

March 2013

News



Tennessee Board of Pharmacy

Published to promote compliance of pharmacy and drug law

227 French Landing, Suite 300 • Nashville, TN 37243
<http://health.state.tn.us/Boards/Pharmacy/index.shtml>

New Electronic Filing Requirements for Professional Privilege Tax

*Be advised that the Tennessee Board of Pharmacy is **not** involved in assessing or collecting the Professional Privilege Tax in any way. Therefore, please do **not** call the Tennessee Board of Pharmacy office with questions about this issue. The Tennessee Department of Revenue, Taxpayer Services Division is the agency administering the Professional Privilege Tax. The Board is merely providing this notice as a courtesy. If issues arise, contact the Taxpayer Services Division at 866/368-6374 or 615/253-0704.*

All professional privilege tax returns filed on or after January 1, 2013, must be filed electronically. Professional privilege tax returns can be filed electronically either by individuals or by companies who file and pay for multiple individuals. The department **will not** be mailing taxpayers a Professional Privilege Tax Return for the \$400 tax due June 1, 2013.

For a step-by-step guide to electronically file an individual Professional Privilege Tax Return, please visit <https://apps.tn.gov/privtx/>.

If you are a company filing and paying for multiple individuals, please visit <https://apps.tn.gov/privbatch/>. Should you have additional questions, feel free to contact the Electronic Commerce Unit at 866/368-6374 for in-state calls or 615/253-0704 for local or out-of-state calls.

Public Chapter 657 (2012) authorizes the commissioner to require that any return, report, claim, statement, application, or other document filed with the department, including any payment or remittance that accompanies such document, be submitted electronically in a manner approved by the commissioner beginning no sooner than 90 days after the commissioner has certified that a system is in place for the electronic submission of such document or payment.

These new electronic filing requirements will permit processing your return and payment more timely and efficiently at a cost savings to the state.

Note: The Tennessee Pharmacists Association recently reported that pharmacists were having difficulty paying the Professional Privilege Tax online and that it may take until April before the system is capable of accepting payment. A reply from the Taxpayer Services Division stated that these issues have been resolved.

Directions Available for Adding or Updating E-mail Addresses for Board Notices/Alerts

As stated in the previous *Newsletter*, the Board shall allow all registrants to have the option of being notified by electronic mail (e-mail) of renewals of the holder's license, certification, or registration; any fee increases; any changes in state law that impact the holder and are implemented or enforced by the entity, including newly promulgated or amended statutes, rules, policies, and guidelines; and any meeting where changes in rules or fees are on the agenda. **To add or update your e-mail address**, simply visit the following Web link, choose the

"update your Professional License information" option, and follow the online instructions: <https://apps.tn.gov/htrs/begin.jsp>.

Board Opinion Clarified in Regard to Bedside Delivery

During the January 16-17, 2013 meeting, the Board agreed that by following the listed criteria, pharmacies would no longer need to appear before the Board in order to be approved for bedside delivery to the hospital bed during a patient discharge. Instead, the pharmacist-in-charge (PIC) may download the attestation form (soon to be loaded to the Board Web site) and return it to the Board office for final approval. The form must be signed and dated by the PIC.

Upon receipt of the completed attestation, the Board office will upload this information into the pharmacy's profile so that the Board investigators may access and inspect the criteria during periodic inspections. The following criteria include:

1. 100% patient counseling:
 - ◆ Pharmacist to patient, face-to-face technology with an acceptable backup plan for technology failure
2. Patient freedom of choice must be maintained.
3. Delivery must occur by pharmacist, pharmacy intern, or certified pharmacy technician.
4. Chain of custody must be direct from pharmacy to patient.
5. Controlled substance (CS) prescriptions must be transmitted to the pharmacy by the hospital's prescribing practitioner or prescribing practitioner's staff as opposed to other hospital staff:
 - ◆ The pharmacy technician may transport the hard copy prescription to the pharmacy
 - ◆ The pharmacy may not dispense until the hard copy is compared to the fax copy
6. A process to address patient complaints must be discussed and implemented.
7. Pharmacies must attest to the compliance of the above, and notify the Board of all pharmacies participating in bedside delivery prior to implementing this service.

