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Tennessee Board of Pharmacy News

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Board Office and Meeting Rooms Are Scheduled to Relocate

As of September 27, 2013, the Tennessee Board of Pharmacy office and future Board meetings are scheduled to be relocated to 665 Mainstream Dr, Nashville, TN 37243. Please note this change of address for future Board meetings. Dates will be added as available on the Board Web site and in future Board *Newsletters.*

Dilliard Accepts Executive Director Position

Serving a former six-year term for the Board, Reginald "Reggie" Dilliard, DPh, has relocated to the other side of the table as the new executive director for the Board. Graduating with a bachelor of science degree in pharmacy from The University of Tennessee Health Science Center (UTHSC), and working as a community practice pharmacist for close to 40 years, Dilliard is no stranger to leadership roles. He has been an active participant in the Tennessee Pharmacists Association (TPA), serving on committees dealing with legislation, emergency preparedness, and political action, as well as president of the organization. Dilliard served on other boards including three years on the National Association of Boards of Pharmacy® (NABP®) Executive Committee (representing District 3), and 12 years on the City of Bartlett Board of Aldermen.

As for appreciation of excellence and passion for pharmacy, Dilliard has received several accolades. Awards include the National Community Pharmacists Association Pharmacy Leadership Award, Merck Award for Outstanding Achievement in the Profession of Pharmacy, Award of Merit from the TPA, and the Outstanding Leadership Award from the University of Tennessee.

Married to Dr Jennifer Dilliard (also a pharmacist), he is the proud father of four children, one of whom is currently enrolled at UTHSC College of Pharmacy.

The Board welcomes Dr Dilliard and looks forward to his first meeting as executive director. It also wishes to thank Dr Terry Grinder, yet again, for serving as interim director. Dr Grinder will step back into the position of pharmacist 2 investigator.

Effective October 1, 2013, 'Tennessee Licensed Dispensers' Only Allowed to Dispense 30 Days of Some Medications and New Reporting Required for Wholesalers/ Manufacturers

Beginning October 1, 2013, according to Public Chapter 430, Section 4, Tennessee Code Annotated (TCA), Section 53-11-308(e):

> **. . . No prescription for any opioids or benzodiazepines may be dispensed in quantities greater than a thirty (30) day supply. . .**

Notice that this statute states "dispensed" as opposed to "prescribed." Therefore, be advised that Tennessee licensed prescribing practitioners and pharmacists that "dispense" medications (in- and out-of-state mail-order pharmacies with Tennessee licenses included) will only be allowed to do so for a 30-day supply "in or into Tennessee" for opioids and benzodiazepines. Note that nothing in this statute prohibits a prescribing practitioner from "prescribing" more than a 30-day supply of opioids or benzodiazepines, nor does it prohibit a patient from presenting a prescription written for more than 30 days to be dispensed by an out-of-state pharmacy site (some pharmacies in bordering states fill Tennessee resident prescriptions). More information on these drug classes may be forthcoming after the Controlled Substance Monitoring Database (CSMD) meeting, which was held on August 20.

In the next paragraph, Section (f) of the same statute continues as follows:

> **. . . If a prescriber dispenses any opioids, benzodiazepines, barbiturates, or carisoprodol, then the prescriber shall submit the transaction to the controlled substances monitoring database operated under title 53, chapter 10, part 3. . .**

This part of the statute shall take effect October 1, 2013.

Furthermore, TCA 53-10 amends definitions and regulations for wholesalers and manufacturers. Any business selling controlled substances (CS) at wholesale will be expected to report to the CSMD Advisory Committee in Automation of Reports and Consolidated Orders System format. As stated in TCA 53-10-312(b):

> **. . . the department of health will establish such rules as are necessary to specify which medications shall**

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Pharmacists Likely to Recommend OTC Medications, CHPA Reports

Patients most often seek a pharmacist's advice on treating coughs, headaches, migraines, and allergies, and 98% of pharmacists recommend or have no reservations recommending over-the-counter (OTC) products to treat such ailments, according to a recent survey. The Consumer Healthcare Products Association's (CHPA) report, "Understanding Trust in OTC Medicines: Consumers and Healthcare Provider Perspectives," presents the results of the survey, which was developed to better understand what drives consumer and health care provider trust in OTC products. The survey, developed and conducted by Nielsen and IMS, included over 1,100 consumer respondents, and over 500 health care provider respondents, composed of pharmacists, pediatricians, nurse practitioners, and primary care providers.

