December 2015

News

Tennessee Board of Pharmacy

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Notice of Rulemaking Hearing Date Set to Discuss Pharmacy, Manufacturer, Wholesaler/Distributor, Outsourcing Facility, and Oxygen Supplier Regulations

On December 18, 2015, the Tennessee Board of Pharmacy will sit for a hearing of several proposed revisions, new amendments, and new sections to Tennessee pharmacy regulations. **Current** Board rules are located in Section 1140, and the proposed rules may be found at *http://share.tn.gov/sos/rules_filings/10-22-15.pdf*. Among others, topics include: collaborative care, long-term care, fees, peer assistance programs, non-allowance of financial incentives (ie, coupons for prescription transfers), drug take-back provisions, pilot program applications, automated dispensing systems, and Controlled Substance Monitoring Database reporting. The meeting is scheduled to begin at 9 AM and is open to the public. It will be held at 665 Mainstream Dr in Nashville, TN. Registrants are encouraged to review and comment at the Board meeting.

Board Disciplinary Action Report

For information on the violation, please visit the disciplinary report website (RT = registered pharmacy technician).

July 2015

Wanda G. Binkley, RT, Nashville – Registration revoked.

Chelsey Boothe, RT, Knoxville, TN – License suspended.

Jason Bowden, RT, Tullahoma, TN – License suspended.

Cristen B. Buchanan, RT, Indian Mound, TN – License revoked.

Christie Nicole Carlill, DPh, Hendersonville, TN – Assessed $1,000 civil penalty; must submit to the Board an acceptable, store-specific, corrective plan of action that addresses the failure to counsel in accordance with Rule 1140-03-.01.

James Edward Casey II, RT, Parsons, TN – Voluntarily surrendered license.

Brian L. Cole, DPh, Smyrna, TN – License revoked.

CVS Pharmacy #7630, Pharmacy, Portland, TN – Assessed $1,000 civil penalty; must submit to the Board an acceptable, store-specific, corrective plan of action that addresses the failure to counsel in accordance with Rule 1140-03-.01.

Del-Mar Medical, Pharmacy, Mt Juliet, TN – Assessed $1,000 civil penalty; plus costs not to exceed $10,000.

Thomashia D. Ford, RT, Memphis, TN – License revoked.

Food City Pharmacy #673, Pharmacy, Knoxville – Assessed $100 civil penalty; must submit to the Board an acceptable, store-specific, corrective plan of action that addresses key storage/access to the pharmacy in accordance with Rule 1140-01-.13.

Terry Lynn Golden, RT, Memphis – Registration revoked; assessed costs not to exceed $10,000.

Neyle Suzanne Gray, RT, Springfield, TN – Registration voluntarily surrendered.

Lee's Total Health at Middle Creek, Pharmacy, Sevierville, TN – License placed on probation for two years with terms; assessed $22,390 civil penalty.

Brittany Jones, RT, Memphis – Registration revoked; assessed cost not to exceed $200.

Antonio Marchetti, DPh, Cottontown, TN – License placed on probation for five years with terms.

Jessica Lyn Millsaps, RT, Madisonville, TN – Registration revoked.

Kevin L. Morrow, RT, Old Hickory, TN – License suspended.

Jennifer Nevils, RT, Murfreesboro, TN – License suspended.

OK Compounding #5259, LLC, Pharmacy, Skiatook, OK – License voluntarily surrendered.

Raquel Oliver, RT, Smyrna – License suspended.

Parsons Pharmacy, Inc, Pharmacy, Lewisburg, TN – Assessed $1,230 civil penalty; plus costs not to exceed $10,000.

Tiffany Fawn Patterson, RT, Cookeville, TN – License revoked.

John Polston, DPh, Tompkinsville, KY – License suspended with terms.

P & S Pharmacy, Inc, Pharmacy, Kingsport, TN – Assessed $1,000 civil penalty; must submit to the Board an acceptable, store-specific, corrective plan of action that addresses the failure to counsel in accordance with Rule 1140-03-.01.

RT Medical, LLC, Manufacturer/Wholesaler/Distributor, Hermitage, TN – Assessed $1,700 civil penalty.

Richard A. Shumaker, DPh, Johnson City, TN – License placed on probation for two years with terms.

Deaun Thornton, RT, Nashville – License suspended.

