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Tennessee Board of Pharmacy News

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Board Welcomes New President and Vice President

With a new year beginning, the Tennessee Board of Pharmacy has completed elections. Dr Nina Smothers has taken the helm as president, and Dr William Bunch has moved to the vice president's chair. Former President Dr Jason Kizer will remain on the Board until a new member is appointed by the governor. The Board thanks Dr Kizer for his service, and continues to look forward to his independent retail pharmacy and management insight on Board issues.

Follow Proper Reporting Regulations When Theft or Significant Loss Is Discovered

When theft or significant loss of a controlled substance (CS) is noticed, it is required to contact Drug Enforcement Administration (DEA) "within one business day" of the discovery as stated in Title 21 Code of Federal Regulations (CFR) §1301.76. It is also required to notify the Board (Board Rule 1140-03-.09).

If located in central or western Tennessee, DEA Diversion Investigator Rhonda Phillips states that the registrant should report the theft or significant loss to the Nashville, TN, Resident Office at 615/736-2559 or via facsimile at 615/736-2558.

For eastern Tennessee registrants, Phillips advises to report to the Knoxville, TN, Resident Office at 865/584-9364 or via facsimile at 865/584-8763.

Visit *www.deadiversion.usdoj.gov/21cfr_reports/theft* for the online DEA Form 106, Report of Theft or Loss of Controlled Substances, or use the paper form directions if the online function is unavailable to complete the process. **Do not hesitate** to report the theft or loss. Once an audit is taken, send the DEA Form 106 report as soon as possible.

Also, it is advised to complete a full audit as discussed in the December 2014 *Tennessee Board of Pharmacy Newsletter* (page four), which may be found at *www.nabp.net/system/rich/rich_files/rich_files/000/000/696/original/tn122014.pdf.*

Furthermore, all Board registrants are required to report loss of prescription medications and/or devices to the Board office as stated in the following rule.

> **1140-03-.09 Loss of Prescription Drugs, Devices and Related Materials.**
>
> The pharmacist in charge shall immediately report to the board any robbery, embezzlement, theft, burglary, or fire or disaster resulting in a loss of prescription drugs, or controlled substances or medical devices or related materials. The report shall include a list, including amounts, of such prescription drugs or controlled substances or medical devices or related materials lost or damaged.

For additional questions, contact the Board executive director, an area Board investigator, or local DEA office. Contact phone numbers and emails for the Board director and investigators may be found on page five of the December 2013 Board *Newsletter,* which is available at *www.nabp.net/system/rich/rich_files/rich_files/000/000/141/original/tn122013.pdf.*

With Increased Pharmacy Audits, DEA Points to CFR 1304.21 for 'A Complete and Accurate Record' and Other Regulations

With the hiring of three additional Board investigators, pharmacists and other registrants are experiencing more timely inspections. However, some registrants are also being inspected by that other regulatory administration, also known as DEA.

So, what are they looking for? A few helpful hints are as follows. First, read 21 CFR 1304.21, which may be found at *www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_21.htm.* Pay close attention to Section (a). As a registrant,

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DEA Finalizes Rule on CS Prescription Drug Disposal

In September 2014, Drug Enforcement Administration (DEA) published its final rule, titled the Disposal of Controlled Substances, that allows some DEA registrants to modify their registration to become authorized collectors. Under the new rule, some DEA registrants, including retail pharmacies, hospitals/clinics with an on-site pharmacy, manufacturers, distributors, reverse distributors, and narcotic treatment programs, may modify their registration with DEA to become authorized collectors. The final rule implements the Secure and Responsible Drug Disposal Act of 2010, which authorized DEA to develop and implement regulations that would allow authorized entities other than law enforcement to collect unused and unwanted prescription drugs, including controlled substances (CS), for disposal purposes. Proper disposal of unused prescription medication is a key method of preventing and reducing prescription drug abuse. The final rule took effect on October 9, 2014.

The full rule is available on the *Federal Register* website at *www.federalregister.gov/articles/2014/09/09/2014-20926/disposal-of-controlled-substances.*

