



Tennessee Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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<http://health.state.tn.us/Boards/Pharmacy/index.shtml>

The New England Compounding Center Surrenders Pharmacy License

On October 15, 2012, a consent order was executed for the voluntary surrender/revocation of the Tennessee pharmacy license held by The New England Compounding Center (NECC), located at 697 Waverly Street, Framingham, MA. For complete information, please visit the following Web link: <https://health.state.tn.us/Boards/Pharmacy/PDFs/NewEnglandCompounding101512.pdf>.

Furthermore, as of October 23, 2012, a consent order was executed for the voluntary surrender/revocation of the Tennessee pharmacist's license held by the pharmacist-in-charge for NECC. Violations cited include:

A pharmacist shall not knowingly condone or assist in the dispensing, promoting or distributing of drugs or devices which are not of good quality, which do not meet standards by law, or which lack therapeutic value for the patient. The pharmacist in charge shall immediately notify the board in writing in the event of termination of business by the pharmacy practice site at which the pharmacist in charge practices. The designated pharmacist in charge shall report to the board any situation in which a medical or prescription order has caused serious personal injury or death.

Board Rules for Compounding Reemphasized

In the wake of the tragic events causing harm and loss of life across the country, including several deaths in Tennessee, due to the fungal meningitis outbreak, it is important to review the current definitions and rules for Tennessee-licensed pharmacies practicing the art of compounding.

To start this discussion, it is important to understand the difference between compounding and manufacturing. Refer to the following definitions:

Tennessee Code Ann. §63-10-204 Definitions.

(4) "Compounding" means the preparation, mixing, assembling, packaging or labeling of a drug or device:

(A) As the result of a prescription order or initiative based on the prescriber-patient-pharmacist relationship in the course of professional practice;

(B) In anticipation of prescription orders based on routine, regularly observed prescribing patterns; or

(C) For the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing;

(12) "Dispense" means preparing, packaging, compounding or labeling for delivery and actual delivery of a prescription drug, nonprescription drug or device in the course of professional practice to a patient or the patient's agent by or pursuant to the lawful order of a prescriber;

(21) "Manufacturer" means any person, except a pharmacist compounding in the normal course of professional practice, engaged in the commercial production, preparation, propagation, conversion or processing of a drug, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis, or both, and includes any packaging or repackaging of a drug or the labeling or relabeling of its container and the promotion and marketing of such drugs or devices;

(13) "Distribute" means the delivery of a drug or device, other than by administering or dispensing, to persons other than the patient or the patient's agent;

Therefore, be advised that the patient-specific prescription **via** the prescriber-patient-pharmacist (also known as the three-legged stool) **is required** for the pharmacist to prepare and dispense a **compounded prescription**.

To sell a manufactured drug **without a prescription** in Tennessee, (ie, office or hospital use) a wholesaler/manufacture/distributor (W/M/D) license, issued by the Tennessee Board of Pharmacy, is required as discussed in the July 27-28, 2011 Board meeting minutes:

A company with the business model of providing admixture pharmacy services, appeared before the board to ask for permission to operate as a pharmacy in Tennessee. The representative explained that the company would compound sterile preparation in anticipation of institutional pharmacies' prescription orders and it would be based on the institution prescriber's routine prescribing patterns. The compounded admixture is not patient specific but the company would like to send the admixture to institutions based on past usage of the product. After discussion, a member of the Board made the motion that based on the business model discussed with this company, it would be necessary that they be licensed in Tennessee as a manufacturer/wholesaler/distributor. Furthermore, the motion stated that if they decided to dispense patient specific, they would have to be licensed as a pharmacy as well. The motion was seconded and carried.

Currently, there are pharmacies licensed by the Board that carry both W/M/D and pharmacy licenses. However, be advised that Food and Drug Administration and Drug Enforcement Administration (DEA) regulations may require licensure or other certifications to also manufacture drug products for sale, purchase, or transfer.

For pharmacists practicing the art of sterile compounding under a **pharmacy license for patient-specific prescriptions**, it is advised to review the current Tennessee Board of Pharmacy rules found at the following Web link: www.state.tn.us/sos/rules/1140/1140-07.pdf. Board rules require documentation to be completed and readily

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AHRQ Toolset Can Assist Pharmacies Using e-Prescribing

A toolset released by the Agency for Healthcare Research and Quality (AHRQ) can assist independent pharmacies with the implementation of e-prescribing and may also provide useful guidance to those pharmacies already using e-prescribing. The toolset for independent pharmacies consists of seven chapters that provide guidance on topics ranging from planning the implementation process and launching the system, to troubleshooting common problems and moving into more advanced pharmacy services, states AHRQ. Flyers for use in communicating the launch to patients, templates for communicating with providers about the launch, tools for assessing pharmacy workflow, and a spreadsheet to determine return-on-investment, among other tools, are also available to pharmacies. The toolset can be downloaded from the AHRQ Web site at http://healthit.ahrq.gov/portal/server.pt/community/health_it_tools_and_resources/919/a_toolset_for_e-prescribing_implementation_in_independent_pharmacies/30595.