Matthew James Zeleznak, DPh, Hixson, TN – License voluntarily surrendered.

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FDA Issues Warning About Name Confusion for Brintellix and Brilinta

Due to similar brand names, there have been incidents where the antidepressant Brintellix® (vortioxetine) and the anti-blood clotting medication Brilinta® (ticagrelor) have been confused, resulting in prescribing and dispensing errors, warns Food and Drug Administration (FDA). The agency notes that no reports indicate that a patient has ingested the wrong medication; however, reports of prescribing and dispensing errors continue. FDA recommends that health care providers include the generic name of the medication in addition to the brand name, as well as the indication for use when prescribing these medications. Patients are advised to check their prescriptions to ensure that the correct medication was dispensed. More information is available in an FDA safety alert at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm456569.htm.*

Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!

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.*

This is part two of a three-part series on seven persistent safety gaffes of 2014.

3) Vaccine Errors: Repetitive Errors Reported in the Last Decade

How often do DTaP (diphtheria and tetanus toxoids, and acellular pertussis) and Tdap (tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis) vaccine mix-ups need to occur before regulatory action is taken to prevent confusion? Whatever the number, we can say that health care providers have probably met that threshold! Yet, vaccine errors like this continue to occur at an alarming rate (based on those reported to ISMP alone). Vaccine mix-ups occur often because of age-dependent formulations of the same vaccine, similar vaccine abbreviations, similar vaccine containers and labels, and storage near each other. Confusion between the diluent and vaccine has led to administration of the diluent alone or use of the wrong diluent. With an unfortunate rise in parents choosing not to vaccinate their children or themselves, health care providers cannot continue to make errors when vaccinating those who choose to be immunized; the impact on both individual and community immunity may be far-reaching.

4) Wrong Patient Errors: Not Opening the Bag at the Point of Sale

Community pharmacies are vulnerable to dispensing correctly filled prescriptions to the wrong patient at the point of sale, a risk that is well substantiated in the literature. This error is not influenced by the attributes of a specific medication; thus, dispensing any prescription medication to the wrong patient at the point of sale carries a similar level of risk. Based on an ISMP study, the error happens frequently at an estimated rate of 1.22 per 1,000 prescriptions. Among approximately 56,000 community pharmacies in the United States, this error rate suggests that 332,755 prescriptions will be dispensed to the wrong patient each month, or about six every month per pharmacy. One of the most effective ways to prevent this error is to open the bag of filled prescriptions at the point of sale to verify that the medications are for the correct patient. According to the ISMP study, this simple step reduces the risk of error by 56%, yet few pharmacies follow this practice.

5) Disrespectful Behavior: A History of Tolerance in Health Care

Bullying, incivility, and other forms of disrespectful behavior are still rampant in health care and allowed to exist. Health care providers tolerate the behavior, remain silent, or make excuses in an attempt to minimize the profound devastation that disrespectful behavior causes. An ISMP survey conducted in 2003 clearly demonstrated the scope of disrespectful behavior among many levels of interdisciplinary staff, and an ISMP survey conducted a decade later demonstrates little progress. Disrespect diminishes a person's ability to think clearly, make sound judgments, speak up regarding questions, or avoid at-risk behaviors. Disrespectful behaviors also underlie a resistance to collaborate with others, follow procedures that promote safe practices, or implement new safety practices. While a culture of disrespect is harmful on many levels, its effect on patient safety makes it a matter of national urgency.

FDA Advises Caution Against Codeine for Treating Colds in Young Patients

FDA is evaluating the safety of using medicines containing codeine to treat patients under 18 years old for coughs and colds because of the possibility of severe side effects. Codeine, an opioid, may cause slowed or difficult breathing in children, especially for those who already suffer from breathing problems, the agency notes. FDA recommends that health care providers use caution when prescribing or recommending codeine for patients under 18 years old, and that parents and caregivers be alert for signs of shallow or noisy breathing, confusion, or unusual sleepiness. FDA is also considering a European Medicines Agency recommendation made in April to not give children under 12 codeine for coughs and colds, and to not use codeine for patients 12 to 18 years old who have asthma or other chronic breathing problems. More information is provided in an FDA safety alert available at *www.fda.govSafety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm453379.htm.*

Daytrana Patch May Cause Permanent Skin Color Changes, FDA Warns

In June 2015, FDA warned health care providers and consumers that Daytrana®, a methylphenidate transdermal system prescribed for treating attention deficit hyperactivity disorder, may cause permanent loss of skin color in the affected area. FDA has added a new warning to the drug label to describe this skin condition, known as chemical leukoderma. Chemical leukoderma is a skin condition that causes the skin to lose color as a result of repeated exposure to specific chemical compounds, according to an FDA safety alert. The condition is not physically harmful, but it is disfiguring.