DEA Gives Notice of Rulemaking for Additional Prescription Drug Take-Back Programs

On April 27, 2013, Drug Enforcement Administration (DEA) will hold another National Prescription Drug Take-Back Day in order to dispose of unneeded medications. Included in this notice is the mention of the Secure and Responsible Drug Disposal Act of 2010. Once these federal rules are finalized, **some states may allow** retail pharmacies, manufacturers, distributors, and reverse distributors to take back, for the purpose of disposal, CS medications from the ultimate user. Visit the following link for additional information: www.deadiversion.usdoj.gov/drug_disposal/takeback/.

continued on page 4



National Pharmacy

(Applicability of the contents of articles in the National Pharmacy Comp...
and can only be ascertained by examining

NIH Database Provides Information on Drugs Associated With Liver Injury

The National Institutes of Health (NIH) has launched a free searchable database with information on prescription and over-the-counter (OTC) drugs, herbals, and dietary supplements associated with liver injury. The LiverTox database, www.livertox.nih.gov, is a free resource for health care providers and researchers studying liver injury associated with these products. The database provides up-to-date, accurate, and easily accessed information on the diagnosis, cause, frequency, patterns, and management of liver injury attributable to prescription and nonprescription medications, herbals, and dietary supplements. The database currently contains information on 700 medications, and 300 more will be added.

Coalition Urges Consumers to 'Double Check, Don't Double Up' on Acetaminophen

With the start of cold and flu season in October 2012, the Acetaminophen Awareness Coalition began urging consumers to double check their medicine labels to make sure they do not double up on medicines containing acetaminophen. The coalition's "Double Check, Don't Double Up" message is aimed to reach the more than 50 million Americans who use acetaminophen every week, encouraging them to take three simple steps to avoid acetaminophen overdose: (1) know if your medicine contains acetaminophen; (2) never take two medicines with acetaminophen at the same time; and (3) always read your medicine label. The coalition also wants to educate consumers that taking more acetaminophen than directed is an overdose and can lead to liver damage. Health care providers can join the effort by educating patients about safe use of acetaminophen, and can refer patients to the KnowYourDose.org Web site for more information. The Acetaminophen Awareness Coalition is made up of a diverse group of organizations representing health care providers and consumers who have joined forces through the Know Your Dose campaign to inform consumers about safe acetaminophen use and preventing liver damage that can result from unintentional overdose.

Root Cause Analysis



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.

To assist pharmacists in the process of minimizing the occurrence of medication errors, many state boards of pharmacy are contemplating or already requiring community pharmacies to have a continuous quality improvement program in place. Many of these state's regulations include the requirement of root cause analysis (RCA) in the case of sentinel events. The Joint Commission defines a sentinel event as an "unexpected occurrence involving death or serious physical or psychological injury or

risk thereof," and recommends completing an RCA for all sentinel events for health care organizations in which they accredit. It is anticipated that RCA for sentinel events may be required as part of an accreditation program for community/ambulatory pharmacies.

RCA is a process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or risk of occurrence of a sentinel event. RCA focuses primarily on systems and processes, not individual performance. Finding and identifying root causes during an investigation adds considerable value by pointing out significant, underlying, fundamental conditions that increase the risk of adverse consequences. These analyses can be of enormous value in capturing both the big-picture perspective and the details of the error. They facilitate system evaluation, analysis of need for corrective action, and tracking and trending.

The RCA process starts by creating a team, holding a meeting, and stating the problem. The team gathers documentation (prescriptions, labels, computer reports, etc) and interviews staff involved in the error to determine the sequence of events.

The RCA team will review the documentation and review the sequence of events and continue asking themselves "Why did this happen?" until they arrive at each root cause.

The team must assume that any problem is preventable and caused by weak or vulnerable systems rather than individual incompetence. Even in the case of a person making a mistake, the team must ask "Why do our systems allow these types of mistakes to happen so easily?" or "What factors set this person up to make this error?"

The heart of the process is the analysis itself. Table 1 lists basic questions that should be answered during RCA.

Table 1. Basic Questions to Answer During RCA

- | |
|-----------------------------------------------------------------|
| 1. What happened? |
| 2. What normally happens? |
| 3. What do policies/procedures require? |
| 4. Why did it happen? |
| 5. How was the organization managing the risk before the event? |

It is important to answer "What normally happens?" (Question 2, in the above table). The difference between "What normally happens?" and "What do the policies and procedures require?" (Question 3) helps determine the reliability of processes and how often staff cut corners to get the work done.

