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Tennessee Board of Pharmacy News

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New Officers Elected, Dr Hill's Board Term Set to Expire

As a six-year term winds down for Tennessee Board of Pharmacy member Larry Hill, DPh, the Board has elected Brenda Warren, DPh, as president, and Charles "Buddy" Stephens, DPh, as vice president. The Board unanimously approved both nominations.

Dr Hill was appointed to the Board in 2006. When elected president in 2011, he steered the Board through numerous challenges. His objectivity and focus on the tasks presented before him helped the Board and staff to remain positive through several changes in administration including the commissioner's office, legal staff, Board staff, and several legislative issues. His community pharmacy expertise, strong ethics, and dedication to the practice of pharmacy will be missed.

Per TCA 63-10-302,

> . . . (e). The Tennessee Pharmacists Association shall annually recommend five (5) duly qualified persons for each vacancy from whom the governor shall be requested to make appointments. Appointees shall, within ten (10) days after appointment, make oath or affirmation to be filed with the secretary of state that they will faithfully and impartially perform their duties . . .

Dr Hill's term will end when the governor names the new appointee.

Temporary Absence of a Pharmacist

In regard to a pharmacist needing to leave temporarily from the pharmacy during the open hours of operation, the Board recommends that all registrants revisit Tennessee Board of Pharmacy Rule 1140-03-.07.

> . . . A pharmacist is permitted one (1) temporary absence for a period not exceeding one (1) hour per day. During the absence of a pharmacist from the pharmacy practice site, a sign containing the words **"pharmacist not on duty"** must be conspicuously displayed in the pharmacy practice site. It shall be unlawful to fail or refuse to display the required sign in a conspicuous place when a pharmacist is absent. **No medical or prescription order may be compounded or dispensed during the absence of a pharmacist. Additionally, during the absence of the pharmacist the prescription department shall be closed off by physical barrier from floor to ceiling . . .**

Also, refer to Tennessee Board of Pharmacy Rule 1140-02-.02:

> **. . . (4)** A registered pharmacy technician may, **in the presence of and under the supervision of a pharmacist,** perform those tasks associated with the preparation and dispensing process except those tasks identified in Rule 1140-02-.01(13) that must be personally performed by a pharmacist or pharmacy intern **under the personal supervision and in the presence of a pharmacist . . .**

Therefore, be advised that personal issues, as well as other issues that cause the pharmacist to be absent from the pharmacy practice site, do not exempt the pharmacist or pharmacy technician from these rules. Other arrangements should be made or the pharmacy should be closed from "floor to ceiling" and a "pharmacist not on duty" sign should be posted until the pharmacist returns to practice. Furthermore, no other employee should be located in the pharmacy. Also be advised that prescriptions already filled and awaiting "pick up" are not allowed to be released in the absence of the pharmacist.

Criminal Background Check and Instructions for Health Related Boards Applicants

Every year via this *Newsletter,* registrants are notified of the informal background check to be followed per Public Chapter 1084, which may be found at the Web link *http://state.tn.us/sos/acts/106/pub/pc1084.pdf*. Note that **the employer** may perform this basic procedure by simply checking the registries listed. This public chapter is summarized as follows: 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 state sex offenders registry, the state abuse registry, and the abuse registries for states in which the prospective employee has lived in the previous seven years, according to Public Chapter 1084. Be advised that this background check is required for **employment** and has to be completed on everyone involved in direct patient care. Also note that the check may have to be repeated every time an employer changes.

Read Public Chapter 1084; Tennessee Sex Offender Registry; National Sex Offender Registry; Tennessee Abuse Registry; and Other Abuse Registries.

Formal Background Check Rules in Effect for Pharmacists and Technicians

Not to be confused with the health related Board criminal background check previously mentioned for employment, as of April 3, 2012, the Tennessee Board of Pharmacy has passed rules specifically requiring criminal background checks for **pharmacists before approving licensure and pharmacy technicians before approving registration.** All applicants applying for **initial licensure** in Ten-

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DEA Provides Information Regarding Carisoprodol Prescriptions

A Drug Enforcement Administration (DEA) announcement provides information regarding the scheduling of carisoprodol, effective as of January 11, 2012. The DEA Final Rule making the drug a Schedule IV controlled substance was published December 12, 2011, and states that effective January 11, 2012, all prescriptions for drugs containing carisoprodol shall comply with DEA regulations. Specifically, a pharmacy may only fill or refill a prescription for a drug containing carisoprodol if all of the following requirements are met:

- the prescription was issued for a legitimate medical purpose by a DEA-registered practitioner acting in the usual course of professional practice (21 CFR §1306.04);
- the prescription contains all the information required by 21 CFR §1306.05; and
- the number of refills authorized by the prescribing practitioner is five or less (21 USC §829(b)).