System-Based Causes of Vaccine Errors

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.*

Immunizations are widely recognized as one of the most successful and cost-effective health interventions ever introduced worldwide. However, errors with vaccines can result in an unintended and unrecognized source of vulnerability. While the immediate impact of a vaccine-related error on a patient may not be serious, such errors may render the vaccine ineffective or reduce its effectiveness, leaving patients unprotected against serious diseases such as hepatitis A, hepatitis B, diphtheria, tetanus, measles, cervical cancer, and many others. In September 2012, ISMP (in cooperation with the California Department of Public Health) established the ISMP National Vaccine Errors Reporting Program (VERP) to collect data about the type of vaccine errors occurring and the reasons they occur. In ISMP's November 28, 2013 newsletter *(www.ismp.org/sc?id=307),* ISMP provided a summary analysis of error reports submitted to the ISMP VERP during its first year. The vaccinations that are most frequently associated with errors included *Haemophilus influenzae* type b conjugate (Hib); diphtheria and tetanus toxoids, acellular pertussis adsorbed, and inactivated poliovirus (DTaP-IPV); tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis adsorbed (Tdap); diphtheria, tetanus toxoid, and acellular pertussis adsorbed (DTaP); hepatitis A (HepA); hepatitis B (HepB); human papillomavirus quadrivalent (types 6, 11, 16, and 18), recombinant (HPV4); zoster; and measles, mumps, rubella, and varicella (MMRV). The most common contributing factors associated with the reported vaccine errors included mistakes in choosing age-dependent formulations of vaccines intended to prevent the same diseases; unfamiliarity with the vaccine, particularly its dose, dosing schedule, age specifications, route of administration, and the vaccine's various components (eg, combination vaccines, diluents, and powder); failure to check or verify the patient's age, health record, or state registry; similar vaccine names and abbreviations; similar and confusing vaccine labeling and packaging; unsafe storage conditions (eg, stored near other similar vaccines or unwanted temperature fluctuations); and expiration dates not noticed or misunderstood.

Practice Recommendations. Involve the patient or parent(s)/caregiver(s) in a vaccine verification process by:

1) Documenting the vaccine name, formulation (pediatric or adult, if applicable), lot number, and expiration date on the patient's vaccine record **prior** to preparation/administration of the vaccine,
2) Bringing the vial and syringe or the prefilled syringe along with the immunization record into the exam room,
3) Asking the patient or parent/caregiver to simultaneously verify the information on the immunization record while a health care provider reads the information on the label aloud,
4) Asking the patient or parent/caregiver if the verified vaccine is what he or she expected to be administered (based on an immunization schedule provided to the patient or parent/caregiver previously),
5) Preparing and administering the vaccine immediately after verification, and
6) Documenting the vaccine on the patient's medical record.

FDA Warns of Growing Network of Rogue Wholesale Drug Distributors

Through a new educational program called Know Your Source, Food and Drug Administration (FDA) is warning pharmacists and other health care providers to watch for counterfeit and unapproved drugs. Aimed at protecting patients from unsafe and ineffective drugs, the program advises providers to only purchase drugs from wholesale drug distributors licensed in their state. Further, FDA offers tips to providers to protect patients, including being wary of offers too good to be true, and ensuring that all drugs received are FDA-approved medications.

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws, as well as NABP's VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous

review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo a site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the United States drug supply.

Additional information about the VAWD program is available in the Programs section of the NABP website. Know Your Source is available at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm389121.htm*.

PTCB Implements Changes to CE Requirements

In 2015, the Pharmacy Technician Certification Board (PTCB) will implement two changes in recertification requirements for certified pharmacy technicians (CPhTs) in accordance with its certification program changes announced in 2013. First, any continuing education (CE) hours earned by a CPhT will need to be pharmacy technician-specific in order to qualify toward recertification. Second, PTCB will reduce the number of allowable "in-service" CE hours from 10 to five. PTCB's certification program changes are intended to support and advance improved patient care and safety throughout pharmacy practice, a PTCB press release indicates. The changes are the result of a PTCB initiative that began with a 2011 summit on future directions for pharmacy technicians.

Additional information can be accessed on the PTCB website at *www.ptcb.org*.

Security Guidelines Available as Rate of Pharmacy Robberies Still a Concern

Nationally, pharmacy robberies dipped slightly from 745 in 2012, to 713 in 2013, according to a report compiled by *Drug Topics* using DEA statistics. The 10 states that had the most robberies are in stark contrast to other states that had no robberies (South Dakota, North Dakota, and Alaska) or as few as one or two (such as Montana and Illinois), reports *Drug Topics*. However, fueled by the prescription drug abuse epidemic, pharmacy robberies still pose a threat to the safety of personnel and customers. The report lists the top 10 states that had the most pharmacy thefts in 2013. Arizona experienced the most pharmacy robberies in 2013 with 77 incidents, and Indiana took second place with 71 robberies. The report, titled "Top 10 states for pharmacy robberies," may be found at *http://drugtopics.modernmedicine.com/drug-topics/content/tags/arizona/top-10-states-pharmacy-robberies?page=full.*

