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Tennessee Board of Pharmacy News

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Tennessee Announces Increased Fees for Fingerprint-Based Background Checks

Effective October 1, 2016, for those applicants needing a fingerprint-based background check, the revised user fees are as follows: Tennessee Bureau of Investigation (TBI)/Federal Bureau of Investigation (FBI) applicant fingerprint-based background checks: $32.65; TBI/FBI volunteer fingerprint-based background checks: $30.15; and TBI-only fingerprint-based background checks: $20.65. Moreover, TBI will no longer accept paper fingerprint card submissions (for civil purposes). For more detailed information, please click here.

Board Welcomes New Member

In accordance to Tennessee Code Annotated (TCA) 63-10-302, Governor Bill Haslam made his decision and appointed the next member to the Tennessee Board of Pharmacy.

Therefore, on November 8, members extended a warm welcome to Katy Wright, MBA, PharmD, BCPS, who will be traveling in from East Tennessee (Oak Ridge, TN). The Board sends a sad but appreciative farewell to Dr Nina Smothers, who continues her hospital pharmacy duties in West Tennessee (Huntingdon, TN).

Dr Wright is currently employed as assistant director of pharmacy at Cardinal Health Innovative Delivery Solutions, Methodist Medical Center of Oak Ridge. She brings many aspects of pharmacy practice experience to the Board, including leadership for, and oversight of, pharmacists and technicians in the daily operations of the pharmacy department. She also continues to provide pharmaceutical care to patients as a clinical staff pharmacist.

Dr Wright has been involved in many projects including software implementation for total parenteral nutrition compounding, Sigma Spectrum Infusion Pump with Master Drug Library creation for smart pumps, AdminRx for nursing, computerized provider order entry order set and formulary build, and United States Pharmacopeia Chapter <797> compliance.

Additional responsibilities include instructing as a preceptor for students from the University of Tennessee Health Science Center College of Pharmacy, South College School of Pharmacy, Bill Gatton College of Pharmacy (East Tennessee State University), and Belmont University College of Pharmacy.

Dr Wright earned her pharmacy doctorate while attending the University of Tennessee College of Pharmacy (2001) and recently (2016) earned her master of business administration from the University of Memphis. She is a member of several pharmacy organizations including the American Society of Health-System Pharmacists, American College of Clinical Pharmacy, Tennessee Pharmacists Association (currently serving as Tennessee Society of Health-System Pharmacists secretary/treasurer), and the Board of Pharmacy Specialties.

She is a graduate of the Pharmacy Leadership Institute-Boston University and a past recipient of the American Pharmacists Association Academy of Student Pharmacists Senior Recognition Certificate and the Mortar and Pestle Professionalism Award.

When not presenting on topics such as electronic medical record implementation or medication review, Dr Wright enjoys spending time with her husband, Bryan Wright, PharmD, and her two children, Will and Ian. So, without further ado – **Dr Wright, welcome to the Board!**

Investigator Reports Discussion From the FDA 50-State Inter-governmental Working Meeting on Pharmacy Compounding

Scott Denaburg, PharmD, investigator for the Board, attended the 2016 Inter-governmental Working Meeting on Pharmacy Compounding that was held on September 20-21, 2016, at the Food and Drug Administration (FDA) White Oak Campus in Silver Springs, MD. During the discussion on compounding, Dr Denaburg was informed that for the year 2016, FDA had performed 77 inspections of 503A pharmacies **(think in terms of traditional**

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National Pharmacy

The applicability of articles in the *National Pharmacy Compliance*
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National Vaccine Safety Surveillance Program Available for Reporting Adverse Events

The Vaccine Adverse Event Reporting System (VAERS) eSubmitter program, a national vaccine safety surveillance program cosponsored by the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA), is available for the reporting of any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States. VAERS information is analyzed by CDC and FDA to identify new safety concerns. VAERS reports can be filed by anyone, including health care providers, manufacturers, state immunization programs, and vaccine recipients. Vaccine recipients are encouraged to seek help from their health care provider when filling out the VAERS form. Health care providers can find information about submitting a report on the VAERS website at *https://vaers.hhs.gov/professionals/index*.

