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Tennessee Board of Pharmacy News

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Law Books Available

Copies of *Tennessee Pharmacy Laws* (the most current edition, 2015) are still available. To order, click here and then navigate to the second bullet point, which reads "2015 Law Books (limited supply)."

Tennessee Pharmacists Are Permitted to Provide Hormonal Contraceptive Therapies

Effective April 27, 2016, pharmacists may provide hormonal contraceptive therapies through collaborative pharmacy practice agreements. Requirements include completing a training program approved by the Tennessee Department of Health (to be developed as a collaboration between the Tennessee Board of Pharmacy, Tennessee Board of Medical Examiners, and Tennessee Board of Osteopathic Examination); providing the patient with a self-screening risk assessment tool developed or approved by the Department of Health; providing the patient with documentation about the provided hormonal contraceptive and referring the patient to a primary care physician or women's health care practitioner; providing the patient with a fact sheet containing indications, contraindications, drug method of use, importance of medical follow-up, and other appropriate information; and providing the patient with the contact information of a primary care physician or women's health care practitioner within a reasonable time after the provision of the hormonal contraceptive.

After determining if a patient should receive a contraceptive, the health care practitioner will dispense or refer the patient to a pharmacy that may dispense the contraceptive.

Eligible patients are 18 years of age or older or, if under 18 years of age, are in the category of an emancipated minor as defined in Tennessee statute 39-11-106. Click here to view the entire Public Chapter (PC) 942.

Board Clarifies When a Pharmacy Technician Is Eligible for Probationary Period If Registration Expires

At the July 27, 2016 meeting, the Board clarified Rule 1140-02-.02(2)(a) regarding the probationary period for pharmacy technicians. If a pharmacy technician allows the registration to expire and does not renew for six months, then he or she must reapply for a new registration before working as such. Furthermore, after the six-month period, a pharmacy technician becomes eligible to perform technician duties for 90 days before registration is again required.

Background Checks Required to Provide Patient Care

As directed to report by way of newsletter annually per statute, the Board reminds all registrants of regulation requiring registry checks before the hiring of employees as directed in former PC 1084, which is now incorporated into statute 63-1-149(3)(f), which states in part that "each applicable licensing board shall notify all of its licensees at least annually through board newsletters of their obligations under this statute." Before any person who will be providing direct patient care is hired, health care facilities, emergency medical services, and individual health professionals are required by law to conduct background checks using the **Tennessee sex offender registry, the Tennessee abuse registry, and the abuse registries for any state in which the prospective employee has lived in the previous seven years.** Please visit the Department of Health background checks resource page for additional information about Public Chapter 1084, the Tennessee Sex Offender Registry, National Sex Offender Registry, Tennessee Abuse Registry, and Other Abuse Registries.

Clarification of PC 1002 – Pharmacists Are Now Required to Check the CSMD

Pharmacists are now **required** to check the Controlled Substance Monitoring Database (CSMD) (exemptions found in subsection 6 in PC text below). **For this part of the statute, pharmacists are defined as "healthcare practitioners."** Per Tennessee Code Annotated (TCA) 53-10-302(9), **"healthcare practitioner"** means:

> (A) A person licensed, registered, or otherwise permitted to prescribe, distribute, or dispense a controlled substance in the course of professional practice; [or]

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FDA Calls for Review of Opioids Policy, Announces Action Plan

As part of a broad national campaign to address opioid abuse, dependence, and overdose, Food and Drug Administration (FDA) Deputy Commissioner for Medical Products and Tobacco, Dr Robert Califf, along with other FDA leaders, developed a comprehensive action plan to reassess the agency's approach to opioid medications. The objective of the plan is to "focus on policies aimed at reversing the epidemic, while providing patients in pain access to effective relief," indicates the FDA news release. FDA's plan is to:

- Re-examine the risk-benefit paradigm for opioids and ensure that the agency considers their wider public health effects;
- Convene an expert advisory committee before approving any new drug application for an opioid that does not have abuse-deterrent properties;
- Assemble and consult with the Pediatric Advisory Committee regarding a framework for pediatric opioid labeling before any new labeling is approved;
- Develop changes to immediate-release (IR) opioid labeling, including additional warnings and safety information that incorporate elements similar to the extended-release/long-acting (ER/LA) opioid analgesics labeling that is currently required;
- Update Risk Evaluation and Mitigation Strategy requirements for opioids after considering advisory committee recommendations and review of existing requirements;
- Expand access to, and encourage the development of, abuse-deterrent formulations of opioid products;
- Improve access to naloxone and medication-assisted treatment options for patients with opioid use disorders; and
- Support better pain management options, including alternative treatments.

FDA will also seek guidance from outside experts in the fields of pain management and drug abuse. The National Academies of Sciences, Engineering, and Medicine has been asked by FDA to help develop a framework for opioid review, approval, and monitoring that balances individual need for pain control with considerations of the broader public health consequences of opioid misuse and abuse. The news release is available on FDA's website at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm.*

More Selected Medication Safety Risks to Manage in 2016

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.*

Manufacturer Drug Labeling, Packaging, Nomenclature – Per Liter Electrolyte Content on Various Sizes of Manufacturers' IV Bags

The way electrolyte concentrations are expressed on intravenous (IV) bags in volumes less than or greater than one liter has tripped up many practitioners over the years. Concentrations are listed per liter, not per container volume. For example, a 250 mL 0.9% sodium chloride injection container label lists the sodium chloride content as 154 mEq/1,000 mL, rather than 38.5 mEq/250 mL. Commercially available parenteral nutrition products available in containers greater than one liter also express the electrolyte ingredients "per liter."

An error occurred while a pharmacist was preparing a bag of 3% sodium chloride after the pharmacy unexpectedly ran out of the commercially available bags. The pharmacist mistakenly set the proportion up as 154 mEq/0.9% = x/3% and calculated that he needed 513 mEq of sodium chloride, when he actually only needed 256-257 mEq of sodium chloride for a 500 mL bag (77 mEq/0.9% = x/3%).

For single- and multiple-dose injectables, the United States Pharmacopeial Convention (USP) requires the strength per total volume as the primary, prominent display on the label, followed in close proximity by the strength per mL enclosed in parentheses. This should apply to large volume parenterals as well. Until it does, pharmacists who calculate electrolyte quantities should seek out an independent double check. Sufficient quantities of commercially available products should be used whenever possible. For products that routinely require admixture, an instruction sheet should be available to guide the process.

Patient Education – Discharging Patients Who Do Not Understand Their Discharge Medications

Despite the importance of teaching patients about the medications to take after discharge, studies suggest health care providers are not successfully preparing patients for the transition home. Between 30% and 70% of patients make a medication error in the immediate weeks following hospitalization,[1-5] and the Centers for Medicare & Medicaid Services reports an average national hospital readmission rate of 17.5% to 19.5%.[6] The discharge process is often rushed and interrupted, making it difficult to ensure patients know what medications to take, the correct doses, and how to take them after discharge. Immediately prior to discharge is not an ideal time for education either, as patients may be overwhelmed with the amount of information being provided at once.

Medication errors that occur during the first few weeks after discharge from the hospital can cause significant harm. In fact, one study showed that almost a quarter of all post-discharge errors were considered serious or life-threatening, and that

most of these errors happened within the first 14 days after discharge.[5] The highest predictors of post-discharge errors included low health literacy and low subjective numeracy (self-reported measure of the ability to perform mathematical tasks and the preference for numerical versus prose information (ie, ordinary words)).[4]

Perhaps this risk is best addressed with a redesigned discharge process that facilitates the most effective means of teaching patients about their medications, initiating education earlier in the hospital stay, and providing post-discharge support.