Pharmacists surveyed reported that they were more likely to recommend OTC products that demonstrated successful patient outcomes and consistent outcomes, and products known to be as efficacious as a prescription drug, and those containing ingredients known to be safe.

The survey also asked health care providers whether they recommended OTC products without, before, or in conjunction with recommending prescription drugs for certain symptoms. A majority of pharmacists surveyed, over 60%, recommend OTC medications to treat stomach symptoms and pain, without recommending a prescription treatment, and over 70% recommended OTC allergy, sinus, and flu medications without advising that a prescription drug is needed.

CHPA notes that with the expansion of patient self-care, OTC products will play an increasingly important role in health care. The potential for more prescription products to become OTC products in the new paradigm under consideration by Food and Drug Administration (FDA) could further impact this trend. As consumers are becoming more empowered in making health care decisions, they are also relying more on their pharmacist for medication advice. In fact, Nielsen and IMS findings show that multigenerational households, Hispanic households, and households who care for an adult outside of their home place a high value on pharmacist recommendations regarding selecting appropriate OTC medications, notes CHPA.

The full CHPA White Paper is available at *www.yourhealthathand.org/images/uploads/OTC_Trust_Survey_White_Paper.pdf.*

ISMP Study on Targeted Mandatory Patient Counseling

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.*

In a recent study funded by a grant from Agency for Healthcare Research and Quality, ISMP evaluated the use of a combined checklist and patient information leaflet used during mandatory counseling sessions for consumers who pick up a filled prescription for 11 targeted medications:

- Opioid-containing analgesics
  - fentanyl patches
  - hydrocodone with acetaminophen
  - oxycodone with acetaminophen
- Anticoagulants
  - warfarin
  - enoxaparin
- Antidiabetic drugs (insulin analogs)
  - Humalog® (insulin lispro)
  - NovoLog® (insulin aspart)
  - Levemir® (insulin detemir)
  - Lantus® (insulin glargine)
  - Apidra® (insulin glulisine)
- Antineoplastic drug (non-oncologic use)
  - methotrexate

All 11 medications are on ISMP's list of high-alert medications dispensed from community pharmacies. Errors with high-alert medications may not be more frequent than errors with other medications; however, the consequences of errors with high-alert medications are often harmful. These 11 medications are also among the top 200 drugs dispensed in the United States, and many are used to treat chronic conditions, thus increasing the potential impact on public safety.

The medications were flagged in some manner to identify mandatory counseling opportunities. When a patient or patient representative picked up a flagged prescription, a pharmacist conducted a short counseling session (one to three minutes) that included the exchange of several key points on the checklist. At the end of the counseling session, the pharmacist provided the leaflet to the patient, along with a survey to complete and send back to ISMP.

Counseling sessions for these drugs were conducted for a consecutive period of four weeks, during which time, one trained ISMP staff member observed the counseling sessions for one day (six hours) to collect information on factors that facilitate or inhibit the counseling sessions. At the end of the four-week period of mandatory counseling, pharmacists at participating pharmacies were asked to complete a short mail-in survey regarding their perceived value of the process.

Results of the study showed that these consumer leaflets offer important safety tips for taking medication safely. Each leaflet begins with, "High-alert medicines have been proven to be safe and effective. But these medicines can cause serious injury if a mistake happens while taking them. This means that it is vitally important for you to know about this medicine and take it exactly as intended."

ISMP tested the readability, usability, and perceived value of the leaflets. Ninety-four percent of patients felt the leaflets provided great information or good information to know. Ninety-seven percent felt the information in the leaflets was provided in a way they could understand. Eighty-two percent of patients taking the drug for the first time and 48% of patients who had previously taken the medication reported learning something new. Overall, 85% of the patients felt they were less likely to make a mistake with the medication because they had read the leaflet.

The leaflets are available for download and can be reproduced for free distribution to consumers at *www.ismp.org/AHRQ/default.asp?link=ha.*

Generic Drug Substitution Requires Pharmacist Attention to State Laws and Regulations

While 40 years ago, most states forbade prescription drug substitution, almost all states now have drug product selection laws that allow, encourage, or mandate pharmacists to substitute generics for brand-name

drugs. These laws vary widely from state to state and pharmacists are therefore encouraged to review their state's substitution laws to ensure that they understand and comply with the state's requirements.

FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* publication, commonly known as the *Orange Book,* is generally considered the primary source for identifying suitable generic alternatives for a brand-name drug, and while not mandated by FDA regulations, the majority of states use the *Orange Book's* determinations of therapeutic equivalence to legally guide pharmacists in substituting generics.