FDA Database Provides Information on Pediatric Medications

A Food and Drug Administration (FDA) database provides information on pediatric medications, making it easier for both health care providers and caregivers to locate this information. The Pediatric Labeling Information Database is a one-stop resource, where providers and caregivers can search for information by the product's commercial or chemical name, or by the condition for which it was studied. The database was developed by FDA's Office of Pediatric Therapeutics (OPT), in collaboration with the Center for Drug Evaluation and Research. The OPT also provides a Safety Reporting page with information on products that have been tied to safety problems that specifically relate to children. Additional information and a link to the database is available in the Consumer Updates section of the FDA Web site at www.fda.gov/ForConsumers/ConsumerUpdates/ucm305040.htm.

Inattentional Blindness: What Captures Your Attention?



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.

A pharmacist enters a prescription for methotrexate daily into the pharmacy computer. A dose warning appears on the screen. The pharmacist reads the warning, bypasses it, and dispenses the medication as entered. The patient receives an overdose of the medication and dies.

This error, and many more, have happened because the person performing the task fails to see what should have been plainly visible, and later, they cannot explain the lapse.¹ People involved in these errors have been labeled as careless and negligent. But these types of accidents are common – even with intelligent, vigilant, and attentive people. The cause is usually rooted in inattentional blindness.¹

Accidents happen when attention mistakenly filters away important information and the brain fills in the gaps with what is aptly referred to as a “grand illusion.”² Thus, in the example above, the brain of the pharmacist filtered out important information on the computer screen, and filled in the gaps with erroneous information that led him to believe he had read the warning appropriately.

Inattentional blindness is more likely to occur if part of your attention is diverted to secondary tasks, like answering the phone while entering prescriptions into the computer, or even thinking about your dinner plans while transcribing an order.

Low workload causes boredom and reduces the mental attention given to tasks, as does carrying out highly practiced tasks, such as counting out medication. We spend a large majority of our waking life functioning with the equivalent of an automatic pilot, with occasional conscious checks to ensure tasks are being carried out properly. This makes us particularly prone to inattentional blindness.

Our past experiences also teach us what is relevant. Errors occur when new or unusual circumstances happen in highly familiar situations. The pharmacist who did not notice important information on a computer warning had rarely encountered a clinically significant computer alert. The pharmacist had subconsciously learned that there was nothing important to see when reading alerts. Nothing had ever happened, so attention was automatically filtered away from the details to conserve mental processing.

Conspicuity is the degree to which an object or piece of information “jumps out” and captures your attention. The best way to achieve this effect is through use of contrast, color, or shape to call attention to differences in packaging or text.

It is difficult to reduce the risk of inattentional blindness, as it is an involuntary and unnoticed consequence of our adaptive ability to defend against information overload. Error-reduction strategies such as education, training, and rules are of little value. Instead, efforts should center on increasing conspicuity of critical information, and decreasing diversions of attention and secondary tasks when carrying out complex tasks.

1. Green M. “Inattentional blindness” and conspicuity. *Visual Expert*. 2004. Accessed at www.visualexpert.com/Resources/inattentional_blindness.html, March 1, 2012.

2. Angier N. Blind to change, even as it stares us in the face. *The New York Times*. April 1, 2008.

Know Your Dose Game Teaches Safe Acetaminophen Use

As part of the Know Your Dose campaign, the Acetaminophen Awareness Coalition has developed an interactive educational game to teach safe use of acetaminophen. The game not only answers some of the most common questions surrounding the safe use of acetaminophen, it gives an engaging face to the issue. The game, available on the

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Know Your Dose Web site at www.knowyourdose.org/game, invites consumers to follow three characters through a typical day of aches and pains while helping the characters learn how to take medicine that contains acetaminophen safely.

