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Board Office Staff and Investigators Create Compliance Reminders: The Take-Home Message

Tennessee Board of Pharmacy office staff and investigators remind registrants of issues that continue to be marked as out-of-compliance. In each *Tennessee Board of Pharmacy Newsletter,* some of these regulations will be noted. As always, you are encouraged to reach out to your investigators and/or the Board office with questions or concerns. **Note that the word "shall" is defined in Board rules and "means that compliance is mandatory."** Some of the most common compliance issues are as follows:

- "Medical and prescription orders shall be transferred between pharmacy practice sites." The transferor should immediately reverse any adjudicated claim or fill if the prescription has not been dispensed. Otherwise, the transferred information for refills will be incorrect. The Board voiced opinion regarding the transfer of a prescription that has never been filled (ie, placed on file or hold at the pharmacy) and reiterates that there is no issue of a non-controlled medication being transferred regardless if it is a refill or a new prescription. See the next bullet point regarding controlled substances (CS).
- View the Board's policy on transfer of CS prescriptions placed on file or hold here.
- Change of employment, work address, home address, and other contact information shall be updated with the Board (click here to print form).
- Name change shall be updated with the Board (click here to print form).
- Unless located in an institutional facility, all pharmacy, pharmacist, and pharmacy technician (including certified pharmacy technician) certificates **shall be posted** in a conspicuous place. Institutional facilities shall have these registration certificates available for investigator review. Simply printing the Board's website verification page does not meet the requirement.
- Technician registries (ie, a written or typed list of all pharmacy technicians) are required by all pharmacies. Do not forget to add new hires, probationary employees, and transfers.
- Technician affidavits are to be kept on file for investigator review (click here for form).
- No food should be kept in a refrigerator or freezer where drugs are stored.
- Name tags shall be worn with appropriate titles (eg, pharmacist, DPh, certified pharmacy technician, or CPhT).
- Only a pharmacist is allowed to possess a key to the pharmacy.
- Only pharmacists are allowed to have pharmacy access after the close of business.
- Hot and cold running water is required. The water should reach a temperature hot enough to appropriately wash glassware after compounding.
- Pseudoephedrine and other methamphetamine precursor sales regulations require the pharmacist to discuss with the patient or caregiver the appropriate product and use and determine legitimate need.
- Only a maximum of a 30-day supply of opioids and benzodiazepines is allowed to be dispensed to patients in Tennessee. This requirement includes in-state and out-of-state registrants who use mail order to dispense into Tennessee.
- The Board shall be immediately notified of a change or loss of a pharmacist-in-charge (PIC).

DEA Indicates Pharmacy Inspections May Increase and Reveals Tips for Compliance

Drug Enforcement Administration (DEA) officials passed on to the Board office some helpful hints as to what kind of issues investigators are finding out of compliance as they increase their inspections of pharmacies. Although not a conclusive list, the following issues were noted:

- Controlled Substance Ordering System (CSOS) passwords are being shared and/or posted in the pharmacy. This action results in immediate CSOS revocation when discovered.

continued on page 4

.Pharmacy Domain Signals Safety on the Web

With only 4% of websites selling prescription drugs online following United States pharmacy laws and practice standards, consumers seeking medications online are faced with the daunting task of finding a safe site. To assist consumers and those legitimate pharmacies with an online presence, NABP has streamlined its website verification programs. As of September 1, 2017, NABP is only offering the .Pharmacy Verified Websites Program and the Verified Internet Pharmacy Practice Sites® (VIPPS®) program, providing an easy choice for safety-minded consumers and pharmacies alike. The .Pharmacy Program, which was launched in 2014, enables qualified pharmacies and pharmacy-related businesses to register a web address with the .pharmacy domain. A .pharmacy domain (pronounced "dot pharmacy") is part of a website's address like ".com" or ".biz": *www.safe.pharmacy.* It enables people to identify an online pharmacy or pharmacy-related website as safe and legitimate. Since .pharmacy is a verified domain, websites are evaluated against a set of safety standards before an applicant is approved to register the domain.

In addition to showing patients that they operate a safe website, the .pharmacy domain allows pharmacies and related entities to advertise online through Google, Bing, and Yahoo! The .Pharmacy Program replaces the e-Advertiser Approval℠ and Veterinary-VIPPS® programs for those entities that are not eligible to apply for VIPPS but want to advertise with the search engines.

