and encouraged the writing of future regulations that met the needs and safety of patients over his own benefit in pharmacy practice.

Therefore, Dr "Buddy," from the Board and staff, we thank you for your service and wish you all the best! You will be missed.

Pursuant to Tennessee Code Annotated (TCA) 63-10-302(a), Governor Bill Haslam has appointed east Tennessee Pharmacist Debra Wilson of Jonesborough, TN, as the newest member of the Board. Wilson brings a wealth of experience as president of three pharmacy service organizations, including Clinical Management Concepts, Inc; ProCompounding Pharmacy; and Pharmacy Network Services, Inc. She is involved in pharmacy compounding (sterile and nonsterile), pharmacy-based disease management programs (including health and wellness), pharmacy benefit management, and institutional pharmacy services (servicing long-term care, assisted living, hospital, and correctional facilities). Wilson also has experience in retail and infusion pharmacy services. She is a current member of the Tennessee Pharmacists Association (TPA) and the National Community Pharmacists Association.

Involved in the founding of East Tennessee State University (ETSU) Bill Gatton College of Pharmacy, Wilson served on the original admissions committee and also served on the ETSU Nursing Advisory Board. She received her bachelor of science degree from The University of Tennessee Health Science Center College of Pharmacy in March 1975, and is a 2001 graduate of the University of Pennsylvania Wharton School GlaxoSmithKline Executive Management Program for Pharmacy Leaders. The Board welcomes Dr Wilson, and looks forward to her expertise and input.

Board Executive Director Discusses Proper Dispensing of Controlled Substances

At the TPA Annual Convention & Trade Show held in South Carolina July 21-24, 2014, Dr Reggie Dilliard covered many topics regarding the challenges for pharmacists when deciding to dispense or decline to fill a controlled substance (CS) prescription. Dilliard referred to Title 21 Code of Federal Regulations (CFR) 1306.04(a), which explains, in part, that "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."** You may wish to visit *www.deadiversion.usdoj.gov/21cfr/cfr/1306/1306_04.htm* for the full regulation. Dilliard expressed that the Controlled Substance Monitoring Database (CSMD) should be used regularly as a part of the normal drug utilization review.

Found in the Drug Regimen Review in Board Rule 1140-03-.01(3)(a), specifically numbers 1, 2, 5, and 7, the pharmacist's **responsibility** includes (among other things), review of over-utilization, therapeutic duplication, and clinical abuse/misuse. (The rule may be viewed at *www.state.tn.us/sos/rules/1140/1140-03.20090207.pdf.)* According to Dilliard, the CSMD may be a very useful tool to help assess the patient's utilization in these areas and to help alert and prevent patient risk of harm and overdose.

Next, Dilliard stated that the CSMD has become very useful in determining abuse in regard to dispensing and prescribing patterns that might be considered red flags. Notice that he stated "might." This tool is not necessarily the "definitive" reason to decline to fill a prescription. However, along with other indicators, it certainly may show cause to question and research additional red flags. Other enhancements to the CSMD include alerts for the average daily morphine equivalent dosage, database ease of use and increased speed, user reports more readily available, laws changed to allow enhanced usage by prescribers, top 50 prescribers and dispensers reported for review, and pharmacists in other states beginning to have the ability to share the database.

So, what are other potential red flags? Dilliard voiced the following.

- Many patients:
  - ◊ receiving the same combination of prescriptions (ie, oxycodone/alprazolam/carisoprodol cocktail),
  - ◊ receiving the same strength of CS,
  - ◊ paying cash for their prescriptions,
  - ◊ presenting with the same diagnosis,

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National Pharmacy

(Applicability of the contents of articles in the National Pharmacy Comp
and can only be ascertained by examini

New Educational Video for Pharmacists Addresses Prescription Drug Abuse

The National Association of Boards of Pharmacy® (NABP®) and the Anti-Diversion Industry Working Group (ADIWG), a consortium of pharmaceutical manufacturers and distributors of controlled substances (CS), have released an educational video for pharmacists to help them identify the warning signs of prescription drug abuse and diversion when dispensing CS prescriptions. The video, entitled "Red Flags," encourages pharmacists to help combat this national problem by exercising their professional judgment to ensure that the prescriptions they dispense were written for a legitimate medical purpose, and to act upon any unusual behavior they observe.