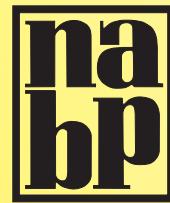
RCA also includes a method to measure the effectiveness of these strategies over time. Targeting corrective measures at the identified root causes is the best way to ensure that similar problems do not occur in the future.

USP Releases Universal Standards for Prescription Labels

New United States Pharmacopeial Convention (USP) standards for a universal approach to the format, appearance, content, and instructions for medicines in containers dispensed by pharmacists have been released. "Wide variability in prescription container labels exists today across individual prescriptions, pharmacies, retail chains and states. The USP standards provide specific direction on how to organize labels in a 'patient-centered' manner that best reflects how most patients seek out and understand medication instructions," as explained in a USP press release. Lack of universal standards for medication labeling can contribute to patients

Compliance News

pliance News to a particular state or jurisdiction should not be assumed
ng the law of such state or jurisdiction.)



misunderstanding dosage instructions and can lead to medication errors. Elements of the new USP standards, contained in General Chapter <17> Prescription Container Labeling, of the USP and the National Formulary, include:

- ◆ Emphasizing instructions and other information important to patients
- ◆ Improving readability
- ◆ Giving explicit instructions
- ◆ Including purpose for use
- ◆ Addressing limited English proficiency
- ◆ Addressing visual impairment

Descriptions of each standard including examples, as well as more information about the development of the standards, are provided in a USP press release, available at <http://us.vocuspr.com/Newsroom/ViewAttachment.aspx?SiteName=USPharm&Entity=PRAsset&AttachmentType=F&EntityID=109587&AttachmentID=5dc9eb96-5706-4e61-b0fa-ce9673fb3010>.

Enforcement of the standards will be the decision of individual state boards of pharmacy, which may choose to adopt it into their regulations, notes USP. The National Association of Boards of Pharmacy® (NABP®) member boards adopted Resolution 108-1-12 at the NABP 108th Annual Meeting stating that the Association should support state boards of pharmacy in efforts to require a standardized prescription label. NABP also convened a task force on this issue in December 2008. The resolution and the Report of the NABP Task Force on Uniform Prescription Labeling Requirements are available in the Members section of the NABP Web site.

New Law Increases Penalties on Medical Cargo Theft

New legislation signed into law by President Obama on October 5, 2012, increases penalties for medical product cargo theft, a significant problem that threatens patient safety when these stolen products are reintroduced into the legitimate supply chain. The Strengthening and Focusing Enforcement to Deter Organized Stealing and Enhance Safety Act of 2012 (SAFE DOSES Act) prohibits theft of medical products as well as trafficking, buying, selling, or distributing illegally obtained pre-retail medical products. The law "prescribes criminal and civil penalties for violations, including a civil penalty of up to the greater of 3 times the economic loss attributable to the violation or \$1 million." According to the Coalition for Patient Safety and Medicine Integrity, "current federal criminal laws do not distinguish between stealing a load of insulin and stealing a truck full of paper clips." By increasing the penalties for medical theft, the SAFE DOSES Act should help deter such theft. The text of the new law is available for download from the Government Printing Office Web site at www.gpo.gov/fdsys/pkg/BILLS-112hr4223enr/pdf/BILLS-112hr4223enr.pdf.

NABP Implements Action Plan to Assist States in Regulating Compounding Pharmacies

Supporting state board of pharmacy efforts to enforce compounding regulations, NABP is implementing a four-part action plan centered around inspection of nonresident compounding pharmacies and creating an information-sharing network of regulatory details on such pharmacies. Focusing on inspections of nonresident compounding pharmacies and sharing this data among boards of pharmacy nationwide was determined by NABP and its member state boards of pharmacy to be key to preventing future tragedies like the current meningitis outbreak.

NABP developed the action plan at a November 2012 meeting of board of pharmacy executive directors where the attendees expressed a strong

commitment to correcting system failures that allowed the meningitis outbreak to occur, and implementation began quickly thereafter. The Iowa Board of Pharmacy recently requested NABP to develop an inspection program for entities that are licensed by the state as nonresident pharmacies and dispensing compounded drugs in Iowa. Those in attendance expressed their support of this inspection initiative, which became a cornerstone of the four-part action plan.