NABP partnered with DEA to create an educational pamphlet identifying key strategies pharmacists can take to secure their stores against robberies, which can be downloaded at *www.deadiversion.usdoj.gov/pubs/brochures/pharmtheft.pdf*. In addition, some boards of pharmacy have identified best practices for preventing pharmacy theft, and have supported these practices through regulations or recommendations for their licensees. For example, the New Jersey State Board of Pharmacy's *Pharmacy Security Best Practices* document recommends that all Schedule II and III CS be stored in a "safe or substantially constructed steel cabinet that is locked at all times," with only licensed pharmacists having access. Additional recommendations include annual pharmacist-in-charge self-assessments and interfacing with prescribers and customers, among others. The best practices document can be downloaded from the New Jersey Consumer Affairs website at *www.njconsumeraffairs.gov/press/05012013.pdf.*

Private organizations have also developed resources to assist pharmacies in improving security. One such resource is the RxPATROL program, which works with law enforcement, the pharmacy community, and security professionals to maintain a database containing detailed information about pharmacy robberies and other losses. In addition, the RxPATROL website, *www.rxpatrol.com*, provides training videos and a pharmacy security checklist.

Further, NABP members directed the Association to convene a task force to review strategies that states have taken to prevent theft and drug diversion. The Task Force to Examine Strategies for Preventing and Reacting to Pharmacy Robberies and Thefts met on October 22-23, 2014, to discuss these issues.

Assured Brand Naproxen Tablets Recalled Due to Packaging Error

In October 2014, Contract Packaging Resources of Greensboro, NC, a drug repackaging company, issued a voluntary recall of nearly 12,000 boxes of Assured brand naproxen sodium tablets because some cartons contain bottles of 200 mg ibuprofen softgels instead, a press release posted to the FDA website indicates. The packaging error affected boxes of Assured brand naproxen sodium tablets 220 mg, 15 count (Lot Number FH4102A), which were distributed to and sold at Dollar Tree stores and on the Dollar Tree website. Contract Packaging Resources is contacting customers to arrange for replacement of all recalled products. Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting Program.

More information is available on the FDA website at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm419769.htm.*

Martin Avenue Pharmacy Issues Voluntary Recall for All Sterile Compounded Preparations

Martin Avenue Pharmacy, Inc, of Naperville, IL, issued a voluntary recall for all in-date compounded sterile preparations due to a lack of sterility assurance in August 2014. Following a recent FDA inspection that revealed "quality control procedures that present a risk to sterility assurance," the company issued the recall out of an abundance of caution, indicates a news release posted to the FDA website. Martin Avenue Pharmacy supplied compounded sterile preparations to offices of licensed medical professionals and individuals in multiple states including Illinois, Wisconsin, Ohio, Michigan, Florida, Alabama, and Texas until August 20, 2014. A full list of recalled products is available on the Martin Avenue Pharmacy website (registration required). FDA urges consumers and health care providers to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information Adverse Event Reporting Program.

More information is available on the FDA website at *www.fda.gov/Safety/Recalls/ucm412431.htm*.

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you are required to keep a **"complete and accurate record"** of your CS medications. To clarify, if an audit is performed, your on-hand CS medication counts should reconcile with the last CS inventory that was taken. DEA requires an inventory to be taken every two years. Additionally, the Board requires that a CS inventory also be taken during a change of pharmacist-in-charge. However, do you really want to rely on an inventory that is taken only during those time periods? And even then, are you just making counts, or are you actually looking at (reconciling) usage reports, invoice orders, credit returns, and other thefts or losses to make sure the counts are correct for the time period in question? DEA diversion and Board investigators are performing audits, and it is strongly advised that registrants also perform these audits to ensure ". . . a complete and accurate record of each such substance. . ." Although a perpetual inventory is not required by DEA per this same regulation, it is certainly good practice to keep one on those high-theft or usage medications.

On a different topic, be sure to keep prescription hard copies and invoices properly separated or in proper order as stated in 21 CFR 1304.04(h), found at *www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_04.htm*. DEA requires that all invoices shall be dated on the date **received,** etc, as indicated in 21 CFR 1304.21(d). Ask yourself this question: Do my invoices have a recorded received date actually noted on each and every CS invoice? If not, start documenting immediately.

Furthermore, if you are ordering your Schedule II medications through the Controlled Substance Ordering System (CSOS) and you have shared your access code (password) with others, you may be found in violation of 21 CFR 1311.30 and have your certificate revoked. This regulation may be viewed at *www.deadiversion.usdoj.gov/21cfr/cfr/1311/subpart_b10.htm#30*. And, when ordering by way of CSOS, do not forget to **enter the received date in the CSOS computer system** as opposed to just having it recorded on a printed version, as noted by DEA Diversion Investigator Rhonda Phillips.