Drug Enforcement Administration and various state pharmacy boards have described "red flags" as circumstances surrounding the presentation of a CS prescription that should raise reasonable suspicion about the validity of that prescription. The video highlights a number of these potential warning signs, some of which are not easy to spot, by weaving personal narratives with interactions between pharmacists and customers.

The video is available in the Pharmacists section of the AWAR$_X$E® Prescription Drug Safety website at *www.AWARERX.ORG/pharmacists*.

Root Causes: A Roadmap to Action

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 Error Reporting Program Report online at* www.ismp.org. *E-mail: ismpinfo@ismp.org.*

Errors are almost never caused by the failure of a **single** element in the system. More often, there are **multiple** underlying system failures that lead to an error, many of which can be identified when the involved health care providers take the time to uncover them.

Consider the following error: A doctor sent a hand-written order for car**bam**azepine 400 mg twice daily for an adult patient with a history of seizures.

The pharmacist entered the medication into the profile of a four-year-old child with the same last name as the adult patient for whom the medication had been prescribed.

The pharmacist failed to notice that the patient was a child, as age was not in a prominent location on the order entry screen. The nurse failed to recognize that the dose was too high and administered 400 mg of car**bam**azepine to the child. She also never thought to question why the pharmacy would send oral tablets for a four-year-old child, considering that the drug is available in chewable tablets and as a liquid suspension.

The nurse **assumed** that the child was receiving the medication because he had a history of seizures. However, the nurse did not check the patient's medical record. In fact, the child did **not** have a history of seizures.

The parents had a very limited understanding of English, so they were unable to intervene to correct the erroneous seizure history.

The error was finally detected after the child became lethargic and developed nausea and vomiting. At the time of discovery, the child's car**bam**azepine level was 18 mcg/mL; levels greater than 12 in pediatric patients are supratherapeutic.[i]

It may be discouraging to see how many things go wrong when a medication error reaches a patient. However, a thorough root cause analysis (RCA) can uncover the latent failures and produce an action plan to avoid future errors.

ISMP, through a generous grant from the National Association of Boards of Pharmacy Foundation™, has developed the *Root Cause Analysis Workbook for Community/Ambulatory Pharmacy.* The workbook is designed to assist community pharmacy personnel in completing RCA for a sentinel event that may have occurred in their pharmacy. The RCA workbook uses a specific set of steps and associated tools to identify the primary causes of the **sentinel event.**

The goal of the RCA is to create an action plan framework, including risk-reduction strategies, communication and implementation strategies, and measurement of effectiveness.

RCA for **sentinel events** is required in the Center for Pharmacy Practice Accreditation's standards developed by NABP, American Pharmacists Association, and American Society of Health-System Pharmacists Association, as well as by several boards of pharmacy in conjunction with their continuous quality improvement regulations.

This ISMP RCA workbook is suitable for use in community pharmacy, mail-order pharmacy, or other ambulatory pharmacy practice settings that need to investigate a **sentinel event.** For more information and to access the **free** workbook, visit *www.ismp.org/tools/rca/.*

[i] *http://pediatrics.aappublications.org/content/113/2/406.abstract*

FDA Withdraws Approval of Some High Dose Acetaminophen Products

Food and Drug Administration (FDA) is withdrawing approval of 108 abbreviated new drug applications (ANDAs) for prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit. For the 108 ANDAs, the manufacturers asked to withdraw their applications, as announced in the March 27, 2014 *Federal Register* notice. A second *Federal Register* notice addresses the applications of six manufacturers who have discontinued marketing their products, but who have not withdrawn their applications. The notice also announces FDA's intention to begin the process of withdrawing approval of those applications.

In light of these announcements, and to protect patients from inadvertent acetaminophen overdose, NABP advises that pharmacies no longer dispense combination drugs containing more than 325 mg of acetaminophen per dosage unit. NABP also advises that pharmacists consult with prescribers to discuss alternative products with lower acetaminophen doses.

