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Tennessee Board of Pharmacy News

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Tennessee Board of Pharmacy March 2012 Meeting Date Changed

The Tennessee Board of Pharmacy meeting date for March 21-22, 2012, located in the Poplar Room at 227 French Landing, Nashville, TN, **has been moved to March 6-7, 2012, and will be held in the Iris Room,** also located at the address of 227 French Landing.

Law Books Now Available

The Tennessee Board of Pharmacy 2011 Edition Law Book is currently available for sale. The price is $14, which includes shipping and handling. Please submit your request in writing along with a check or money order payable to the Tennessee Board of Pharmacy, and mail to the Tennessee Department of Health, Health Related Boards, Tennessee Board of Pharmacy, 227 French Landing, Suite 300, Nashville, TN 37243

Understanding the Correct Transfer for 'Office Use'

Pharmacists have often asked how to follow the proper procedures when transferring a medication to another pharmacy or prescribing practitioner. Please note that the only place in the Tennessee Board of Pharmacy rules that mentions "office use" is in Rule 1140-06-.02 (5), which states " . . . A nuclear pharmacy practice site may also furnish radiopharmaceuticals for office use to authorized practitioners for individual patient use . . . "

Therefore, what is allowed? Refer to Tennessee Board of Pharmacy Rule 1140-09-.01, which states:

> " . . . (3) The requirement of a license [referring to a Manufacturer/Wholesaler license] shall not apply to the following types of distributions . . . [*](i) The sale, purchase or trade of a prescription drug, or an offer to sell, purchase or trade of a prescription drug by a pharmacy practice site to another pharmacy practice site or to authorized prescribing practitioners, except that the total gross dollar volume of such transfers shall not exceed five percent (5%) of the total medical and prescription orders sales revenue of either the transferor or transferee pharmacy during any twelve (12) consecutive month period . . . "

Therefore, instead of transferring pursuant to a **prescription for "office use only,"** pharmacists are advised to **invoice the medication or medical device** while complying with section (i), and hold this readily retrievable record for two years. In this manner, the medication can then be delivered to the prescribing practitioner's office or pharmacy.

Furthermore, the rules change/add when dealing with a **controlled substance.** For a Schedule II medication, Drug Enforcement Administration (DEA) Form 222 must be completed between the seller and buyer, while one copy is kept in the pharmacy for two years per Title 21, Code of Federal Regulations (CFR) 1307.11, which may be found at the following Web link: *www.deadiversion.usdoj.gov/21cfr/cfr/1307/1307_11.htm.* An invoice with the following information must also be kept for Scheduled III through V medication including the name, address, and DEA registration number of both parties, the name, strength, quantity, and dosage form of the drugs, and the date of the transaction, pursuant to CFR 1304.22. CFR 1304.22 may be found at the following Web link: *www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_22.htm*. It is advised to obtain a signature of each registrant on the invoice. This record must be kept for two years per DEA CFR 1304.04., found at the following Web link: *www.deadiversion.usdoj.gov/21cfr/cfr/1304/1304_04.htm.*

According to CFR 1307.11, the pharmacy must make certain that the distribution ". . . does not **exceed 5% of total dosage units** of controlled drugs dispensed and distributed during the same calendar year unless licensed as a distributor by DEA . . . " This regulation is in addition to the Tennessee Board of Pharmacy rule stated previously, which refers to **5% of total order sales revenue.** (See asterisked section of Rule 1140-09-.01 referenced at the beginning of this article.)

A Professional License Does Not Supercede Pharmacy Technician Rules in a Pharmacy Practice Site

Can a licensed veterinarian or nurse perform pharmacist or pharmacy technician duties by using his or her professional licensing credentials, (ie, doctor of veterinary medicine, registered nurse, or licensed practice nurse) in a pharmacy?