The full text of the notice is available on the DEA Web site at *www.deadiversion.usdoj.gov/drugs_concern/carisoprodol/index.html.*

Pfizer Recalls Several Lots of Two Oral Contraceptive Products

Pfizer Inc recalled 14 lots of Lo/Ovral®-28 (norgestrel and ethinyl estradiol) tablets and 14 lots of norgestrel and ethinyl estradiol tablets (generic) due to potential for inexact count and out-of-sequence tablets. A Pfizer investigation found that some blister packs of the affected products may contain an inexact count of inert or active ingredient tablets and that the tablets may be out of sequence. As a result of this packaging error, the daily regimen for these oral contraceptives may be incorrect and could leave women without adequate contraception, and at risk for unintended pregnancy. Food and Drug Administration (FDA) advises that patients who have the affected product should notify their physician and return the product to the pharmacy. A Pfizer press release includes a list of the affected products with the National Drug Code (NDC) number, lot number, and expiration date for each, and is available at *www.fda.gov/Safety/Recalls/ucm289770.htm.*

Changes in Medication Appearance Should Prompt Investigation by Pharmacists and Patients

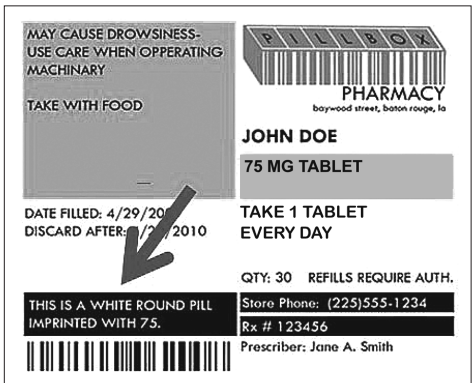
This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

As the numbers of generic products continue to increase, it seems that both patients and practitioners have become desensitized to changes in medication appearance. So much so that patients may not question a change or, when they do, practitioners may simply reassure them that it was due to a change in manufacturer without actively investigating the reason. It is not uncommon for ISMP to receive reports from both practitioners and consumers where a change in medication appearance was not fully investigated and subsequently contributed to an error.

In one case, a man shared an account of what his 86-year-old father experienced over the course of nine days after his prescription for minoxidil was mistakenly refilled with another medication. He had been taking minoxidil 2.5 mg for years at a dose of 5 mg (2 tablets) twice daily. Due to failing vision, he did not realize that his minoxidil tablets looked different. His daughter noticed the change, but was unconcerned since the tablets had previously changed appearance. The pharmacy was contacted about the change and a staff member explained that it was a different generic for minoxidil, and that the pills could be exchanged for those that he usually received. There was no mention of a mistake being made when the medication was exchanged. He was taken to the hospital the following day, when he could barely walk.

After this incident was explained to hospital staff, they contacted the pharmacy. It was then revealed that he was given methotrexate by mistake because the bottles were stored next to each other. By this time, the man had taken 36 methotrexate 2.5 mg tablets, his white blood cell and platelet counts were extremely low, and he was in critical condition. We later learned that he passed away during that hospital visit.

Your pharmacy may be providing an important patient safety tool on the prescription label that may be overlooked by patients and their caregivers: a description of the shape, color, and imprint code of the medication that should be inside. This information can help ensure accuracy since it's based on the NDC number. Teach patients to look for this description and question any differences. In addition, the patient needs to know if the medication name on the pharmacy generated label is the medication he or she was expecting to receive. Even if the generic manufacturer is different each time the prescription is renewed, the description on the label should match the NDC number and thus the product inside.



With so much information on prescription labels such as patient and doctor name, drug name, instructions, and warnings – this added information can easily be missed. But it's important, so look for it and put it to use!