FDA asked manufacturers to voluntarily withdraw these products from the market to reduce the risk of severe liver injury from inadvertent acetaminophen overdose. In January 2014, FDA recommended that providers consider prescribing acetaminophen products containing 325 mg or less per dose. The original announcement may be found in the Drug Safety and Availability section of FDA's website at *www.fda.gov/Drugs/DrugSafety*.

NCPDP Recommends Standardized Metric Measurements on Oral Liquid Medication Labels

The National Council for Prescription Drug Programs (NCPDP) has issued new recommendations and guidance for standardizing the dosing designation used on prescription container labels of oral liquid medications dispensed by community pharmacies in order to reduce dosing errors. NCPDP notes that such errors have been "a source of concern for many years," and that dosing errors involving young children are of particular concern because they may be more susceptible to harm from measurement errors and overdoses. The paper outlines the following recommendations for the dosing designation on prescription container labels for oral liquid medications:

- The millimeter (mL) should be used as a standard unit of measurement.
- Dose amounts should always use leading zeros before decimal points for amounts less than one and should not use trailing zeros after a decimal point.
- Dosing devices with numeric graduations and units corresponding to the container label should be made easily and universally available. For example, a device should be included with each dispensed medication.

The white paper was developed following a meeting with stakeholders representing 27 participants, including NABP. In addition to its general recommendations, the white paper also issued calls to action for relevant stakeholders, including government agencies, standards organizations, pharmacists and pharmacy technicians, pharmacy leadership, and health care associations. The white paper, *NCPDP Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications,* is available for download from the NCPDP website at *http://ncpdp.org/Education/Whitepaper*.

USP Proposes New General Chapter Addressing Compounding of Hazardous Drugs

In an effort to protect health care providers and personnel who handle hazardous drugs, United States Pharmacopeial Convention (USP) has proposed new General Chapter <800> Hazardous Drugs–Handling in Healthcare Settings. The new proposed chapter addresses standards that apply to all personnel who compound hazardous drug preparations and all places where hazardous drugs are prepared, stored, transported, and administered. The new chapter also covers standards for receiving, storing, compounding, dispensing, administering, and disposing of nonsterile and sterile products and preparations. The proposed chapter applies to all personnel who are involved in handling hazardous drugs, including health care providers and staff, occupational health and safety specialists, and human resources. General Chapter <800> was published in the May/June issue of *Pharmacopeial Forum,* and may currently be viewed on the USP website at *www.usp.org/usp-nf*. Comments were accepted until July 31, 2014.

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- ◊ driving long distances to visit prescribing practitioners and/or to fill prescriptions, and/or
- ◊ visiting the pharmacy in groups, each with the same prescriptions from the same physician.

♦ Prescriptions resulting in therapeutic conflicts.

♦ Constant requests for early refills.

Multiple red flags may be a reason to deny the fill.

So, what do I do as a pharmacist now? Dilliard reiterated to utilize the CSMD, checking for early refills, and the daily morphine equivalent dosage that can be found on the CSMD. Any dosage over 120 morphine equivalents is another red flag, but is **not** a complete reason to deny the fill by itself. There may be other reasons why the dose is high, including treatment for an acute pain or severe pain not controlled by lower doses. (For example, is there any documentation where the patient started on a lower dose and was increased gradually?) It is advised to document any discussion or file any written report substantiating the reason(s) for the dose or duration. Dilliard summarized with the following comments: Utilize the CSMD, use common sense, use your education and training, and be part of the solution, not part of the problem.

And remember, a prescription for oxycodone 30 mg, 1 tablet, four times a day, #120, filled even one day early every month **continuously** for 12 months, equals 48 extra tablets. That may equal an approximate street value of $1,440. Opana® has been reported to bring as much as $50 per tablet on the street.

For previous Board *Newsletter* discussion on early refills, you may wish to visit *www.nabp.net/publications/assets/TN032010.pdf* and read the article entitled *Beware of the 'Refill Too Soon.'*

PC 872 Requires Government-Issued ID for Some Patients

Effective July 1, 2014, Public Chapter (PC) 872 amends TCA, Title 53, Chapter 11, Part 3, relative to dispensing as follows:

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 53, Chapter 11, Part 3, is amended by adding the following as a new section:

53-11-310.