Improper and Unsafe Vaccine Storage

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition *by visiting* www.ismp.org. *ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

Few issues are more important than proper storage and handling of vaccines, because their ability to prevent disease is dependent on these factors. To maintain stability, most vaccines must be stored in a refrigerator or freezer, and many also require protection from light. Excessive heat or cold – even a single exposure in some instances – can reduce vaccine potency. These temperature excursions are often due to improper refrigeration or freezer units, inadequate thermostat controls, and refrigeration/freezer units with inadequate space to allow good air circulation and even temperatures.

Improper and unsafe storage can also result in serious errors caused by selecting the wrong vaccines, diluents, and other medications with look-alike names and/or labeling and packaging. Storing vaccines close to each other has led to dispensing and administering the wrong vaccine or wrong form of vaccine (eg, adult versus pediatric). Storing vaccines too close to non-biologic medications in a refrigerator or freezer has also led to serious adverse outcomes, particularly when the mix-up involved a vaccine and a high-alert medication. For example, vials of insulin have frequently been mistaken as influenza vaccine, and various neuromuscular blocking agents have been used to reconstitute vaccines or were mistaken as influenza or hepatitis B vaccines.

Store vaccines in their own dedicated refrigeration and freezer units. Regular temperature monitoring is necessary, and technology is available to assist with alarmed, continuous monitoring devices that can alert staff via email and pager if a unit is out of specified range. Separate vaccine vials and syringes into bins or other containers according to vaccine type and formulation, keeping diluents with the appropriate vaccines. Never store different vaccines in the same containers. Do not store vaccines with similar labels, names, abbreviations, or overlapping components immediately next to each other or on the same shelf. Separate the storage areas of pediatric and adult formulations of vaccines. Label the specific locations where vaccines are stored to facilitate correct age-specific selection and to remind staff to combine the contents of vials. ISMP's March 26, 2015 newsletter[1] contains additional strategies, as does a Vaccine Storage & Handling Toolkit available from CDC.[2]

References

1. ISMP. Recommendations for practitioners to prevent vaccine errors. Part 2: analysis of ISMP vaccine errors reporting program (VERP). *ISMP Medication Safety Alert!* 2015;20(6):1-6.
2. CDC. Vaccine storage & handling toolkit. www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf. June 2016.

Coalition Reports Impact of Educational Efforts on Safe Acetaminophen Use

The Acetaminophen Awareness Coalition reports that progress has been made to increase consumer awareness about the safe use of acetaminophen. The coalition also notes a decline in unintentional overdoses. The National Poison Data System's 2015 report indicates unintentional acetaminophen exposures, including dosing errors and accidental misuse, have decreased through 2013 after a peak in 2009. In addition, a nationwide survey indicates the number of consumers who understand that exceeding the recommended daily dose of acetaminophen may lead to liver damage has increased to 87% in 2013 from 78% in 2010. The survey also reports the number of consumers who think it is important to check the medicine label for the maximum daily dose increased to 98% in 2013 from 93% in 2010.

Developed in 2011, the Know Your Dose campaign encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use. The Know Your Dose campaign offers a list of helpful health tips to share with patients, including the following:

(1) Read and follow the label.
(2) Know which medicines contain acetaminophen.
(3) Take only one medicine at a time that contains acetaminophen.

(4) Ask a health care provider or pharmacist about dosing instructions or medicines that contain acetaminophen.

Pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website, *www.knowyourdose.org*.

FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA's Division of Drug Information in the Center for Drug Evaluation and Research presents a series of CE webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of FDA's expanded access program and the pregnancy and lactation labeling rule. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm*.