FDA Reminder: Purchasing Unapproved Injectable Cancer Medications Threatens Patient Safety

FDA is reminding health care providers to obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the United States. FDA explains that "current shortages of injectable cancer medications may present an opportunity for unscrupulous individuals to introduce non-FDA approved products into the drug supply, which could result in

serious harm to patients." FDA reports that the agency is aware of promotions and sales of unapproved injectable cancer medications directly to clinics in the US and that the medications were likely administered to patients. Examples of products include unapproved versions of FDA-approved medications such as Faslodex® (fulvestrant), Neupogen® (filgrastim), Rituxan® (rituximab), and Herceptin® (trastuzumab). FDA stresses the risks to patients when such unapproved medications are used. The agency outlines several steps health care providers should take to ensure patient safety:

1. Obtain and use only FDA-approved injectable cancer medications purchased directly from the manufacturer or from wholesale distributors licensed in the US. An FDA Web page, *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm,* provides the online resource for each state for verifying that a wholesale distributor is appropriately licensed.
2. Determine if the medication you have received is FDA-approved by checking the Orange Book or searching the Drugs@FDA database.
3. Question whether a price sounds too good to be true. Deep discounts may be offered because the product is stolen, counterfeit, or unapproved.
4. Carefully inspect the product and packaging and be alert for signs that the product is not FDA approved, such as if the packaging looks different or the dosing recommendations are unfamiliar.

FDA also notes that if a health care provider receives multiple complaints about the same product, such as a new side effect or lack of therapeutic effect, these may signal a product quality issue.

FDA reminds health care providers that in certain circumstances the agency may authorize limited importation of medications that are in short supply. Such medications are imported from approved international sources and distributed in the US through a controlled network, and would not be sold in direct-to-clinic solicitations. If FDA has arranged for limited importation of the foreign version of a medication, information on obtaining that medication will be available in the Drug Shortages section of the FDA Web site, *www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050792.htm.*

Additional details are provided in an FDA Drug Safety Communication, available at *www.fda.gov/downloads/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/UCM287717.pdf.*

Insulin Pens Should Not Be Used for Multiple Patients, Stresses CDC

Centers for Disease Control and Prevention (CDC) issued a notice, reminding health care providers that insulin pens are intended for use by a single patient, and should never be used on more than one patient. CDC indicates that the agency has become "increasingly aware of reports of improper use of insulin pens, which places individuals at risk of infection with pathogens including hepatitis viruses and human immunodeficiency virus (HIV)." The notice explains that regurgitation of blood into the insulin cartridge can occur after injection, creating a risk of bloodborne pathogen transmission if the pen is used for more than one person, even when the needle is changed. CDC provides the following recommendations to help protect patient safety:

- Insulin pens containing multiple doses of insulin are meant for use on a single person only, and should never be used for more than one person, even when the needle is changed.
- Insulin pens should be clearly labeled with the person's name or other identifying information to ensure that the correct pen is used only on the correct individual.
- Hospitals and other facilities should review their policies and educate their staff regarding safe use of insulin pens and similar devices.
- If reuse is identified, exposed persons should be promptly notified and offered appropriate follow-up including bloodborne pathogen testing.

The notice may be downloaded from the CDC Web site at *www.cdc.gov/injectionsafety/PDF/Clinical-Reminder-insulin-pen.pdf.*

US Public Health Service Report Supports Maximizing the Scope of the Pharmacist as Part of Health Care Team

Presenting an evidence-based discussion of the comprehensive patient care services that pharmacists currently provide, a new government report calls for expanded support for such pharmacist-delivered patient care models. The report, *Improving Patient and Health System Outcomes through Advanced Pharmacy Practice,* prepared by the Office of the Chief Pharmacist, US Public Health Service (PHS), is organized into four focus points as follows:

- Focus point 1 discusses how pharmacists are integrated in many practice settings as health care providers, such as through collaborative practice agreements, and provides data showing interprofessional support for such models.
- Focus points 2 and 3 support recognition of pharmacists as health care providers and compensation models that will allow pharmacists to continue to improve patient and health care system outcomes.
- Focus point 4 presents a review of numerous peer-reviewed studies that demonstrate favorable outcomes from pharmacist-delivered care.

RADM Scott Giberson, chief professional officer, PHS Pharmacists, and the primary author of the report, stated that "one of the most evidence-based and cost-effective decisions we can make as a nation is to maximize the expertise and scope of pharmacists, and minimize expansion barriers to successful health care delivery models." The report may be downloaded from the US PHS Web site at *www.usphs.gov/corpslinks/pharmacy/comms/pdf/2011AdvancedPharmacyPracticeReporttotheUSSG.pdf.*

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nessee **(not renewal or reinstatement)** are required to obtain a criminal background check conducted by the Tennessee Bureau of Investigation and the Federal Bureau of Investigation. Please view the following Web link for more information and specific instructions: *http://health.state.tn.us/CBC/index.htm.*

Default of Student Loan or Child Support May Cause Suspension of License or Registration

Pharmacists are advised to check the Web link *https://health.state.tn.us/Boards/Pharmacy/PDFs/Pharm_Non-Compliant_TSAC.pdf*. It is advised to check this site often so as to make certain that no registrant of the Board is working with an invalid/suspended license or registration in accordance with Tenn. Code Ann. §63-1-141.