Contraception Products Sold Online With No Prescription Required, Endangering Public Health

Health care providers should help to educate patients about the risks of prescription contraceptive products marketed online as “no prescription” and “over-the-counter” products, pharmaceutical security researchers conclude. A study by these researchers found that Google searches returned results for prescription contraceptive products such as injections, oral contraceptives, and patches, as well as intrauterine devices (IUDs). All of these products were marketed as available without a prescription and researchers found that sellers provided links to YouTube videos with IUD instructions. The researchers also found that these products were being promoted on social media channels, including Facebook, Twitter, SlideShare, and Flickr. Researchers Bryan A. Liang, MD, JD, PhD, Tim K. Mackey, MAS, and Kimberly M. Lovett, MD, conclude that such online contraceptive sales represent patient safety risks and also suggest that policy makers should “employ legal strategies to address these systemic risks.” The study, “Suspect Online Sellers and Contraceptive Access,” is available in the May 25, 2012 issue of *Contraception*.

New FDA Drug Info Rounds Training Video

FDA Drug Info Rounds, a series of online training videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest Drug Info Rounds video, available at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm313768.htm, pharmacists discuss the Accelerated Approval Program and how FDA helps make new, potentially lifesaving drugs available more quickly. Drug Info Rounds is developed with contributions from pharmacists in FDA’s Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information.

FDA Resources Help Raise Awareness About Health Fraud Scams

To help raise consumer awareness about health fraud scams, FDA provides numerous educational resources in the Health Fraud Scams section of its Web site. Educating consumers on how to avoid such scams, FDA videos present information on various types of fraudulent products such as fake diet, sexual enhancement, and body building products. Consumers can also access information about specific products that are the subject of FDA warning letters, recalls, public notifications, and safety alerts. FDA news releases related to health fraud are also accessible through this section of the Web site.

NABP Accepting Award Nominations for 109th Annual Meeting

The National Association of Boards of Pharmacy® (NABP®) is currently accepting nominations for the Association’s 2013 awards that will be presented during the 109th Annual Meeting, to be held May 18-21, 2013, at the Hyatt Regency St Louis at the Arch in St Louis, MO.

Nominations are currently being accepted for the following awards: 2013 Lester E. Hosto Distinguished Service Award (DSA), 2013 NABP Honorary President, 2013 Fred T. Mahaffey Award, and 2013 John F. Atkinson Service Award.

Nominations for these awards must be received at NABP Headquarters no later than December 31, 2012. New this year, individuals wanting to submit a nomination will be asked to fill out and complete a nomination form, which may be accessed by visiting the Meetings section on the NABP Web site at www.nabp.net/meetings. Criteria for award nominees will also be posted to the Web site. Nomination forms should be sent to the NABP Executive Director/Secretary Carmen A. Catizone at NABP Headquarters, 1600 Feehanville Dr, Mount Prospect, IL 60056. Directions for electronic submission will be available on the online form. The NABP Executive Committee will review the nominations and select the honorary president and award recipients.

For more information, please contact the NABP Executive Office via e-mail at exec-office@nabp.net.

NABP Looking for Exam and Assessment Item Writers

NABP is seeking individuals to serve as item writers for the North American Pharmacist Licensure Examination®, the Multistate Pharmacy Jurisprudence Examination®, the Foreign Pharmacy Graduate Equivalency Examination®, the Pharmacy Curriculum Outcomes Assessment®, and the Pharmacist Assessment for Remediation EvaluationSM. Pharmacists in all areas of practice, and faculty from schools and colleges of pharmacy are encouraged to apply. Interested individuals should e-mail, fax, or mail a letter of interest indicating their current practice/ educational setting, specialties/certifications, and years of experience, along with a résumé or curriculum vitae:

- ◆ via e-mail at exec-office@nabp.net;
- ◆ via fax at 847/391-4502; or
- ◆ via mail to NABP Executive Director/Secretary Carmen A. Catizone at 1600 Feehanville Drive, Mount Prospect, IL 60056.

Please note, applications are accepted on a continuous basis and kept on file for a period of five years. For more information about item writing, contact NABP at custserv@nabp.net. Additional information may also be found in the August 2012 *NABP Newsletter*.



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. Soon all Accreditation Council for Pharmacy Education (ACPE)-accredited providers will require 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. Many have already begun to do so.

Visit www.MyCPEmonitor.net to set up your e-Profile 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.

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available, including flow hood certification, pre-filter records, training, and policies and procedures.

Former Executive Director Kevin Eidson Named to Pharmacy Board

Bringing with him a broad range of knowledge and experience in pharmacy and public service, Dr Kevin Eidson takes his seat as the newest member of the Tennessee Board of Pharmacy.