State laws on generic substitution vary widely. A few states, such as Kentucky or Minnesota, follow a "negative formulary" approach, in which substitution is permitted for all drugs except those that appear on a particular list. Other states, including Massachusetts and Wisconsin, use a "positive formulary" approach, in which substitution is limited to the drugs on a particular list.

States also differ as to whether their substitution laws are permissive, thereby allowing a pharmacist to substitute a generic version of a brand-name drug, provided all prescription requirements are met, or mandatory, thereby requiring substitution. Prescription requirements may include such factors as the availability of a cheaper, therapeutically equivalent drug, the prescriber's specification that a brand-name drug be dispensed, or requiring the patient's or prescriber's consent. As reported in the 2013 NABP *Survey of Pharmacy Law*, 14 boards of pharmacy indicate that generic substitution falls into the "mandatory" category, while 38 boards indicate that their substitution laws are "permissive." Oklahoma law states that "[I]t is unlawful for a pharmacist to substitute without the authority of the prescriber or purchaser."

Other regulatory variations include states specifying the acceptable means for the prescriber to designate that substitution is not authorized, and states requiring patient consent prior to substitution.

The full article on this subject, which also reviews considerations regarding the accuracy of therapeutic equivalent determinations, is available in the June-July 2013 *NABP Newsletter,* which may be accessed in the Publications section of *www.nabp.net.*

NHF Provides Standards of Care for Pharmacies Serving Hemophilia Patients

For pharmacies that offer blood-clotting medications, organizations such as the National Hemophilia Foundation (NHF) emphasize the importance of being able to meet the specialized needs of their patients with bleeding disorders.

NHF's Medical and Scientific Advisory Council (MASAC) issued a standards-of-care recommendation in 2008 to assist pharmacies providing clotting factor concentrates for home use to patients with bleeding disorders. MASAC's guidelines are intended to be minimum standards of care and are divided into six areas:

As a brief overview of the MASAC guidelines, pharmacists wishing to meet the standards should:

1. Have a basic knowledge of bleeding disorders and experience with and knowledge of the full range of clotting factor concentrates, ancillary supplies, and hazardous waste disposal.

Pharmacies wishing to meet MASAC standards:

2. Should be able to provide a full range of available concentrates in all available assays and vial sizes, along with all necessary ancillary supplies, and hazardous waste disposal assistance as well as access to nursing services.
3. Should support reliable access to clotting factor for appropriate home treatment, by filling prescription orders within 48 hours, in the quantities prescribed, with expiration dates commensurate with the individual patient's needs.
4. Should be reliably open during regular business hours; provide 24-hour emergency access; and have an emergency action plan that allows patients to receive factor within 12 hours "in case of emergent need," with a goal of three hours "where logistically possible."
5. Should deliver products to the patient's desired location, meeting federal medication shipping standards, and providing an emergency number for patients to call in case of a problem with a delivery.
6. Should maintain patients' treatment prescription information along with maintaining records in compliance with state and federal requirements and be able to track the clotting factor products from manufacturer to patient, and participate in a recall information system.

The full article on this topic is available in the June-July 2013 *NABP Newsletter,* accessible in the Publications section of *www.nabp.net.* NABP notes that each state needs to review the standards recommended by MASAC to determine whether they coincide with existing state board of pharmacy requirements. NABP recognizes the unique patient needs of hemophiliacs, but also the responsibility of state boards of pharmacy to set required standards for medication dispensing and use. NABP is working with NHF to help the boards of pharmacy gain a better understanding of the medication needs of patients to help achieve uniformity in related regulations.

NABPLAW Online Now Includes Guam, Puerto Rico, and the Virgin Islands

The complete pharmacy acts and regulations of Guam, Puerto Rico, and the Virgin Islands are now included in **NABP***LAW*® Online, the comprehensive national data bank of state pharmacy laws and regulations provided by NABP. **NABP***LAW* Online's powerful search capabilities allow users to research subjects one state at a time or across all 50 states and included jurisdictions. More information about **NABP***LAW* Online and a link to the online subscription order form are available in the Programs section of the NABP Web site at *www.nabp.net/programs/member-services/nabplaw/.*

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be reported, the time frames for such reporting, and other reporting requirements as required. . .

The system is currently under development by Tennessee Department of Health personnel and more information will be disseminated when implementation is finalized.

The entire amended section for all the above-mentioned statutes may be viewed at *www.tn.gov/sos/acts/108/pub/pc0430.pdf*.