FDA advises patients and caregivers to watch for new areas of lighter skin, especially under the drug patch, and to immediately report any changes to their health care providers. Patients should not stop using the Daytrana patch without consulting a health care provider. FDA also recommends that providers for patients who experience these skin color changes consider alternative treatments. More details are included in the FDA safety alert available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm452595.htm.*

FDA Expands NSAID Warning Labels Regarding Risks of Heart Attack, Stroke

The labels of certain non-steroidal anti-inflammatory drugs (NSAIDs) will soon contain more detailed information about the risk that the drugs may contribute to heart attack and stroke, reports FDA. Such warnings have been on prescription and over-the-counter NSAIDs since 2005, but the new requirements take into account new data showing that the risk of heart attack and stroke occurs even during the first few weeks of taking an NSAID. People who have cardiovascular and other heart problems are at even greater risk of adverse effects. An FDA alert available at *www.fda.gov/ForConsumers/ConsumerUpdates/ucm453610.htm* provides more details.

Baxter International, Inc, Recalls Three Lots of IV Solutions Due to Particulate Matter

In July 2015, Baxter International, Inc, voluntarily recalled two lots of intravenous (IV) solutions distributed to hospitals and other health offices because of the presence of particulate matter identified as an insect. The problem was identified before patient administration and no adverse health effects have been reported. The recall affects 0.9% sodium chloride injection, USP 50 mL and 100 mL, lot numbers P319921 and P327635, which were distributed to US customers between October 7, 2014, and July 14, 2015. Additional information is available in an FDA press release at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm455421.htm.*

Baxter also voluntarily recalled one lot of IV solution to the hospital/user level because of the potential for leaking containers, particulate matter, and missing port protectors. This recall affects 0.9% sodium chloride injection, USP (AUTO-C) with lot number C964601 (National Drug Code 0338-0049-03; expiration date: April 30, 2016). This recalled lot was distributed to customers and distributors nationwide between January 22, 2015, and February 12, 2015. Leaking containers, particulate matter, and missing port protectors could result in contamination of the solution and, if not detected, could lead to a bloodstream infection or other serious adverse health consequences, explains FDA. The agency notes further that "injecting a product containing particulate matter, in the absence of in-line filtration, may result in blockage of blood vessels, which can result in stroke, heart attack or damage to other organs such as the kidney or liver. There is also the possibility of allergic reactions, local irritation and inflammation in tissues and organs." More information about this recall is available in an FDA safety alert at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm456793.htm.*

FDA Warns Against Unapproved Prescription Ear Drops

FDA has ordered the manufacturers of certain prescription ear drops to stop making and distributing the products because they are not FDA-approved. The product labels do not disclose that they lack FDA approval, and health care providers may not be aware of the unapproved status, notes FDA. The agency took action against unapproved prescription otic drug products containing these ingredients:

- benzocaine;
- benzocaine and antipyrine;
- benzocaine, antipyrine, and zinc acetate;
- benzocaine, chloroxylenol, and hydrocortisone;
- chloroxylenol and pramoxine; and
- chloroxylenol, pramoxine, and hydrocortisone.

These drugs are frequently given to relieve ear swelling and pain in young children, and FDA took this action to protect patients from the risks of taking unapproved drugs with no proven safety or effectiveness information. Further, such drugs may be contaminated or manufactured incorrectly, notes the agency. More information is provided in an FDA news release available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453348.htm.*

Acino Products in New Jersey Ordered to Stop Selling Rectacort-HC and GRx HiCort 25

Under the direction of FDA, a federal judge for the District of New Jersey has ordered Acino Products, LLC, of Hamilton, NJ, to stop selling and destroy certain unapproved and misbranded prescription drugs in its possession.