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FDA Recommends Use of Sterile Needle and Syringe for Administration of Inactivated Influenza Vaccines

Food and Drug Administration (FDA) recommends that health care providers use a sterile needle and syringe to administer inactivated influenza vaccines. The recommendation was released in response to questions regarding the use of jet injector devices to administer inactivated influenza vaccines. FDA advises that "inactivated influenza vaccines that are approved by FDA have information in their labeling stating how the vaccines should be administered, such as, by intramuscular (IM) or intradermal (ID) administration." Further, FDA clarifies its October 21, 2011 communication "to inform the public that inactivated influenza vaccines labeled for IM injection are intended for administration using a sterile needle and syringe. There is one inactivated influenza vaccine labeled for ID administration, this vaccine is supplied in its own pre-filled syringe. The live attenuated influenza vaccine is given through the nose as a spray; the sprayer is not a jet injector." FDA also notes the following:

- Currently, there is only one vaccine, Measles, Mumps, and Rubella (MMR), that is approved and specifically labeled for administration by jet injector.
- Safety and effectiveness information that would support labeling inactivated influenza vaccines for delivery by jet injector have not been submitted to FDA.
- At this time, there are no inactivated influenza vaccines that are approved and specifically labeled by FDA for administration by jet injector.

FDA recommends that all approved vaccines, including influenza, be administered in accordance with their approved labeling, and FDA advises that if a vaccine has been approved for administration with a jet injector, information specifically addressing vaccine use with a jet injector will appear in the vaccine labeling. Additional background information is available in the communication posted on the FDA Web site at *www.fda.gov/BiologicsBloodVaccines/Vaccines/QuestionsaboutVaccines/ucm276773.htm.*

The Centers for Disease Control and Prevention continues to encourage people to get vaccinated throughout the flu season, which can begin as early as October and last as late as May. For information about the flu vaccine visit *www.cdc.gov/flu.*

'Tell Back' Works Best to Confirm Patient Understanding

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.*

In the past few years, multiple studies have demonstrated that patients often leave medical encounters with a poor understanding of their health conditions and recommended treatment. One recent study on this subject demonstrates the low level of understanding patients have about follow-up care and medication therapy upon discharge from the emergency department (Engel KG et al. Patient Comprehension of Emergency Department Care and Instructions: Are Patients Aware of When They Do Not Understand? Ann Emerg Med. Available on the journal Web site).

Given the importance of patient understanding of medical information, there are surprisingly few studies that point out how to approach this task. However, a study published in 2008 offers some insight into what approach to assessing understanding of medical information patients most prefer and perceive to be the most effective (Kemp EC, et al. Patients Prefer the Method of "Tell Back-Collaborative Inquiry" to Assess Understanding of Medical Information. J Am Board Fam Med 2008;21(1):24-30). Researchers tested three types of inquiry about the patient's understanding:

- Yes-No
- Tell Back-Directive
- Tell Back-Collaborative

The Yes-No approach asked closed-ended questions to assess patient understanding. (Example: "I've given you a lot of information. Do you understand?") The Tell Back-Directive method used open-ended questions that were physician-centered and paternalistic in that it was clear authority and control still remained with the physician. (Example: "It's really important that you do this exactly the way I explained. What do you understand?") The Tell Back-Collaborative approach used open-ended questions that were patient centered, making it clear that power and responsibility were shared between the health care provider and patient. (Example: I imagine you are really worried about your blood pressure. I've given you a lot of information. It would be helpful to me to hear your understanding about your clot and its treatment.)

Patients showed a significant preference for the Tell Back-Collaborative inquiry over other tested approaches. Because of the potential for embarrassment if patient misunderstandings are exposed, one might anticipate health care providers' reluctance to put patients "on the spot" with open-ended questions. But a collaborative approach to Tell Back allows the patient to save face for misunderstandings by acknowledging the large amount of information being provided. Patients might also view the request for Tell Back as evidence of the health care provider's care and concern for them personally, or evidence of the provider's attention to detail and competence. So, when counseling patients about their medications, instead of asking "Do you have any questions?" or "Do you understand?" ask them to restate their understanding of the information you provided in their own words within a shame-free, blame-free environment.

