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Tennessee Board of Pharmacy News

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Board Approved Five Million Dollar Civil Penalty from NECC and Former PIC

Nearly two years ago on October 15, 2012, after several Tennessee patient illnesses and deaths were reported in conjunction with sterile products compounded by an out-of-state pharmacy, a consent order was executed for the voluntary surrender of the Tennessee pharmacy license held by the New England Compounding Center (NECC), located at 697 Waverly Street, Framingham, MA. Also, Barry James Cadden, former pharmacist-in-charge (PIC) and part owner of NECC, agreed to the surrender of his Tennessee pharmacist license, which was accepted and completed by the Board on October 23, 2012.

During the May 12, 2014 meeting, William West, legal counsel for respondents Paul D. Moore, Chapter 11 Trustee of the Estate of New England Compounding Pharmacy, Inc, dba New England Compounding Pharmacy, Inc, and Cadden, agreed to a $5 million civil penalty levied by the Tennessee Board of Pharmacy on behalf of itself and the Division of Health Related Boards. **(Under the terms of the consent order, all victims' claims are to be settled before any assessments are collected by the Board.)** The civil penalty assessments included violations for the following statutes and Board rules.

Tennessee Code Annotated:

- 63-1-134(a) Penalty for violation of statute, rule or order -- Recovery. (". . . authorized by any board, commission or agency attached to the division of health related boards, each respective board, commission or agency may assess a civil penalty against such person in an amount not to exceed one thousand dollars ($1,000) for each separate violation of a statute, rule. . .")
- 63-10-305. Power of board to suspend, revoke, or refuse to issue licenses -- Civil penalties.
- 63-1-144. Payment of costs of investigation and prosecution.

Tennessee Board of Pharmacy Rules:

- 1140-01-08 Application for Pharmacy Practice Site, Manufacturer and Wholesaler/Distributor Licenses.
- 1140-03-.08 Repackaging.
- 1140-03-.03 Medical and Prescription Orders.
- 1140-03-.14(8). Pharmacist-In-Charge. (Board notification of termination of business)
- 1140-03-.14(14) Pharmacist-In-Charge. (PIC shall report prescription order that caused serious personal injury or death)
- 1140-03-.06 Labeling Requirements.
- 1140-07-.06 Labeling.

Upon this agreement, Cadden and the bankruptcy court agreed that "Any and all licenses granted by the Board to NECC or Mr. Cadden shall be deemed to be irrevocably voluntarily surrendered; . . ." as stated in the executed consent order.

Professional Privilege Tax Reminder

All professional privilege tax returns, which were due June 1, 2014, must be filed electronically. Taxable professionals holding an active license in Tennessee must pay the $400 tax. More information on Tennessee's professional privilege tax may be found online at *www.tn.gov/revenue/tntaxes/proftax.shtml.*

Top Five Board Violations Noted

Following the Board directive to educate registrants on continuing issues presented for disciplinary action, Executive Director Reggie Dilliard reported the top five complaints brought to the Board.

1. Patient counseling (prescription and pseudoephedrine)
2. Pharmacy technician registrations (expired or never registered), affidavits, and technician registry documents maintained by the PIC
3. Readily retrievable records (if the PIC is not available, the pharmacist-on-duty should know where all documents, including Drug Enforcement Administration biennial inventory, invoices, technician registry, prescription records, etc, are)
4. Pharmacists/manufacturers/wholesaler-distributors unaware of requirements, including notification of relocation, recognizing board authority, opening oxygen locations without licensing, etc
5. Proper documentation of verbal orders (ie, they must be recorded completely with the initials of the pharmacist or certified pharmacy technician recorded per Board rule)

Fines and/or other discipline may increase if these issues continue to escalate. The Board advises all registrants to take note of these violations and correct these issues immediately to avoid additional consequences.

New USP Webpage Answers Common Questions About USP Chapters <795> and <797>

In response to questions concerning United States Pharmacopeia-National Formulary (USP-NF) General Chapters <795> and <797>, USP has created a new frequently asked questions (FAQs) page on its website. The FAQs answer questions related to the Revision Bulletin for Chapter <795> that was issued on November 22, 2013, and became official on January 1, 2014. Among other topics, the FAQs address common questions regarding beyond-use dating and the differences between testing stability with strength (potency) or stability-inducing methods. The FAQs can be accessed at *www.usp.org/support-home/frequently-asked-questions/compounding*. Question four on the page includes a link to a USP article, "Strength and Stability Testing for Compounded Preparations."