According to FDA, Acino has marketed unapproved hydrocortisone acetate 25 mg suppositories, under the brand names Rectacort-HC and GRx HiCort 25, for treatment of medical conditions including inflamed hemorrhoids, chronic ulcerative colitis, and other inflammatory conditions. The drugs have not been FDA-approved and also fail to carry adequate directions for use on their labels. Acino continued to market and sell the products despite several warnings from FDA investigators. The FDA news release is available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm453466.htm.*

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August 2015

Jacob Bolton, RT, Hixson – License suspended.
Tiffany Gordon, RT, Kingsport – License suspended.
Andricka Hannah, RT, Columbia, TN – License suspended.
Kristin Hodges, RT, Knoxville – License suspended.
Kathryn Johnson, RT, Munford, TN – License suspended.
Beverly McCurry, DPh, Knoxville – License suspended.
Deebony McMurry, RT, Gallatin, TN – License suspended.
Amy Ann Rhinehart, RT, Memphis – License revoked; assessed costs not to exceed $10,000.
Natasha Womble, RT, Jefferson City, TN – License suspended.

September 2015

April L. Anglea, DPh, Marion, AR – License voluntarily surrendered.
Chad Everett Bradley-Scruggs, RT, Niota, TN – Registration revoked; assessed costs not to exceed $10,000.
Leshonda N. Couch, RT, Chattanooga, TN – License suspended.
Charity Galloway, RT, Cordova, TN – License suspended.
Brennis Graffed, RT, Nashville – License suspended.
Abdi Isse, RT, Nashville – License suspended.
Peggy Lakins, RT, Knoxville – License suspended.
Christopher Madden, RT, Murfreesboro – License suspended.
Tyson W. Milligan, RT, Mount Carmel, TN – Registration revoked; assessed costs not to exceed $10,000.
Samantha G. Morelock, RT, Mount Carmel – Registration revoked; assessed costs not to exceed $10,000.
Dana Cherie Parton, RT, Woodbury, TN – Registration revoked.
Telisa Pylant, RT, Nashville – License suspended.
Kim Rheinheimer, RT, Joelton, TN – License suspended.
Joshua Ricketts, RT, Harrogate, TN – License suspended.
Vanderbilt HC/Walgreens IV & RT Services, #3433, Pharmacy, Brentwood, TN – License suspended for one year with terms; assessed $15,000 civil penalties.

Additional Public Chapters That May Affect Pharmacy Practice

To view the actual Public Chapter (PC), click on the blue, hyperlinked PC numbers.

PC 352 Gives Some Allowance of Cannabis Oil for Certain Conditions

PC 352 legislation decriminalizes the possession of cannabis oil as long as all of the following are met.

- The oil contains less than 0.9% of THC and is labeled as such by the manufacturer. The person in possession retains proof of the legal order or recommendation from the issuing state.
- The person in possession retains proof that the person or person's family member has been diagnosed with intractable seizures or epilepsy by a physician licensed to practice in Tennessee.

This act became effective on April 16, 2015.

PC 82 Sets Age Limit for Dextromethorphan Sales

As of January 1, 2016, PC 82 will prohibit the retail sale of products containing dextromethorphan to persons less than 18 years of age.

- A valid government photo identification is required before the sale unless the person appears to be at least 30 years old or shows proof of emancipation if under 18 years of age and is an emancipated minor. An emancipated minor is defined in Tennessee Code Annotated (TCA) 39-11-106(10) and in the first paragraph of the Mature Minor Doctrine, Tennessee.
- A prescription generated by a prescribing practitioner or a pharmacist is exempt from this section.
- Other exemptions include:
  - ◊ If delivered or dispensed at health care facilities licensed under TCA 68-11-2, and/or TCA 33-2-4; or
  - ◊ If delivered or dispensed by a licensed health care practitioner to inmates at a jail or correctional facility.

Frequently Asked Questions

Q. What changes may a pharmacist make to a Schedule II prescription? (Found on the Board website under "Policies.")

A. Rules for the multiple issuances of Schedule II prescriptions by Drug Enforcement Administration (DEA) appeared to conflict with the long-standing DEA policy regarding what a pharmacist may change on Schedule II prescription after consultation with the prescribing practitioner.

In the preamble to the rule, DEA stated that the "essential elements of the [Schedule II] prescription written by the practitioner (such as the name of the controlled substance, strength, dosage form, and quantity prescribed . . .) may not be modified orally."