Public Chapter 336 Prohibits Dispensing of CS from Pain Management Clinics

As stated in Public Chapter 336:

. . . Tennessee Code Annotated, Title 63, Chapter 1, Part 3, is amended by adding the following as a new section: 63-1-313. (a) Notwithstanding any provision of this title or title 53, chapters 10 and 11 to the contrary, no pain management clinic or medical doctor, osteopathic physician, advanced practice nurse with certificates of fitness to prescribe, or physician assistant working at a pain management clinic shall be permitted to dispense controlled substances. . .

These practitioners may, however, provide a sample of a Schedule IV or V CS in a quantity adequate to treat the patient for no more than 72 hours. This new amendment to existing law became effective July 13, 2013, and may be viewed at *www.capitol.tn.gov/Bills/108/Bill/SB0962.pdf*.

Public Chapter 276 Reiterates Current Board Rule for Pharmacists' Professional Judgment

Tennessee Board of Pharmacy Rule 1140-02-.01(7) states:

. . . A pharmacist shall not agree to practice under terms or conditions which tend to interfere with or impair the proper exercise of professional judgment and skill, which tend to cause a deterioration of the quality of professional service and patient care, or which require the pharmacist to consent to unethical conduct. . .

According to Public Chapter 276 containing a new amendment to TCA 53-10-112:

(b) A pharmacy owner, manager or operator shall respect the professional judgment of the pharmacist in holding the health and safety of a patient to be their first consideration.

(c) A pharmacist shall, by utilizing education, skill, experience and professional judgment, make every reasonable effort to prevent the abuse of drugs which the pharmacist dispenses. In doing so, a pharmacist may decline to dispense to a patient a legend drug which in that pharmacist's professional judgment, lacks a therapeutic value for the patient or which is not for a legitimate medical purpose.

(d) A pharmacist shall not be subject to any penalty or fine when fulfilling their obligation to uphold the health and safety of a patient which results in their decline to dispense any legend drug.

(e) It shall be a Class A misdemeanor, punishable by fine only, for the owner, manager or operator of a pharmacy to knowingly restrict or interfere with, or knowingly require a protocol or procedure that restricts or interferes with, a pharmacist's professional duty to counsel with patients and to evaluate the patients' appropriate pharmaceutical needs and the exercise of the pharmacist's professional judgment as to whether it is appropriate to dispense a legend drug to a patient. . .

This act took effect July 1, 2013, and may be viewed in its entirety at *http://state.tn.us/sos/acts/108/pub/pc0276.pdf*.

Interstate Data Sharing Added to CSMD

According to Andrew "Andy" Holt, PharmD, with the CSMD, interstate data sharing is now active through NABP PMP InterConnect®. The first two states were Michigan and South Carolina, with Virginia added soon after. Holt is working with additional states and vendor, Optimum Technology, to share data with additional states, placing emphasis on bordering states.

Note that it is not currently mandatory for practitioners to search other state databases, and it may (or may not) take longer for a report to run with multiple states. "If someone wants to only search Tennessee, they can still do so without choosing any other states," Holt said. "Tennessee data is set as the default."

Be advised that certain user-types may not be authorized to view records in another state. For example, some states do not allow technicians or other extenders (licensed or unlicensed) to view CSMD data. "In these cases," Holt explained, "a message will be returned with a message stating . . . **'Your user classification is not authorized to view prescription data in this state'** . . . and the remaining authorized data will be displayed. A pharmacist may be required to log in to view the report, depending on the state."

Holt further explained that a universal patient identifier does not exist among state prescription monitoring programs. Therefore, when searching for a patient, multiple entries may show up with the same (or similar) names and dates of birth. Therefore, pharmacists are advised to evaluate the information carefully before selecting a patient for incorporating data into a report. "This action applies to Tennessee-only searches as well," Holt said. Pharmacists are encouraged to e-mail Dr Holt at andrew.holt@tn.gov with any feedback on CSMD operations.

Live Hours of Continuing Education Are Available for Attending Board Meetings

Tennessee Board of Pharmacy Rule 1140-05-.01 (1) states in part that:

. . . in order to fulfill the fifteen (15) live contact hour requirement, a pharmacist shall obtain the hours from a program designated as "live" by the [Accreditation Council for Pharmacy Education] ACPE-approved provider, **from a program that is approved by the Board prior to the expiration of the pharmacist's license** or from an out-of-state program that is approved by the board of pharmacy in the state where the program was presented. . .