For more information about the .Pharmacy Program, including the application and domain name registration process and fees, visit *www.safe.pharmacy/apply.*

Quality Processes, Risk Management, and Culture: HR-Related Policies That Conflict With a Just Culture

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.*

As health care organizations move toward a "Just Culture," one of the areas potentially overlooked is human resource (HR)-related policies and procedures. Because these policies and procedures typically describe staff expectations, individual accountability, and disciplinary processes, they must be reviewed and often revised to ensure alignment with the tenets of a Just Culture. Otherwise, the journey will be long and unsuccessful if the policies are in conflict with a Just Culture.

In a Just Culture, HR-related policies and procedures regarding safety should hold all individuals equally accountable for the quality of their behavioral choices and should not focus on errors (which are not a behavioral choice), except for the expectation to report them. Policies and procedures should reflect a tone that is proactive toward risk identification, rather than reactive to errors and adverse outcomes. They should define human error as inadvertent, with a response of consoling individuals and conducting an investigation to determine how to redesign systems to prevent errors or detect them before reaching the patient. Policies and procedures should describe how to investigate a procedural violation to determine its causes and scope, and how to coach staff who have engaged in at-risk behaviors under the mistaken, but good faith, belief that the risks were insignificant or justified. For outcome-based duties related to a business code of conduct, such as arriving to work on time and wearing identification badges, policies should be clear about expectations and the actions that will be taken when they are not met. When describing reckless behavior (actions involving a conscious disregard of what an individual knows is a substantial and unjustifiable risk), remove any reference to "negligent" or "criminal" conduct as the basis for disciplinary action. Regrettably, mere human error can result in legal action (criminal negligence), but human error is never reckless behavior. Also ensure that event reporting and investigation policies and procedures support the tenets of a Just Culture.

While HR-related policies and procedures cannot guarantee that the desired actions will be realized in practice, they are a critical step for building an organizational foundation for success. Old punitive policies risk slipping back into an unjust culture. As organizations align actual practice with a Just Culture, they also need to align supporting policies and procedures.

AMA Task Force to Reduce Opioid Abuse Promotes Safe Storage, Disposal of Opioids

The American Medical Association (AMA) Task Force to Reduce Opioid Abuse released a resource document that urges physicians and other health care providers to promote safe storage and disposal of opioids and all medications. The AMA document indicates physicians and other providers need to:

- educate patients about safe use of prescription opioids;
- remind patients to store medications out of children's reach in a safe place; and
- talk to patients about the most appropriate way to dispose of expired, unwanted, and unused medications.

The AMA resource document and additional information can be found at *www.ama-assn.org/opioids-disposal.* Options for disposing of medications safely are available in the Initiatives section of the NABP website at *www.nabp.pharmacy* under AWAR$_X$E®.

CDC Guide Shows Importance of Physicians, Pharmacists Working Together

Collaborative care by at least two practitioners working together with the patient to accomplish shared goals has been shown to improve hypertension control and cholesterol management, especially when the team involves a physician or nurse and a pharmacist, notes a new guide developed by the Centers for Disease Control and Prevention (CDC) Division for Heart Disease and Stroke Prevention, in collaboration with the American Pharmacists Association and AMA. The guide,

Creating Community-Clinical Linkages Between Community Pharmacists and Physicians, discusses the importance of community-clinical linkages specific to community pharmacists and physicians and provides a framework for how community pharmacists and physicians might approach the development of a link to help patients. In addition, the guide provides examples of existing community-clinical linkages between community pharmacists and physicians and discusses common barriers to and potential solutions for creating community-clinical linkages. The guide is available at *www.cdc.gov/dhdsp/pubs/docs/ccl-pharmacy-guide.pdf.*

FIP Report Shows Value of Pharmacists' Role in Consumers' Self-Care

Support from pharmacists will assist consumers in better health maintenance and greater health system efficiency, indicates a recently released report from the International Pharmaceutical Federation (FIP). The report, *Pharmacy as a gateway to care: Helping people towards better health,* discusses the various factors involved in individual self-care and the evidence that pharmacists can increase value for those individuals through many opportunities because informed, engaged, and educated consumers will play a greater and critical role in caring for themselves. The definition of self-care this report adopts is that of the World Health Organization: "the ability of individuals, families and communities to promote health, prevent disease, and maintain health, and to cope with illness and disability with or without the support of a health care provider."

The report is available at *www.fip.org/files/fip/publications/2017-04-Pharmacy-Gateway-Care.pdf.*

FDA Restricts Use of Codeine and Tramadol Medicines in Children; Recommends Against Use in Breastfeeding Women

As of April 2017, Food and Drug Administration (FDA) is restricting the use of codeine and tramadol medicines in children. FDA is also recommending against the use of these medicines in breastfeeding mothers due to possible harm to their infants. Codeine and tramadol medicines carry serious risks, including slowed or difficult breathing and death, which appear to be a greater risk in children younger than 12 years, and should not be used in this age group. These medicines should also be limited in some older children. Single-ingredient codeine and all tramadol-containing products are FDA-approved only for use in adults.