DEA followed up with a statement: "DEA recognizes the resultant confusion regarding this conflict and plans to resolve the matter through a future rulemaking. Until that time, pharmacists are instructed to adhere to state regulations or policy regarding those changes that a pharmacist may make to a schedule II prescription after oral consultation with the prescriber."

Per the previous statements from DEA, the following three items on a Schedule II prescription **may not be changed:**

1. Name of the patient;
2. Name of the drug (except for generic substitution permitted by state law); or
3. Name of the prescribing practitioner (including signature).

Any other item, such as the strength of the drug, quantity of the drug, and directions for use **may be changed, provided** the pharmacist:

1. Contacts the prescribing practitioner and obtains verbal permission for the change; and
2. Documents on the prescription the following information:
   a. Change that was authorized;
   b. Name or initials of the individual granting the authorization; and
   c. Initials of the pharmacist.

This policy statement was amended at the March 6, 2012 Board meeting.

Q. Can a pharmacy accept electronically sent prescriptions for controlled substances, including Schedule II prescriptions?

A. Yes, if all regulations are met as stated in DEA's resource for Electronic Prescriptions for Controlled Substances.

Q. Can a pharmacist receive from any patient or other person the return of any portion of an order that has been taken from the premises of the pharmacy practice site or other place of business?

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A. Yes, if all regulations are met as stated in DEA's resources for Drug Disposal Information and the disposal policy statement provided by the Board. **("If" passed,** future Board rules will also reflect this change.)

Q. What information do I need to submit to the Board if I want to open an automated dispensing system in a remote site such as a nursing home or hospice facility?

A. Information may be found in the "Board Gives Direction for Automated Dispensing System Pharmacy Waiver" article on page one of the December 2013 Board *Newsletter.*

Q. How do I find the chronic pain guidelines, and how should I use this documentation in my pharmacy practice?

A. Please read the Tennessee Department of Health pain management guidelines. Among other areas of interest, many of the pain management guideline topics include: initiating and ongoing opioid therapy; women's issues, including pain management in pregnancy; risk assessment; tapering protocols; morphine equivalent doses; and naloxone use.

By understanding these guidelines, it may be one of many tools to help the pharmacist understand and develop a prescribing practitioner-pharmacist professional relationship in order to increase positive outcomes of patient pain management, as well as lower the risk of addiction. It may also help the pharmacist with the recording of documentation using professional judgement on whether to dispense or deny to dispense a prescription in correlation with the drug regimen review and **consultation with the prescribing practitioner.**

Q. I heard that there are new regulations regarding the amount of milligrams allowed in the dispensing of buprenorphine. Where do I find these and how should I dispense this medication if the prescribing practitioner prescribes more than the dose allowed?

A. First, it is advised to review **PC 396** in its entirety. TCA 53-11-3(d)(1) is amended and states, in part:

> A prescriber who treats a patient with more than sixteen milligrams (16 mg) per day of buprenorphine or its therapeutic equivalent for more than thirty (30) consecutive days for treatment of opioid dependence shall clearly document in the patient's medical record why the patient needs the higher dosage amounts of buprenorphine. A prescriber who does not meet the requirements established in the manner described in subdivision (d)(2) and treats a patient with more than twenty milligrams (20 mg) per day of buprenorphine or its therapeutic equivalent for more than thirty (30) consecutive days for treatment of opioid dependence shall, to the extent possible, either consult with an addiction specialist meeting the requirements established in the manner described in subdivision (d)(2) or refer the patient to the addiction specialist for management of the patient's treatment plan. If a prescribing physician cannot make the required consultation or referral as outlined in this subsection (d), the reasons shall be set out in the medical record.

Therefore, if a prescription is received in a Tennessee registered pharmacy, Dr Reggie Dilliard, DPh, executive director for the Board, advises pharmacists to contact the prescribing practitioner, document the reasons for the increased dosage amount, and use professional judgement as to whether to fill or deny to dispense the prescription as he or she would with any medication.

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.*

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 start at 9 AM on the first day, and at 8 AM on the second day, unless otherwise noted. 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: January 12-13, March 8-9, May 10-11, July 26-27, September 20-21, and November 8-9. A rulemaking hearing is scheduled for December 18, 2015.

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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Dr William J. Bunch – Vice President
Dr Mike Dickenson – Board Member
Dr Kevin Eidson – Board Member
Dr Debra Wilson – Board Member
Dr Jason S. Kizer – Board Member
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