Also, the link *https://health.state.tn.us/Boards/Pharmacy/PDFs/Pharm_Non-Compliant_DHS.pdf* lists names of registrants that are suspended due to lack of paying child support in accordance with Tenn. Code Ann. §36-5-706. Currently, there is no alert sent to the registrant's employer for either of these violations.

Therefore, it is the **responsibility of the pharmacist-in-charge, pharmacy owner, or pharmacist-on-duty** to check the Web link and remove any licensed pharmacist or registered technician from their respective duties if the registrant's license/registration has been suspended.

The Board Updates Schedule II Prescription Change Information Policy to Include Date

At of the March 2012 meeting, the Board decided to allow for the date on a Schedule II prescription blank to be changed after oral consultation from the prescribing practitioner. This policy statement is valid until the Drug Enforcement Administration final Code of Federal Regulations is approved. Once approved, the more strict regulation will apply. Be advised that the pharmacist must speak directly to the prescribing practitioner to approve the change. Please view the following link for the current policy statement from the Board: *https://health.state.tn.us/Boards/Pharmacy/PDFs/Schedule%20II%20Prescriptions.pdf.*

Expired Medications Continue to Be Found on Pharmacy Shelves

As a reminder to all pharmacy personnel, it is advised to segregate all expired medications from stock, mark for destruction, and immediately destroy or return these items to a reverse distributor for destruction. Also, do not forget to check **compounding medications and ingredients that are past the beyond-use or expiration date.** Refer to Tennessee Board of Pharmacy Rule 1140-03-.11, which states:

> . . . The owner or pharmacist in charge of a pharmacy practice site **shall immediately return or destroy all outdated, defective, or deteriorated prescription drugs and devices and related materials;** except that the destruction of controlled substances listed in any schedule shall be performed by a board approved agent or vendor.

Historically, the Board has approved issuance of a letter of warning and/or civil penalties, depending on the facts associated with the violation.

Contact Information for NPLEx/PSE Reporting is Listed

If your pharmacy sells ephedrine and/or pseudoephedrine (PSE) over-the-counter, you are required to report to the National Precursor Log Exchange (NPLEx). By visiting *www.NPLExSurvey.com* and choosing the state of Tennessee tab, you may complete the survey for an account. Once your account has been verified, you will be contacted by an Appriss representative, (the provider of NPLEx), to inform you of the next steps. Account Manager Krista McCormick has been assigned to the Tennessee NPLEx project. She will assist with any questions or concerns, and may be reached at Appriss, Inc, 10401 Linn Station Rd, Louisville, KY 40223. Office phone: 502/815-5678, cell phone: 502/693-8055, e-mail address: kmccormick@appriss.com.

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 bimonthly meetings in Nashville, TN. The following dates are scheduled for 2012:

- **July 26-27, 2012 Board Meeting:** Iris Room – 227 French Landing
- **September 12-13, 2012 Board Meeting:** Poplar Room – 227 French Landing
- **November 14-15, 2012 Board Meeting:** Iris Room – 227 French Landing

Please check the Board Web site as these dates can be subject to change. Meetings generally begin at 9 AM.

Board of Pharmacy Disciplinary Actions

The health related boards disciplinary report may be found at *http://health.state.tn.us/boards/disciplinary.htm.*

Mandatory Practitioner Profiles

The Board of Pharmacy wants to remind its licensees that the Mandatory Practitioner Profile must be completed and updated as information changes. The Web site to obtain a copy of the Mandatory Practitioner Profile may be found at *http://health.state.tn.us/Downloads/g6019027.pdf.*

Verify the current information on your practitioner profile by accessing the following link: *http://health.state.tn.us/Licensure/index.htm.*

Completed/updated profiles should be submitted by mailing to the Tennessee Department of Health c/o the address provided as part of the questionnaire instructions.

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Dr Charles (Buddy) Stephens – Vice President
Dr William J. Bunch – Board Member
Dr A. Larry Hill – Board Member
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