Fresenius Kabi Recalls Sensorcaine-MPF (Bupivacaine HCl) Injection, USP

In April 2016, Fresenius Kabi USA recalled a single lot of Sensorcaine®-MPF (bupivacaine HCl) injection, USP, 0.75%, 7.5 mg/mL, 30 mL fill in a 30 mL vial, because of visible particulate matter characterized as glass observed by the company during inspection of reserve samples. The recalled product was shipped in the US to wholesaler and distributor outlets between March 4, 2016, and March 21, 2016, and has an expiration date of September 2019. The recall affects lot number 6111504, product code 470237, and National Drug Code number 63323-472-37. The product is supplied as 0.75% strength in a 30 mL single-dose flint molded vial and is packaged in units of 25. To date, Fresenius Kabi has not received any reports of adverse events regarding this recall, indicates the press release posted to the FDA website.

Health care facilities that have the affected lot are instructed to immediately discontinue distributing, dispensing, or using the lot and return all units to Fresenius Kabi. Distributors are instructed to immediately notify their customers who have been shipped or may have been shipped the recalled product. Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program at *www.fda.gov/MedWatch*. Additional details are available on FDA's website at *www.fda.gov/Safety/Recalls/ucm497812.htm*.

Oral Liquid Docusate Sodium by PharmaTech Recalled Due to Contamination

In July 2016, FDA alerted health care providers that PharmaTech, LLC, of Davie, FL, voluntarily recalled all non-expired lots of Diocto Liquid, a docusate sodium solution distributed by Rugby Laboratories of Livonia, MI. The affected product was distributed nationwide in one-pint (473 mL) bottles with a Rugby label. FDA confirmed the product has been contaminated with *Burkholderia cepacia,* a bacteria linked to an outbreak in five states. The safety alert indicates FDA has received several adverse event reports of *B. cepacia* infections in patients, and some of these reports identify liquid docusate sodium products manufactured by companies other than PharmaTech. FDA and CDC continue to investigate the extent of this issue in order to identify other potentially contaminated liquid docusate sodium products. FDA joins CDC in recommending that clinicians not use any liquid docusate sodium product as a stool softener or for any other medical purpose. Adverse events or side effects may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch*. More information may be found in the safety alert on FDA's website at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm511528.htm*.

NABP Seeks Pharmacists From Districts 1, 5, and 7 to Serve as Volunteer Item Writers

The National Association of Boards of Pharmacy® (NABP®) is seeking pharmacists who reside in states in the following districts to serve as volunteer item writers:

- **District 1:** Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.
- **District 5:** Iowa, Minnesota, Nebraska, North Dakota, and South Dakota.
- **District 7:** Alaska, Idaho, Montana, Oregon, Washington, and Wyoming.

In an effort to secure more individuals representative of these areas of the country, NABP encourages pharmacists in all areas of practice as well as school and college of pharmacy faculty who reside in these states to apply.

NABP uses volunteer item writers to develop questions for the following examination programs: North American Pharmacist Licensure Examination® (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), Pharmacy Curriculum Outcomes Assessment® (PCOA®), and Pharmacist Assessment for Remediation Evaluation® (PARE®).

Interested individuals should complete the online Item Writer Volunteer Interest Form available at in the Meetings section of the NABP website. Individuals who are selected will receive further information on opportunities to attend and participate in NABP-hosted workshops.

For more information about NABP item writing, visit the Meetings section of the NABP website at www.nabp.pharmacy, or contact CompAssess@nabp.pharmacy.

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patient-specific prescription-dispensing/administering pharmacies) with 20 follow-up inspections. According to FDA, **insanitary conditions may cause drugs to be adulterated** and may prompt an inspection. Such insanitary conditions may be found in the following locations, among others: pharmacies, hospitals, surgery centers, and prescribing practitioner practices, whether preparing **sterile or nonsterile** medications. For the detailed report with examples of current findings, please click here.

Board Office Reiterates Prescription Dispensing When Death of a Prescribing Practitioner Occurs

A common question to the Board concerns the validity of a prescription once a prescribing practitioner has died. In July 2010, an act was passed that addresses this issue.