DEA Clarifications on Certification Process for Audits of EPCS Software

Drug Enforcement Administration (DEA) emphasizes that third-party audits of software applications for Electronic Prescriptions for Controlled Substances (EPCS) must encompass all applicable requirements in DEA regulations, including security, and must address "processing integrity" as set forth in the regulations. Further, DEA recommends that where questions or gaps may arise in reviewing a particular applica-

tion, federal guidelines set forth in National Institute of Standards and Technology Special Publication 800 – 53A should be consulted. DEA has also announced the first DEA-approved certification process for EPCS. Certifying organizations with a certification process approved by DEA pursuant to the regulations are posted on DEA's Web site at *www.deadiversion.usdoj.gov/ecomm/e_rx/thirdparty.htm#approved*. Detailed background information is provided in the Federal Register Notice, available for download at *www.gpo.gov/fdsys/pkg/FR-2011-10-19/pdf/2011-26738.pdf*.

'Script Your Future' Provides Tools and Outreach to Encourage Medication Adherence

United States Surgeon General Regina Benjamin called upon pharmacists, physicians, nurses, and other health care providers to talk with their patients about the importance of taking medications as directed to help prevent serious health complications at the recent launch of the national campaign, "Script Your Future." Benjamin also "encouraged patients with chronic conditions to speak with their health care professionals about their medication" as noted in a press release. A survey released by the National Consumer League, the organization that developed Script Your Future, indicates that "patients who do not always take their medication as directed are less likely to have received a full explanation of the consequences of their condition, and are less convinced of the importance of adherence." The Script Your Future campaign is targeting six regional areas with outreach activities and advertising, and more information is available at *www.ScriptYourFuture.org*. The campaign brings together "stakeholders in health care, business, and government to offer practical tools for patients to help them better adhere to their medication, and to help health care professionals better communicate with patients." More information about the campaign is available in a press release at *www.prnewswire.com/news-releases/us-surgeon-general-joins-baltimore-launch-of-the-national-script-your-future-campaign-to-highlight-importance-of-taking-medication-as-directed-133077423.html*.

FDA Releases 'Use Medicines Wisely' Video

FDA Office of Women's Health has released a new public service announcement (PSA) video titled, "Use Medicines Wisely," to help raise awareness about safe medication use. As stated in an FDA news release, "Millions of people benefit from FDA approved medications and are living longer productive lives. However, when medications are used incorrectly, they can cause serious injuries, even death. Many of these injuries can be prevented."

The video shows simple steps women can take to use medications wisely. Viewers are reminded to:

- Make a list of the medications they take
- Keep their medication list with them at all times
- Know the name of each medication, why they are taking it, how much to take, and when to take it
- Talk with their doctor, nurse, or pharmacist to find out how to safely use their medications

In addition to the video, a medications record-keeper, fact sheets, and other safe medication use resources are available on the FDA Web site.

Training Video Provides Tips on Preventing Pharmacy Robbery

Rx Pattern Analysis Tracking Robberies and Other Losses (RxPATROL) has released a training video discussing pharmacy robbery and how to prevent it. The video features a pharmacist and law enforcement liaison as they tour a pharmacy, evaluating security measures and discussing additional steps that can be taken to prevent robbery. RxPATROL is an initiative designed to collect, collate, analyze, and disseminate pharmacy theft intelligence to law enforcement throughout the nation. RxPATROL is designed to gather and disseminate critical information to help protect pharmacists, guard against potential robberies, and assist law enforcement in their efforts to successfully apprehend and prosecute those involved in controlled substance pharmacy crime. The training video can be accessed on the RxPATROL Web site at *http://rxpatrol.org/TrainingVideos.aspx*.

Nearly 20 Products Marketed as Natural Supplements Contain Sibutramine, FDA Warns

FDA has posted public warnings regarding 19 products, frequently marketed as natural supplements, and found to contain sibutramine, a controlled substance that was removed from the US market in October 2010 for safety reasons. These products pose a threat to consumers because sibutramine is known to substantially increase blood pressure and/or pulse rate in some patients and may present a significant risk for patients with a history of coronary artery disease, congestive heart failure, arrhythmias, or stroke. These products may also interact in life threatening ways with other medications a consumer may be taking. FDA warnings included products marketed as "Slender Slim 11," "Dream Body Slimming Capsule," "Acai Berry Soft Gel ABC," and 16 other product names. The products included in the warnings are being sold on Web sites and in some retail stores. FDA advises consumers not to purchase or use the products listed in the warnings. Consumers who have purchased any of these products should stop use immediately. And if consumers have experienced any negative side effects from using these products, they should consult a health care provider as soon as possible. The complete list of warnings is available on the FDA Web site at *www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm234592.htm*.