(a) Prior to an authorized dispenser dispensing a prescription **for any schedule II-IV opioid, benzodiazepine, zolpidem, barbiturate, or carisoprodol medication for greater than a seven (7) day supply**, a pharmacist, pharmacy technician, pharmacy intern, or any other person authorized to dispense controlled substances shall require the person taking possession of the dispensed prescription to present a valid government issued identification or public or private insurance card, unless the person is personally known to the pharmacist, pharmacy technician, pharmacy intern or any other person authorized to dispense controlled substances. The identification requirements described in subsection (a) shall apply to all authorized dispensers who dispense schedule II-IV opioid, benzodiazepine, zolpidem, barbiturate, and carisoprodol medications for greater than a seven (7) day supply.

(b) Should any person who is a minor or who is homeless seek to take possession of a dispensed prescription for a schedule II-IV opioid, benzodiazepine, zolpidem, barbiturate, or carisoprodol medication not have a valid identification, the pharmacist, pharmacy technician, pharmacy intern or any other person authorized to dispense controlled substances shall use professional judgment in determining whether to dispense the prescription to the person.

(c) Nothing in this section shall be construed to:

(1) Require that the person taking possession of a schedule II-IV opioid, benzodiazepine, zolpidem, barbiturate, or carisoprodol medication and the person for whom the prescription is written be the same person;

(2) Apply to any controlled substance dispensed by a licensed veterinarian;

(3) Apply to drug samples dispensed by a healthcare professional; or

(4) Apply to prescriptions written for:

(A) Inpatients in a hospital;

(B) Outpatients of a hospital where the prescriber writes the order in the medical chart and the order is given directly to the hospital pharmacy and the patient does not have the opportunity to handle the written order;

(C) Residents of a nursing home or an assisted living facility;

(D) Inpatients or residents of a mental health hospital or residential facility licensed under title 33;

(E) Inpatients or residents of any facility that is registered by the United States drug enforcement administration as a narcotic treatment program and is subject to the record keeping provisions of 21 CFR §1304.24;

(F) Individuals incarcerated in a local, state or federal correctional facility;

(G) Patients receiving prescriptions from mail order pharmacies; or

(H) Patients receiving home deliveries from pharmacies.

(d) A healthcare provider in violation of this section shall only be subject to a civil penalty assessed by the provider's licensing board. Section 53-11-401 shall not apply to penalties imposed under this section.

(e) The board of pharmacy is authorized to promulgate rules to implement this section in accord with title 4, chapter 5.

SECTION 2. This act shall take effect July 1, 2014, the public welfare requiring it.

PC 623 Allows for Dispensing of Opioid Antagonists to At-Risk Persons, Family, and/or Friends

An act to amend TCA, Title 63, Chapter 1, Part 1, relative to health regarding opioid antagonist dispensing (ie, naloxone) is as follows.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 63, Chapter 1, Part 1, is amended by adding the following language as a new, appropriately designated section:

(a) As used in this section, "drug-related overdose" means an acute condition, including mania, hysteria, extreme physical illness, coma, or death resulting from the consumption or use of a controlled substance, or another substance with which a controlled substance was combined, and that a layperson would reasonably believe to be an opioid related drug overdose that requires medical assistance.

(b) As used in this section, "opioid antagonist" means naloxone hydrochloride which is approved by the federal Food and Drug Administration for the treatment of a drug overdose.

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(c) A licensed healthcare practitioner otherwise authorized to prescribe an opioid antagonist acting in good faith and exercising reasonable care may, directly or by standing order, prescribe an opioid antagonist to the following persons:
  (1) A person at risk of experiencing an opiate related overdose, or
  (2) A family member, friend, or other person in a position to assist a person at risk of experiencing an opiate-related overdose.