Please give careful consideration to the differences in state and federal law. The **more stringent** regulation applies in regard to the dispensing of controlled substances (CS).

TCA Title 53, Chapter 10, Part 1 states in part:

> (a) Notwithstanding any other provision of law to the contrary, when a pharmacist becomes aware that a healthcare practitioner authorized to prescribe by the law of this state has died, a prescription issued by the practitioner may continue to be dispensed based on the pharmacist's professional judgment and in accordance with the following requirements:
>
> (1) If the prescription is a new prescription that has not been previously dispensed, it may be dispensed within ninety (90) days of the date on which the practitioner has died;
>
> (2) If the prescription has been previously dispensed and has valid authorization to be refilled, the refills may be dispensed but not for a period of more than ninety (90) days from the date on which the practitioner died for Schedule III, IV and V drugs and one hundred eighty (180) days from the date on which the practitioner died for non-scheduled drugs; and
>
> (3) Nothing in this section shall authorize the dispensing of a prescription that was issued for a controlled substance unless permitted by the federal Controlled Substances Act and regulations of the [United States Drug Enforcement Administration].
>
> (b) These provisions shall not apply to a schedule II controlled substance.

Therefore, be advised that federal regulations **prohibit the dispensing of CS once the practitioner has died or has ceased to legally exist or discontinues business or professional practice** pursuant to Title 21 Code of Federal Regulations (CFR) 1301.52 Termination of registration; transfer of registration; distribution upon discontinuance of business.

For the reading of the complete rules and regulations stated above, please refer to TCA Title 53, Chapter 10 and TCA Title 63, relative to prescriptions in cases where a prescriber dies, and Title 21 CFR 1301.52(a-d).

Question: Why did the legislators use language for CS that would be null and void by the more stringent federal regulation?

Answer: According to Dr Baeteena Black, former executive director for the Tennessee Pharmacists Association, there were prescribing practitioners who expressed a hope for federal regulation changes allowing CS to be dispensed as stated in the Tennessee legislative rule. If the federal regulation was amended, this forward thinking would take effect immediately, and no time would be needed for an amendment to the state rule.

Tennessee DEA Office Gives Guidance for Reporting Theft or Loss

Per Title 21 CFR 1301.76(b), registrants must notify their local Drug Enforcement Administration (DEA) office, in writing, of the theft or significant loss of CS **within one business day of discovery.** Tennessee registrants may now satisfy this requirement by submitting all relevant information via email to **tntheftorloss@usdoj.gov. Registrants must still complete a DEA Form 106** and may do so online via the DEA website. If you have questions, please contact DEA Diversion Investigator James N. Stevens at 615/736-7343. You may also satisfy the Board regulation to report by sending a copy to Dr Terry Grinder at terry.grinder@tn.gov.

Link for Disciplinary Action

Monthly disciplinary action information is available by clicking here. This web page also contains specific registrant verification as well as the option to receive a monthly disciplinary email report.

Help Is Available for Impaired Pharmacists Through the Tennessee Pharmacists Recovery Network

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 email at bblack@tnpharm.org.

An information link (including the reporting form) is located at *www.tnpharm.org/member-center/tn-pharmacists-recovery-network.*

Board Meeting Schedule

The Tennessee Board of Pharmacy extends an open invitation for all registrants and the general public to attend its public meetings at 665 Mainstream Drive, Nashville, TN 37243. The meetings are currently scheduled to begin at 9 AM. Pharmacists may receive up

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to two hours of live continuing education, valid for their Tennessee pharmacist license, on a full meeting day, and one hour on a half-day. As always, check for schedule changes on the Board website under the "Meeting Schedule" tab.

The **2017** meeting schedule is listed as follows:

- January 24-25
- March 14-15
- May 9-10
- July 11-12
- September 12-13
- November 14-15

Tentative dates set for contested hearings include the following:

- April 12-13
- June 13-14

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://tn.gov/health/article/pharmacy-applications* 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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