Therefore, be advised that the Board has authorized pharmacists to obtain two live contact hours on a full day and one live contact hour on a designated half day if visiting a Board meet-

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ing. Note that these hours are not ACPE approved and may not satisfy other state licensure requirements. Board President Buddy Stephens stated that he hopes this incentive will bring more pharmacists to the Board meetings as this education should greatly enhance their knowledge of pharmacy law and current events.

Board President Suggests Review of DEA Record Keeping Requirement

As more pharmacies are opening with the business model of licensing a pharmacy and registering an automated dispensing system or facility with Drug Enforcement Administration (DEA), Board President Buddy Stephens suggested that registrants review the Code of Federal Regulations in regard to prescription record keeping. He specifically wanted to convey a reminder of where CS hard copy prescriptions must be kept for the two-year period required by the Board and DEA. This information may be found at the following Web site for review: *www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_04.htm.*

Warren Steps Down as New Board Member is Welcomed in

With her six-year term completed, Dr Brenda Warren has stepped down from the Board. Warren brought expert discussion on regulatory affairs and felt very strongly about the importance of communication and education of Board opinion via the *Newsletter,* Web site, and Board presentations. "During her term, Dr Warren paid great attention to detail, and cited many important points of discussion," President Buddy Stephens said. "We thank Dr Warren for volunteering her time and service and we will miss her input."

Moving to the beginning of a six-year term, the Board welcomes in Dr Robert Michael "Mike" Dickenson. Dickenson received his bachelor of science degree in pharmacy from UTHSC in 1977 (with honors) and his master of business administration from Belmont University Jack C. Massey Graduate School of Business in 1992, and is a member of the TPA. He currently serves as director of pharmacy at Dialysis Clinic, Inc, where he has worked for over 20 years. Dickenson's pharmacy experience includes community, hospital, and managed care not-for-profit business. He planned, developed, implemented, and currently operates the corporate pharmacy of the fourth largest renal dialysis provider in the United States.

Dickenson's past experience includes working as the medical/surgery unit adult pharmacy coordinator at Vanderbilt University Medical Center, as well as in community pharmacy for Jeff-Co Discount Drugs and East Tennessee Discount Drugs. Outside of pharmacy, his board experience includes serving as the president of "The View at Brentwood Pointe" Homeowners Association for about seven years, and he is a volunteer for the Middle Tennessee Medical Reserve Corps where he trains to respond to emergency and non-emergency situations.

The Board looks forward to Dr Dickenson's pharmacy business expertise and insight for the betterment of pharmacy practice in Tennessee.

Legal Counsel Appointed to the Board

Hired by the Office of the General Counsel in November 2012, Stefan Cange, JD, has been selected to continue the important task of representing and advising the Board in regard to legal matters.

A May 2012 graduate of Florida State University College of Law located in Tallahassee, FL, Cange hit the ground running while he sat in as an intern on the Board meeting in September 2012, and then as legal counsel in the November 2012 meeting. He was born in Baton Rouge, LA, and spent much of his childhood days in Oak Ridge, TN. Cange has worked with organizations such as the National Multiple Sclerosis Society – South Florida Chapter, the Innocence Project of Florida, and the Howard H. Baker, Jr. Center for Public Policy, Knoxville, TN.

During his transition to the Tennessee Department of Health, he advised department staff on legal matters including Health Insurance Portability and Accountability Act compliance and public health officials' scope of authority. He presented information on the implementation of the Tennessee "SAVE Act" and performed research dealing with regulatory and constitutional issues.

The Board welcomes Mr Cange to the team and looks forward to his guidance on the future legal challenges of Tennessee pharmacy.

New Investigator Positions to Be Filled

As the window has closed to apply for the three pharmacist 2 investigator positions, interviews should soon be underway. The Board discussed the need for more investigators as it concluded that all sterile compounding pharmacies are to be inspected at least every 12 months. An administrative position was also approved and will be added to help with increased office duties and filing of reports.

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 date is scheduled for 2013:

- November 13-14, 2013 – Iris Room (665 Mainstream Dr, Nashville, TN 37243)

Please check the Board Web site as this date is subject to change. Meetings generally begin at 9 AM.

Tennessee Board of Pharmacy Members

Dr Charles (Buddy) Stephens – President

Dr Jason S. Kizer – Vice President

Dr William J. Bunch – Board Member

Dr Mike Dickenson – Board Member

Dr Kevin Eidson – Board Member

Dr Nina Smothers – Board Member

Ms Joyce McDaniel – Public Board Member

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