Last but not least, it is advised to review 21 CFR 1301.75 and 1301.76 for security controls. Continuous or high theft/loss can prompt an investigation, and additional security measures may be imposed. For additional information, visit the following links:

- 21 CFR 1301.75: *www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_75.htm*
- 21 CFR 1301.76: *www.deadiversion.usdoj.gov/21cfr/cfr/1301/1301_76.htm*

Again, do not hesitate to contact your area pharmacy Board investigator, Board executive director, or local DEA office with questions or clarifications.

Holt Steps Down, Bess Hired as CSMD Director

As Dr Andrew "Andy" Holt has stepped down to take a new position in the private sector, the Board extends its gratitude to him for his efforts in moving the Controlled Substance Monitoring Database (CSMD) forward using innovative reporting methods.

Accepting the nod as director of the CSMD is Dr David "Todd" Bess, who brings an abundance of past research and presentation experience to the position. Some of his many works (and collaborations) include titles such as:

- "Development of an Outcomes Data Collection Tool within a Central Registry for Opioid Treatment Programs;"
- "2011 Pharmacy Update Seminar: Board of Pharmacy Update: Public Policy and Governmental Issues Relating to Medication Use, Misuse and Abuse;"
- "Policy Issues Relating to Prescription and OTC Drugs of Misuse and Abuse;"
- "From Pain to Addiction;" and
- "Tennessee Controlled Substance Database."

A 1986 doctor of pharmacy graduate from the University of Tennessee Health Science Center (UTHSC) College of Pharmacy, with a post-doctoral residency completed in 1987, Bess continues to hold board certification in pharmacotherapy. Also at UTHSC, he served as assistant dean for Middle Tennessee, College of Pharmacy, and as director of the Nashville Clinical Education Center and Statewide Community Pharmacy Residency Program at the UTHSC College of Pharmacy. He has consulted for the State of Tennessee Department of Mental Health and Substance Abuse Services, the State of Tennessee Department of Intellectual and Developmental Disabilities, the Tennessee Board of Medical Examiners, and as a clinical pharmacy manager for the United States Department of Veterans Affairs and Saint Thomas Hospital.

As for understanding the Board rules, regulations, and procedures, Bess needs no learning curve as he sat on the Board from 2004 to 2010, serving as president for 18 months between the years of 2008 and 2010.

He has served on committees including the Controlled Substance Monitoring Database Advisory Committee, Request for Proposal Committee for Tennessee's first CS database, and the TennCare Joint Committee for the Review of Narcotic Management.

Furthermore, he has served in different capacities for several other groups, including the Tennessee Pharmacists Association and the National Association of Boards of Pharmacy® (NABP®). Bess has numerous professional honors, including recent recognition from NABP for serving on the Advisory Committee on Examinations from 2008 to 2014, as well as his appointment to the

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University of Tennessee Leadership Institute and the Institute for Health Outcomes and Policy Research Education Executive Council for UTHSC College of Graduate Health Sciences.

Board Executive Director Reginald "Reggie" Dilliard is excited to have Dr Bess on board and looks forward to working with him. "Dr. Bess brings a wealth of knowledge and experience to the CSMD office," Dilliard said. "His past experience as a former Board of Pharmacy member, his work over that period of time with the CSMD, and his educational background make him an excellent fit for our goals of enhancement and increased utilization of the database."

Help Is Available for Impaired Pharmacists Through the TPRN

If you need help or know an associate who does, please contact Baeteena Black, Tennessee Pharmacists Recovery Network (TPRN) 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.*

Tennessee Board of Pharmacy Meeting Dates

The Tennessee Board of Pharmacy extends an open invitation for all pharmacists, as well as the general public, to attend its public meetings in Nashville. The following dates are scheduled for 2015 (address is 665 Mainstream Drive, Nashville, TN 37243):

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

The meetings are currently scheduled to start at 9 AM on the first day, and at 8 AM on the second day, unless otherwise stated. It is advised to check the Board website, as meeting dates and times can be subject to change.

Mandatory Practitioner Profiles

The Board reminds licensees that the Mandatory Practitioner Profile Questionnaire for Licensed Health Care Providers must be completed and updated as information changes. To obtain a copy of the Mandatory Practitioner Profile Questionnaire, visit *http://health.state.tn.us/boards/Pharmacy/applications.shtml* and click on "Mandatory Practitioner Profile Questionnaire (PH-3585)."

Completed/updated profiles should be submitted by mail to the Tennessee Department of Health, care of the address provided as part of the questionnaire instructions.

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