As an assistant professor at Lipscomb University College of Pharmacy, where he teaches pharmacy law and ethics and community pharmacy management, Dr Eidson currently chairs faculty meetings and serves on the Admissions and Experiential Education Committees. His past experience includes pharmacy ownership in independent and long-term care, where he practiced as manager, consultant, and dispensing pharmacist in Georgia and Florida.

After moving to Tennessee, Dr Eidson served as director of pharmacy in the Department of Health for Tennessee from 2005 to 2007. He worked with regional and county health departments in providing pharmacy services for primary care, and established policies and supply chain guidelines. He assisted with vaccine inventory and storage, as well as treatment regimens for Department of Health covered entities.

Also, as the first Strategic National Stockpile Coordinator (formerly known as the National Pharmaceutical Stockpile), Dr Eidson's duties included assisting in the response to disasters and preparing and updating plans for the mass dispensing of medications. Furthermore, he assisted in the review of the rules and regulations of the Department of Health and the Board of Pharmacy to facilitate responding to disasters.

Serving from 2007 to 2010 as executive director for the Tennessee Board of Pharmacy, Dr Eidson also served on several committees including Tennessee Pharmacists Association Disaster Preparedness, Tennessee Society of Independent Pharmacists, Controlled Substance Monitoring Database Advisory, and the Institutional Review Board committees. Other current memberships include National Association of Drug Diversion Investigators, National Association of Boards of Pharmacy®, American Society of Health-System Pharmacists, American Pharmacists Association, National Community Pharmacists Association, American Association of Colleges of Pharmacy, and MALTA-GON.

Outside of pharmacy, Dr Eidson is a member of Long Hollow Baptist Church, Tropical Lodge 56 Free & Accepted Masons, and a 32nd Degree Scottish Rite Mason. He completed his pre-pharmacy curriculum at Middle Tennessee State University before moving on to graduate from Mercer University's Southern School of Pharmacy in 1993. Dr Eidson stated that he is excited about the challenges and humbled and honored to be the governor's choice for this responsible position. The Board welcomes his return.

Check DEA Numbers at Input

As more prescribing practitioners are checking the Controlled Substance Monitoring Database (CSMD), concerns are growing in regard to the incorrect practitioner being entered into the computer prescription data field, and therefore being incorrectly reported to the CSMD. It is advised to alert all input staff about checking for the correct DEA number at input, as many prescribing practitioners have very similar, or many times, the same names.

Unregistered Technician Violations Continue

Recently, Board Executive Director Andrew Holt noticed the continued rise of unregistered technician registration violations. Pharmacists-in-charge and pharmacy technicians are advised to register and/or track and return renewal registrations upon receipt of notice. The Board staff has also stated that renewal notices may not be received if the most current mailing address has not been updated with the Board or if a forwarding address has not been put in place. It is advised to update mailing addresses (including e-mail addresses beginning January 1, 2013, if you opt for e-mail notification; see next article) with the Board. **Civil penalties may increase if pharmacy technicians continue to be found working with an expired registration or with no initial registration.**

E-mail Option Shall Be Added for Future Board Notifications

As of January 1, 2013, the Tennessee Board of Pharmacy 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. For purposes of notice of any meeting where changes are to be considered, the electronic notice shall be at least 45 days in advance of the meeting, unless it is an emergency meeting, then the notice shall be sent as soon as is practicable. Once this statute takes effect, it is advised that all registrants keep e-mail addresses updated with the Board. Instructions on this process will be forthcoming. For more information on Public Chapter 952, visit <http://tnsos.org/acts/PublicActs.107.php>. Use code 0952 and choose "public chapter" in the drop-down field.

Declaration of Citizenship Added to Application Process for Professional Licensure

As of October 1, 2012, all applicants 18 years of age or older, applying for professional licensure with the Tennessee Board of Pharmacy, must complete the Declaration of Citizenship form, found as part of the application process located on the Board Web site. The application form may also be viewed at <http://health.state.tn.us/Downloads/PH-4183.pdf>. For information on the Systematic Alien Verification for Entitlements program mentioned on the application, visit www.dhs.gov/xlibrary/assets/privacy/privacy_pia_uscis_save.pdf.

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:

- ◆ January 16-17, 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 Brenda S. Warren – President
Dr Charles (Buddy) Stephens – Vice President
Dr Jason S. Kizer – Board Member
Dr Nina Smothers – Board Member
Dr William J. Bunch – Board Member
Dr Kevin Eidson – Board Member
Ms Joyce McDaniel – Public Member

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Brenda S. Warren, DPh, CHC - Tennessee Board of Pharmacy
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