In the first part of its action plan, NABP shared the list of nonresident compounding pharmacies provided by the Iowa Board with other NABP member boards of pharmacy and began coordinating the collection of information on these pharmacies. The boards' collaboration on this data helped NABP identify the initial pharmacies to inspect. NABP believes that the list provided by Iowa represents a significant number of nonresident pharmacies dispensing compounded drugs across the country.

Implementing the inspection program is the second part of the action plan and is currently underway. Initial results will reveal whether the selected pharmacies are compounding pursuant to a prescription in compliance with state regulations, or instead are engaging in manufacturing. Entities that refuse inspection may be subject to disciplinary action by the Iowa Board and such actions will be shared with all of NABP's member boards.

The third part of the action plan includes NABP collecting and maintaining data on the compounding pharmacies identified by the Iowa Board and by other boards of pharmacy. Initial data collected from the boards and the inspection reports will be stored in an NABP Pharmacy e-Profile, allowing the Association to disseminate pertinent public information among state boards. Ultimately, states will be able to submit inspection reports and other related information to NABP for inclusion in pharmacies' e-Profiles. The network will be made available at no cost to boards for use in making licensure and registration determinations for pharmacies, and may also help to identify pharmacies whose operations are more akin to manufacturing than compounding.

As the final part of the action plan, NABP plans to schedule immediate and ongoing training of board of pharmacy inspectors and compliance officers via Webinar and field training opportunities. NABP will also continue cooperative efforts with Food and Drug Administration and legislators to address the regulatory quagmire that exists when traditional compounding is exceeded and manufacturing may be occurring.



Pharmacists & Technicians:

Don't Miss Out on Valuable CPE Credit.

Set Up Your NABP e-Profile and Register for CPE Monitor Today!

CPE Monitor™ integration is underway. Most Accreditation Council for Pharmacy Education (ACPE)-accredited providers should now be requiring you to submit your NABP e-Profile ID, assigned when you set up your NABP e-Profile, along with your date of birth (MMDD), in order to obtain continuing pharmacy education (CPE) credit for any ACPE-accredited activity.

Visit www.MyCPEmonitor.net to set up your e-Profile, obtain your e-profile ID, and register for CPE Monitor and avoid possible delays in your CPE reporting.

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.

continued from page 1

However, Tennessee Board of Pharmacy Rule 1140-03-.03(8) currently prohibits pharmacists from taking drugs back into the pharmacy at this time. As stated:

It is unlawful for any pharmacy practice site, pharmacist, or pharmacy intern or pharmacy technician under the supervision of a pharmacist, or any other place of business engaged in compounding and dispensing prescription drugs and devices and related materials for human consumption to 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, except pursuant to 1140-4-10.

The Board is considering a rule change to possibly reflect the intent of this federal regulation. More information on this topic should become available in the near future.

A Wholesaler/Manufacturer/Distributor May NOT Be Named as to Imply That It is a 'Pharmacy'

As more pharmacies choose to obtain a Board wholesaler/manufacturer/distributor (W/M/D) license, it is advised to revisit the definition of "Pharmacy" in the Tennessee Pharmacy Practice Act. As stated in TCA 63-10-204 (32), "... 'Pharmacy' means a **location licensed by the state where drugs are compounded or dispensed** under the supervision of a pharmacist, as defined in the rules of the board and where prescription orders are received or processed . . ." A **W/M/D may distribute, but not dispense**. As an example, the title name "ABC Pharmacy" implies it is a pharmacy as there is no identifier after the word pharmacy. "ABC Pharmaceutical Supplies" implies it is a supply company. Therefore, be advised to avoid using the word "pharmacy" when selecting a name for the Board W/M/D license.

Board Approves Revised Policy for Contents of Emergency Kits

With recognition to DEA's statement of *Guidelines for Emergency Kits in Long Term Care Facilities*, Appendix H (see Web link www.deadiversion.usdoj.gov/pubs/manuals/pharm2/appendix/appdx_h.htm), and Tennessee Board of Pharmacy Rule 1140-4-.09 **EMERGENCY AND HOME CARE KITS**, the following policy was adopted by the Board during its January 17, 2013 meeting.