References

1. Coleman EA, Smith JD, Raha D, Min SJ. Posthospital medication discrepancies: prevalence and contributing factors. *Arch Intern Med.* 2005;165(16):1842-1847.
2. Mesteig M, Helbostad JL, Sletvold O, Røsstad T, Saltvedt I. Unwanted incidents during transition of geriatric patients from hospital to home: a prospective observational study. *BMC Health Serv Res.* 2010;10:1.
3. Lalonde L, Lampron AM, Vanier MC, Levasseur P, Khaddag R, Chaar N. Effectiveness of a medication discharge plan for transitions of care from hospital to outpatient settings. *Am J Health Syst Pharm.* 2008;65(15):1451-1457.
4. Mixon AS, Myers AP, Leak CL, et al. Characteristics associated with postdischarge medication errors. *Mayo Clin Proc.* 2014;89(8):1042-1051.
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6. American Hospital Association. Rethinking the hospital readmissions reduction program. *TrendWatch.* March 2015.

USP Publishes Chapter on Handling Hazardous Drugs in Health Care Settings

A new general chapter, <800> *Hazardous Drugs—Handling in Healthcare Settings,* has been published as part of a suite of health care quality standards included in the *United States Pharmacopeia – National Formulary (USP–NF)* by USP to help prevent and/or limit hazardous drug exposures in health care. The standard applies to all health care personnel, such as physicians, nurses, veterinarians, pharmacists, and technicians, and all health care facilities where hazardous drugs are handled or manipulated, including their storage and distribution. Health care facilities have more than two years to conform to the new requirements and have until July 1, 2018, to implement the new standard, indicates a USP press release, which is available at *www.usp.org* in the News section. General Chapter <800> is available in both the First Supplement to *USP 39–NF 34* and the *USP Compounding Compendium.*

FDA Provides Training Video on Keeping Medications Safe in Emergency Situations

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the February 2016 Drug Info Rounds video, "Emergency Preparedness – Keeping Medications Safe," pharmacists discuss educating patients about having a plan in place for emergency medication and medical supplies and the resources available for pharmacists to use when advising their patients. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

FDA Requires Class-Wide Labeling Changes for IR Opioid Analgesics

FDA is requiring class-wide safety labeling changes for IR opioid pain medications, which will include a new boxed warning about the serious risks of misuse, abuse, addiction, overdose, and death. The announcement is part of the agency's effort to educate prescribers and patients about the potential risks related to opioid use. FDA is also requiring several safety labeling changes across all prescription opioid products to include additional information on the risk of these medications. The new requirements are part of a plan to reassess the agency's approach to opioid medications. The plan is focused on reversing the epidemic of abuse and overdose while still providing patients in pain access to effective relief, indicates the FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery.*

Further, FDA is requiring updated labeling for all opioids (both IR and ER/LA products) to include safety information about potentially harmful drug interactions with other medicines that can result in a serious central nervous system condition called serotonin syndrome. In addition, updated labeling will include information about opioid effects on the endocrine system, including a rare but serious disorder of the adrenal glands (adrenal insufficiency) and decreased sex hormone levels (androgen deficiency). More information about these risks is available in FDA's Drug Safety Communication announcement, available at *www.fda.gov/Drugs/DrugSafety/ucm489676.htm.*

FDA Issues Alert Regarding All Unexpired Sterile Drug Products Produced by Medaus Pharmacy

On April 1, 2016, FDA alerted health care providers and patients not to use products marketed as sterile from Medaus Pharmacy in Birmingham, AL. Insanitary conditions, including poor sterile production practices, were identified by FDA investigators during a recent inspection at Medaus' facility. The affected products were distributed nationwide and internationally. The alert applies to all unexpired drug products that are intended to be sterile. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from Medaus, and not administer them, indicates the FDA Safety Alert, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsForHumanMedicalProducts/ucm493871.htm.*

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(B) A pharmacy, hospital, or other institution licensed, registered, or otherwise permitted to distribute, or dispense, or administer a controlled substance in the course of professional practice . . .