(d) In order to establish good faith under subsection (c), a licensed healthcare practitioner, prior to prescribing an opioid antagonist, may require receipt of a written communication that provides a factual basis for a reasonable conclusion that:
  (1) The person seeking the opioid antagonist is at risk of experiencing an opiate-related overdose; or
  (2) The person seeking the opioid antagonist other than the person who is at risk of experiencing an opiate-related overdose, and who is seeking the opioid antagonist, is a family member, friend, or other person in a position to assist the person at risk of experiencing an opiate-related overdose.

(e) A person who receives an opioid antagonist that was prescribed pursuant to subsection (c) may administer an opioid antagonist to another person if:
  (1) The person has a good faith belief that the other person is experiencing an opioid related drug overdose; and
  (2) The person exercises reasonable care in administering the drug to the other person.

(f) Evidence of the use of reasonable care in administering the drug shall include the receipt of basic instruction and information on how to administer the opioid antagonist, including successful completion of the online overdose prevention education program offered by the department of health.

(g) The commissioner of health or the commissioner's designee, in consultation with other state, federal or local government personnel, including contractors, shall create and maintain an online education program with the goal of educating laypersons and the general public on the administration of opioid antagonists and appropriate techniques and follow-up procedures for dealing with opioid related drug overdose.

(h) The following individuals are immune from civil liability in the absence of gross negligence or willful misconduct for actions authorized by this section:
  (1) Any licensed healthcare practitioner who prescribes or dispenses an opioid antagonist pursuant to subsection (c); and
  (2) Any person who administers an opioid antagonist pursuant to subsection (e).

(i) A licensed healthcare practitioner acting in good faith and with reasonable care, who prescribes, dispenses, or administers an opioid antagonist to a person the healthcare provider believes to be experiencing or is at risk of experiencing a drug-related overdose or prescribes an opioid antagonist to a family member, friend, or other person in a position to assist a person experiencing or at risk of experiencing a drug-related overdose is immune from disciplinary or adverse administrative actions under title 63 for acts or omissions during the administration, prescription, or dispensation of an opioid antagonist

SECTION 2. This act shall become effective on July 1, 2014, the public welfare requiring it.

Hydrocodone Combination Products Move to Schedule II in October

Effective October 6, 2014, all hydrocodone combination products will move from Schedule III to Schedule II. Note that DEA requires all Schedule II medication biennial inventories to include **an exact count.**

Therefore, on October 6, it is advised to inventory these medications as required and add to the biennial report under the Schedule II section. It is also advised to secure these medications per pharmacy policy and in compliance with 21 CFR 1301.75, which may be viewed at *www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_75.htm.* Do not forget to document, as stated in 21 CFR 1304.11, **". . . as of opening of business or as of the close of business on the inventory date."**

The complete regulation may be viewed at *www.federalregister.gov/articles/2014/08/22/2014-19922/schedules-of-controlled-substances-rescheduling-of-hydrocodone-combination-products-from-schedule.*

Tramadol Products Now Scheduled as Schedule IV per DEA Regulations

As of August 18, 2014, be advised that all tramadol-containing products are required to be inventoried and recorded. See Title 21 CFR 1304.11(d) at *www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_11.htm* for details. Even though tramadol was already controlled in Tennessee, it is recommended that an inventory be taken on August 18, to satisfy DEA requirements. Look for manufacturers to send updated stock bottles with the appropriate ("C-IV") labeling requirements. Refer to Title 21 CFR 1302.03 for more information, as noted in the following link: *www.deadiversion.usdoj.gov/21cfr/cfr/1302/1302_03.htm.* The final rule may be viewed at *www.gpo.gov/fdsys/pkg/FR-2014-07-02/pdf/2014-15548.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 bimonthly meetings in Nashville, TN. The following dates are scheduled for 2014 (The address is 665 Mainstream Drive, Nashville, TN 37243):

- ♦ September 10-11, 2014, Poplar Room
- ♦ November 5-6, 2014, Iris Room

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

Tennessee Board of Pharmacy Members

Dr Jason S. Kizer – President
Dr Nina Smothers – Vice President
Dr William J. Bunch – Board Member
Dr Mike Dickenson – Board Member
Dr Kevin Eidson – Board Member
Dr Debra Wilson – Board Member
Ms Joyce McDaniel – Public Board Member

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