As indicated in the FDA Drug Safety Communication available at *www.fda.gov/Drugs/DrugSafety/ucm549679.htm,* FDA is requiring several changes to the labels of all prescription medicines containing these drugs. These new actions further limit the use of these medicines beyond their 2013 restriction of codeine use in children younger than 18 years to treat pain after surgery from removal of tonsils and/or adenoids. FDA is now adding:

- A *Contraindication* to the drug labels of codeine and tramadol, alerting that codeine should not be used to treat pain or cough and tramadol should not be used to treat pain in children younger than 12 years.
- A new *Contraindication* to the tramadol label, warning against its use in children younger than 18 years to treat pain after surgery from removal of tonsils and/or adenoids.
- A new *Warning* to the drug labels of codeine and tramadol to recommend against their use in adolescents between 12 and 18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems.
- A strengthened *Warning* to mothers that breastfeeding is not recommended when taking codeine or tramadol medicines due to the risk of serious adverse reactions in breastfed infants.

FDA urges health care providers to report side effects involving codeine- and tramadol-containing medicines to the FDA MedWatch program at *www.fda.gov/safety/medwatch.*

AVMA Warns Pharmacists and Pet Owners About Xylitol Pharmaceutical Products

Pharmaceutical products containing xylitol may be dangerous and fatal to dogs, warns the American Veterinary Medical Association (AVMA). Xylitol stimulates an insulin release that can result in severe hypoglycemia and fatal liver damage. Pharmacists and pet owners need to be aware of and protect against xylitol toxicoses, indicates AVMA. FDA-approved gabapentin capsules and tablets do not contain xylitol, but the liquid form does. In addition, xylitol-containing media might be used in compounding products if the pharmacist is uninformed about not using it.

AVMA urges pharmacists to not use xylitol-containing products when compounding for canine patients and to contact the veterinarian if a prescribed product contains xylitol. The veterinarian may be unaware that this sweetener is in the product. AVMA also encourages pet owners and caretakers to verify with the pharmacist when picking up their dog's medication at a human pharmacy that the medication does not contain xylitol. Xylitol-containing peanut butter should not be used to help a dog take its medication.

For more information, visit *atwork.avma.org/2017/05/30/eliminate-xylitol-from-canine-prescriptions.*

CDC Publishes Guide to Help Pharmacists Initiate CPAs With Prescribers

CDC published a guide that provides pharmacists with information and resources to empower them to initiate collaborative practice agreements (CPAs) with collaborating prescribers. The guide, *Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team,* contains a sample CPA and sample language that can be customized by pharmacists and prescribers using their specific state laws to create a CPA. The guide includes an overview of state laws, including which states currently allow CPAs. The guide is available at *www.cdc.gov/dhdsp/pubs/docs/CPA-Team-Based-Care.pdf.*

DEA Releases New Edition of Drugs of Abuse Resource Guide

Drug Enforcement Administration (DEA) released the 2017 edition of *Drugs of Abuse, A DEA Resource Guide,* which serves as a resource on the most commonly abused and misused drugs in the US. The latest edition, which is an update to the 2015 publication, describes the consequences of drug use, a drug's effects on the body and mind, overdose potential, origin, legal status, and other key facts. It also includes the most current information on new and emerging trends in drug misuse and abuse, including fentanyl, other opioids, and synthetic drugs. The 2017 edition can be found at *www.dea.gov/pr/multimedia-library/publications/drug_of_abuse.pdf.*

continued from page 1

- CSOS orders must be closed in the CSOS system, not just the pharmacy system. Printing the sheet and signing and dating is recommended, but this does not close the order in CSOS.
- Each order not closed with the date of receipt in CSOS is considered a separate violation.
- Separate powers of attorney are required for use of CSOS and for hard copy DEA 222 forms.
- The right side of DEA 222 forms must be filled out completely.
- Inventory transfers of Schedule III-V CS medications must be recorded by invoice immediately.
- Schedule II medication transfers must be performed with the use of a DEA 222 form. No borrowing or loaning is permitted.
- CS invoices are to be signed and dated. Violations are frequently found, and each invoice lacking the required information is considered a separate violation.
- Registrants should become familiar with record-keeping requirements and verify compliance.
- Biennial inventories are required, and frequent inventory audits are encouraged. Specific wording is required for an inventory to be considered acceptable. Actual counts are required for Schedule IIs.
- Biennial inventory counts to the unit of Schedules III-V are suggested, but estimates are allowed if stock bottles do not contain more than 1,000 tablets, capsules, or pills.