1. Source of Supply
 - a. All controlled substances contained in the emergency kit must be supplied by the duly licensed and currently DEA registered provider pharmacy designated by the long-term care facility.
2. Security Safeguards, Accountability and Recordkeeping, and Administration of Controlled Substances
 - a. The access, storage and administration of the controlled substances contained in the emergency kit must meet the requirements of Tennessee Board of Pharmacy Regulation 1140-4-.09(1).
 - b. Controlled substance schedule II drugs in the emergency kit must be stored in a cabinet or other structure that provides a double locked secure system.
 - c. The contents of the emergency kit are specifically limited to the following:
 - i. Up to 40 total units of medications in schedules II – V
 1. A maximum of 20 units of medications in schedules II
 2. Up to 5 units of the 40 total units may be in oral liquid formulation. Each unit in oral liquid formulation shall not exceed 30 milliliters.

Board member Charles "Buddy" Stephens clarified that one tablet is defined as one unit as opposed to one bottle of tablets.

Emergency Rules to Clarify Prescription Safety Act

To view recent emergency rules promulgated by the Commissioner of the Tennessee Department of Health in regard to The Tennessee Prescription Safety Act of 2012, refer to the following Web link for Controlled Substance Monitoring Database requirements viewed in Rule 1140-11: www.state.tn.us/sos/rules/1140/1140.htm.

Pharmacies Advised to Revisit Sterile Compounding Board Rules

As discussed in the last two Board meetings, investigators have started to use a more detailed checklist guide when inspecting sterile compounding pharmacies. It is advised that according to Tennessee Board of Pharmacy Rule 1140-07-.03(f), "... **Prefilters in laminar flow hoods shall be changed at least quarterly and a written record of such change shall be maintained...**" Pharmacists may believe that they are in compliance if the semi-annual certification has been satisfied. However, the certifying technician may only be changing the prefilter every six months as opposed to the required three-month period.

Moreover, pharmacists are expected to give examples of compliance with regard to the physical requirements of sterile compounding as stated in Rule 1140-07-.03, labeling as stated in Rule 1140-07-.05, hazardous products as stated in Rule 1140-07-.06, attire as stated in 1140-07-.07, and quality assurance as stated in Rule 1140-07-.08.

As described, pharmacists shall document proper sterile compounding training and annual continuing education of all compounding personnel. Updated sterile compounding policies and procedures are expected to be readily available for investigator review, and should **address each item on the list** located in Tennessee Board of Pharmacy Rule 1140-07-.04. The Board expects for policies and procedures to be complete. Pharmacists are expected to follow these policies and procedures for the health and safety of the patient. Refer to Rule 1140-02-.01(11), which states in part "... A pharmacist shall provide pharmaceutical service: (a) **which is as complete as the public may reasonably expect**; (b) without discriminating in any manner between patients or groups of patients; and (c) **without compromising the kind or extent of services or facilities made available . . .**"

Board Announces New President and Vice-President

The Board announces former Vice-President Charles "Buddy" Stephens as the newly elected president and Jason Kizer as the elected vice-president. Dr Stephens thanked former President Brenda Warren for her service and commented on her ability to keep the Board discussions timely and on point. Dr Warren will continue to serve on the Board and finish her six-year term as stated in the Tennessee Pharmacy Practice Act.

Tennessee Board of Pharmacy Meeting Dates

The Board 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 2013:

- ◆ March 11, 2013, Poplar Room – 227 French Landing
- ◆ March 12-13, 2013, Iris Room – 227 French Landing
- ◆ May 14-15, 2013, Iris Room – 227 French Landing
- ◆ July 9-10, 2013, Iris Room – 227 French Landing
- ◆ September 10-11, 2013, Poplar Room – 227 French Landing
- ◆ November 13-14, 2013, 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.

Tennessee Board of Pharmacy Members

Dr Charles (Buddy) Stephens – President
Dr Jason S. Kizer – Vice President
Dr Nina Smothers – Board Member
Dr William J. Bunch – Board Member
Dr Kevin Eidson – Board Member
Dr Brenda S. Warren – Board Member
Ms Joyce McDaniel – Public Member

Page 4 – March 2013

The *Tennessee Board of Pharmacy News* is published by the Tennessee Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

Buddy Stephens, DPh - Tennessee Board of Pharmacy President and Newsletter Editor

Andrew Holt, PharmD - Executive Director and Newsletter Editor

Scott G. Denaburg, BA, PharmD - Investigator and Contributor,
Tennessee Board of Pharmacy

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Larissa Doucette - Communications Manager