2012 Survey of Pharmacy Law Now Available

Serving as a convenient reference source for individuals seeking an overview of the state laws and regulations that govern pharmacy practice, the updated 2012 *Survey of Pharmacy Law* is now available and can be purchased online for $195 by visiting the NABP Web site at *www.nabp.net/publications*.

The *Survey,* produced in a CD format, consists of four sections including a state-by-state overview of organizational law, licensing law, drug law, and census data. Newly added this year, a question in Section 17, Wholesale Distributor Licensure Requirements, asks which state agency has regulatory authority over medical device distributors. In addition, a newly added question in Section 22, Electronic Transmission of Prescriptions: Computer-to-Computer, asks whether the state allows electronic prescribing of controlled substances.

Updates for the 2012 *Survey* were graciously provided by the state boards of pharmacy. In addition to the boards' support, NABP requested data from relevant health care associations for the *Survey's* prescribing authority and dispensing authority laws in Sections 24 and 25, and laws pertaining to the possession of non-controlled legend drugs and possession of controlled substances in Sections 26 and 27.

All final-year pharmacy students receive the *Survey* free of charge through the generous grant of Purdue Pharma L.P.

For more information on the *Survey,* please contact Customer Service via phone at 847/391-4406 or via e-mail at custserv@nabp.net.

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Reference the following definitions located in Tennessee Code Annotated 63-10-204:

(30) "Pharmacist" means an individual health care provider licensed by the state of Tennessee, pursuant to parts 4-6 of this chapter, to practice the profession of pharmacy;

(32) "Pharmacy" means a location licensed by this 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;

(33) "Pharmacy intern" means an individual enrolled in or a graduate of a recognized school or college of pharmacy under rules established by the board who is serving a period of time of practical experience under the supervision of a pharmacist, as defined in the rules of the board;

(34) "Pharmacy technician" means an individual who is specifically trained and designated to assist pharmacists in the practice of pharmacy; . . .

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

(1) Any person acting as a pharmacy technician shall register with the board by submitting an application on a form prescribed by the board. The applicant shall also:

(a) Provide a statement of good moral character;

(b) Submit an affidavit from his/her employer attesting that the applicant has read and understands the statutes and regulations pertaining to the practice of pharmacy in Tennessee. (A copy of this affidavit shall be retained at the place of employment);

(c) Submit the appropriate application fee as set in Board of Pharmacy Rule 1140-01-.10.

Therefore, if another licensee/registrant of the state wishes **to "assist pharmacists in the practice of pharmacy," he or she must be licensed as a pharmacist, registered as a pharmacy technician, or classified as a pharmacy intern by the Tennessee Board of Pharmacy.** (Pharmacy technician duties may be found at the following Web link under the Tennessee Board of Pharmacy Rule 1140-02-.02: *www.state.tn.us/sos/rules/1140/1140-02.20100323.pdf.)*

PSE – Who May Enter Information into the NPLEx?

For this answer, refer to Tennessee Code Annotated 39-17-431(d):

" . . . **The pharmacist, pharmacy technician, or pharmacy intern shall maintain an electronic record of the sale under this subsection (d) and the record may be maintained in the form of a pharmacist prescription order as provided by §63-10-206(c).** The electronic record shall include the name and address of purchaser; name and quantity of product purchased; date and time purchased; purchaser identification type and number, such as driver license state and number; and the identity, such as name, initials or identification code, of the dispensing pharmacist or pharmacy intern. If a system is not able to record the identification type and number, the pharmacist, pharmacy technician, or pharmacy intern shall write the identification type and number on the prescription order. The electronic record shall also be maintained in a manner that allows for the determination of the equivalent number of packages purchased and total quantity of base ephedrine or pseudoephedrine purchased . . . "