As noted in sections (e), (f), and (g) of TCA 53-10-310 in part (emphasis added):

(e)(1) When prescribing a controlled substance, all healthcare practitioners, unless otherwise exempted under this part, shall check the controlled substance database **prior to prescribing one (1) of the controlled substances identified in subdivision (e)(4) to a human patient at the beginning of a new episode of treatment and shall check the controlled substance database for that human patient at least annually when that prescribed controlled substance remains part of the treatment.** An authorized healthcare practitioner's delegate may check the controlled substance database on behalf of the healthcare practitioner. **A new episode of treatment means a prescription for a controlled substance that has not been prescribed by that healthcare practitioner within the previous twelve (12) months.**

(2) When dispensing a controlled substance, all healthcare practitioners, unless otherwise exempted under this part, **shall check the controlled substance database prior to dispensing one (1) of the controlled substances identified in subdivision (e)(4) to a human patient the first time that patient is dispensed a controlled substance at that practice site. The dispenser shall check the controlled substance database again at least once every twelve (12) months for that human patient after the initial dispensing. The initial dispensing check fulfills the first annual check.** An authorized healthcare practitioner's delegate may check the controlled substance database on behalf of the healthcare practitioner.

(3) Before prescribing or dispensing, a healthcare practitioner shall have the professional responsibility to check the database or have a healthcare practitioner delegate check the database if the healthcare practitioner is aware or reasonably certain that a person is attempting to obtain a Schedule II-V controlled substance, identified by the committee or commissioner as demonstrating a potential for abuse for fraudulent, illegal, or medically inappropriate purposes, in violation of § 53-11-402.

(4) The controlled substances that trigger a check of the controlled substance database pursuant to subdivisions (e)(1) and (2) include, but are not limited to, all opioids and benzodiazepines. By rule, the commissioner, pursuant to § 53-10-311, may require a check of the database for additional Schedule II-V controlled substances that are identified by the committee or commissioner as demonstrating a potential for abuse.

(5) The commissioner, pursuant to § 53-10-311, shall adopt rules in accordance with the Uniform Administrative Procedures Act, compiled in title 4, chapter 5, that establish standards and procedures to be followed by a healthcare practitioner regarding the review of patient information available through the database.

(6) Healthcare practitioners are not required to check the controlled substance database before prescribing or dispensing one (1) of the controlled substances identified in subdivision (e)(4) or added to that list by the committee or commissioner **if** one (1) or more of the following conditions are met:

(A) The controlled substance is prescribed or dispensed for a patient who is currently receiving hospice care;

(B) The committee has determined that healthcare practitioners in a particular medical specialty shall not be required to check the database as a result of the low potential for abuse by patients receiving treatment in that medical specialty;

(C) The quantity of the controlled substance which is prescribed or dispensed does not exceed an amount which is adequate for a single, seven-day treatment period and does not allow a refill; or

(D) The controlled substance is prescribed for administration directly to a patient during the course of inpatient or residential treatment in a hospital or nursing home licensed under title 68.

To review the document in its entirety, view PC 1002.

Board Office Reminds Pharmacists to Check Expirations/Reviews for Standing Orders and Collaborative Care Agreements

It has come to the attention of the Board office that pharmacists are not checking standing orders for expiration dates. As collaborative care agreements become the standard for patient care, the wording is extremely important and should be followed, or violations may be cause for discipline. It is strongly advised to update any existing standing order,

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including vaccines, or any other such order that either expires or has a clause for review by the prescribing practitioner. Keep that verification documentation (signature, etc) for the length of the order, agreement, or other medical documentation. Board investigators may request this information for review as collaborative care agreements increase.

Tennessee DEA Office Gives Guidance for Reporting Theft or Loss

Per Title 21 of the Code of Federal Regulations, Section 1301.76(b), registrants must notify their local Drug Enforcement Administration (DEA) office in writing of the theft or significant loss of controlled substances **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. Furthermore, registrants shall notify the Board and may send the detailed report with a copy of the DEA Form 106 via email to Dr Terry Grinder at terry.grinder@tn.gov or via fax to the Board office at 615/741-2722.

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 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.

Currently, the **2016** meeting schedule is listed as follows:

- September 20-21
- November 8-9

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

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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