Board Takes Action and Gives Recommendations During Complaint Summary

During the Board's September 12-13, 2017 meeting, Board members requested that the following information be shared with registrants:

- The Board warned pharmacies for failure to immediately notify the Board of a PIC absence or change and levied civil penalties.
- Board members voiced concern for patient safety during a complaint discussion regarding the heavy workload placed on a pharmacist, witnessed by two Board investigators. It was indicated that patient files had been purchased from another pharmacy and that there was not enough staff to fill prescriptions, perform counseling, and immunize in a timely manner. The Board instructed the Board executive director to meet with pharmacy district management to discuss staffing issues and obtain a corrective plan of action.
- The Board recommended that a root cause analysis be performed in misfill cases to determine how to fix processes to minimize or eliminate errors.
- Regarding pharmacy technician diversion complaints, the Board directed the Tennessee Office of General Counsel attorney to request that the Accreditation Council for Pharmacy Education look into an accreditation process for pharmacy technician schools. The Board voiced concerns regarding the lack of appropriate background checks and drug testing.

TPRN Receives Contract to Continue Peer Assistance Program for the Board and Offers Additional Registrants Services

As of September 15, 2017, the Tennessee Pharmacy Recovery Network (TPRN) program is contracted with the Board to serve as the Board's formalized peer assistance program for prevention, referral, and monitoring services for impaired pharmacy professionals, including pharmacists, pharmacy student interns, and pharmacy technicians. Under the contract, the Board will provide monetary support for program operations, and the Tennessee Pharmacists Association (TPA) will continue to provide additional resources to support the program's success. The TPRN program does not charge client fees for peer assistance and advocacy services. However, participants are responsible for treatment and testing costs.

TPRN was established by the TPA and operates under the TPA's 501(c)(3) subsidiary, the Tennessee Pharmacists Research and Education Foundation (TPREF). For over 30 years, TPRN has provided peer assistance and advocacy services to pharmacy professionals through a noncontractual working relationship with the Board. Under the leadership of its current program director, Dr Baeteena Black, TPRN continues to provide a highly individualized and focused program tailored to meet the specific pharmacy professional's needs. The program's high rate of success is largely attributed to direct involvement of the TPRN Program Advocacy Committee. This group consists of dedicated pharmacy professionals in recovery who develop peer-to-peer relationships and serve as advocates for program participants.

"TPA, through the TPREF, appreciates this opportunity to establish a formalized contractual relationship between TPRN and the Board of Pharmacy," says TPA Executive Director Dr Micah Cost. "This relationship will allow TPRN to continue to provide high-quality peer assistance and advocacy which will ensure that our pharmacy professionals in Tennessee have access to resources needed to achieve meaningful recovery from the disease of addiction."

Additional information about the TPRN program is available at *https://www.tnpharm.org/member-center/tprn.* If you need help or know an associate who does, please contact Dr Baeteena Black, 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 on the TPA website.

Governor Appoints Rodgers to the Board

By his letter dated August 22, 2017, Governor Bill Haslam appointed Dr James "Adam" Rodgers to the Board. Dr Rodgers fills the position vacated by former Board member Dr Will Bunch. Dr Rodgers worked as the PIC of Target Pharmacy in Brentwood, TN, before taking his current position as CVS pharmacy supervisor, and he is responsible for 28 Target pharmacies in Tennessee and Alabama.

Dr Rodgers received his American Pharmacists Association immunizer certification and also his immunizer certification trainer status. He received his pharmacy doctorate from the

continued on page 5

continued from page 4

University of Tennessee College of Pharmacy in 2002 and is a current member of TPA. The Board welcomes Dr Rodgers and looks forward to his retail pharmacy experience from a pharmacist's and district manager's perspective.

Tennessee DEA Office Gives Guidance for Reporting Theft or Loss

Per Title 21, Code of Federal Regulations, Section 1301.76(b), registrants must notify their local 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,** available 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.

Board Meeting Schedule

The Board 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 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 **2018** meeting schedule is listed as follows:

- January 30-31
- March 13-14
- May 1-2
- July 17-18
- September 11-12
- November 27-28

Tennessee Board of Pharmacy Members

Dr Kevin Eidson – President
Dr Mike Dickenson – Vice President
Dr Debra Wilson – Board Member
Dr Rissa Pryse – Board Member
Dr Katy Wright – Board Member
Dr James "Adam" Rodgers – Board Member
Mrs Lisa Tittle – Public Board Member

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