Therefore, since the National Precursor Log Exchange (NPLEx) system is currently holding the electronic records for the purchase of the pseudoephedrine (PSE) or ephedrine, **only pharmacists, pharmacy interns, and pharmacy technicians, recognized as such by the Tennessee Board of Pharmacy, are to record the required data into the NPLEx system.**

Federal Regulations Place Carisoprodol in Schedule IV Category

As previously accomplished on April 7, 2011, by the Tennessee Legislature, DEA has now issued a final rule, placing carisoprodol into Schedule IV of the Controlled Substances Act, effective January 11, 2012. The DEA notice (PDF) regarding the final rule includes a summary of the background and procedural history of the final rule and a detailed review of the data considered in determining whether the drug should be scheduled. The notice was published in the *Federal Register* on December 12, 2011. For the Tennessee statute regarding this issue, please refer to the following Web link: *www.nabp.net/publications/assets/TN062011.pdf.*

Background Checks Required to Provide Patient Care

Per order of Public Chapter 1084, section (f), as stated below, the Tennessee Board of Pharmacy is reminding all registrants of this statute requiring registry checks before the hiring of employees as directed.

Tennessee Code Annotated 63-1-149, Registry Check

(a) On and after October 1, 2010, before employing or contracting with any person who would be providing direct patient care, for whom a background check has not been completed, a health care professional licensed under any chapter of this title or title 68, chapters 24 and 140, shall initiate and perform a "registry check" which for the purposes of this section is defined as:

(1) A state-by-state look in any state in which the person has lived in the previous seven (7) years of the national sex offender public registry website coordinated by the United States department of justice, including, but not limited to, the sexual offender registry maintained by the Tennessee bureau of investigation pursuant to title 40, chapter 39, part 2; and

(2) Any adult abuse registry maintained for any state in which the person has lived in the previous seven (7) years; and

(3) The department of health's elder abuse registry established pursuant to title 68, chapter 11, part 10.

(b) Should an applicant be listed on any of the registries listed in subdivisions (a)(1)-(3), the health care profes-

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sional shall not employ or contract with the person if the person would be providing direct patient care.

(c) A health care professional who complies with the requirements to perform registry checks under subsection (a), or relies on a documented representation provided by an entity with which the health care professional contracts that the person who will work in the office is not on any of these registries, shall not be subject to civil or criminal liability solely based upon the information provided through a registry check under this section. This immunity shall extend to a claim related to the professional's refusal to employ or contract with a person based on information obtained from a registry check.

(d) This section is not intended to apply to contracted, external staff who provide such services as cleaning services, maintenance of office or medical equipment or other services where direct patient contact is not intended.

(e) This section shall not apply to health care professionals licensed chapter 12 of this title.

(f) The department of health shall post no later than October 1, 2010, in a conspicuous location on its website as well as the website of each applicable licensing board a link to all potential databases the health care professional would be required to check pursuant to subsection (a). In addition, each applicable licensing board shall notify all of its licensees at least annually through board newsletters of their obligations under this section.

Next DEA Drug Take-Back Day Set for April 28, 2012

Please review the following link to obtain information about the upcoming DEA Drug Take-Back Day for your area: *www.deadiversion.usdoj.gov/drug_disposal/takeback/index.html*.

New Web Link and Upgrade Planned for the Controlled Substance Monitoring Database

After March 14, 2012, pharmacists and prescribing practitioners are advised to navigate to the new Controlled Substance Monitoring Database (CSMD) Web link located at *www.TNCSMD.com*. Users that access the current site will be redirected to the new Web link when it becomes available.

The new Web link and software upgrade are expected to allow for faster searches with increased and more accurate results when narrowing the search by adding more information in each field when necessary. It is still advised to start with a broader search and adjust accordingly. For more information about the database, please contact the CSMD Administrator at CSMD.admin@tn.gov or 615/253-1305.

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:

- **March 6-7, 2012 Board Meeting:** Iris Room – 227 French Landing
- **May 16-17, 2012 Board Meeting:** Poplar Room – 227 French Landing
- **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/default.aspx*.

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

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