Only You Can Prevent Look-Alike Sound-Alike Drug Names

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 Error Reporting Program. Report online at* www.ismp.org. *E-mail: ismpinfo@ismp.org.*

VESIcare/Vesanoid Mix-Up. A prescriber's office sent an electronic prescription to the patient's pharmacy; the prescriber intended to prescribe **VESIcare®** (solifenacin succinate) for overactive bladder but inadvertently selected **Vesanoid®** (tretinoin), which is used to induce remission of acute promyelocytic leukemia. The pharmacy technician entered the prescription for generic tretinoin; however, the pharmacy was unable to dispense the medication as the patient's pharmacy benefit manager required a prior authorization. The technician faxed a request and the prescriber's office replied back that VESIcare was intended. Both of these products are available in 10 mg solid oral dosage forms, increasing the risk of confusion. Investigate strategies (eg, tall man letters) to differentiate these products on computer screens. Prescribers should include the indication for the drug with the prescription. As always, providing patient education, especially for new prescriptions, is a good strategy to intercept errors before they impact the patient.

Benazepril Confused With Benadryl. A pharmacist reported a mix-up between benazepril **(Lotensin®)** and **Benadryl®** (diphenhydramine). A patient faxed a request to the pharmacy to ask for her "benazapryl." The pharmacist who received the fax interpreted it as Benadryl and placed a bottle of diphenhydramine in the bag for pick-up. Around this same time, the pharmacy went through a change in wholesaler and many manufacturers of generic products were changed. A few days later, a coworker of the patient picked up the medication (along with several others). The technician at the point-of-sale told the coworker that many of the manufacturers had changed recently and that some of the pills may look different. The patient received the diphenhydramine, filled her medication box with the capsules, and took diphenhydramine daily for three weeks before noticing she was unusually tired. When she brought the bottle back to the pharmacy, the error was recognized.

ISMP continues to receive reports of confused drug name pairs being involved in errors. ISMP wants to inform its readers of these drug name confusions so they may continue evaluating what measures they have in place to protect against these possible confusions.

Your Help Is Needed With Product Safety Testing. If you are a pharmacist, nurse, pharmacy technician, or other health care practitioner who is interested in furthering medication safety and error prevention, you can make a difference! Med-ERRS (a subsidiary of ISMP) is looking for assistance to help evaluate medication labels, drug packaging, and proposed drug names prior to submission by pharmaceutical and biotech companies for approval by Food and Drug Administration (FDA). The process is fun, simple, and easy. A small honorarium is paid. For more information or to sign up, visit *www.med-errs.com* and click on "Become a Reviewer."

FDA Issues Alert on Acetaminophen Products

In light of all the recent news alerts and warnings about the use of acetaminophen and acetaminophen-containing products, FDA issued a recommendation of importance to pharmacists, prescribers, and patients.

FDA recommends that health care providers consider prescribing combination drug products that contain 325 mg or less of acetaminophen. FDA also recommends that when a pharmacist receives a prescription for a combination product with more than 325 mg of acetaminophen per dosage unit that he or she contacts the prescriber to discuss a product with a lower dose of acetaminophen. A two-tablet or two-capsule dose may still be prescribed, if appropriate. In that case, the total dose of acetaminophen would be 650 mg (the amount in two 325 mg dosage units). When making individual dosing determinations, health care providers should always consider the amounts of both the acetaminophen and the opioid components in the prescription combination drug product.

FDA, in its MedWatch Safety Alert, reports that, "There are no available data to show that taking more than 325 mg of acetaminophen per dosage unit provides additional benefit that outweighs the added risks for liver injury. Further, limiting the amount of acetaminophen per dosage unit will reduce the risk of severe liver injury from inadvertent acetaminophen overdose, which can lead to liver failure, liver transplant, and death."

In January 2011, FDA asked manufacturers of prescription combination drug products containing acetaminophen to limit the amount of acetaminophen to no more than 325 mg in each tablet or capsule by January 14, 2014. FDA requested this action to protect consumers from the risk of severe liver damage that

can result from taking too much acetaminophen. More than half of manufacturers have voluntarily complied with FDA's request. However, some prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit remain available. In the near future, FDA intends to institute proceedings to withdraw approval of prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit that remain on the market.

Boards of pharmacy have received inquiries from pharmacists about remaining stock of the higher dose acetaminophen and what procedures should be followed. The FDA recommendation notes that pharmacists are advised to contact prescribers and request a change in the prescription. If the prescriber is not willing to make the change in the prescription, unfortunately, there is no clear cut recommendation at this point as to whether to dispense the higher dose acetaminophen product. It would appear that the higher dose acetaminophen-containing products will be regarded by FDA as unapproved and delisted from FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations,* commonly known as the "Orange Book." Until this occurs, pharmacists must make a judgment regarding continuing to dispense the higher dose acetaminophen containing products in light of the FDA recommendation and concern for patient safety.

Some Rohto Eye Drops Products Recalled

The Mentholatum Company of Orchard Park, NY, has issued a voluntary recall of some Rohto® eye drop products due to a manufacturing review at the production facility in Vietnam involving sterility controls. The recall has been issued at the retail level and includes Rohto Arctic, Rohto Ice, Rohto Hydra, Rohto Relief, and Rohto Cool eye drops that were manufactured in Vietnam. Products made in other facilities are not affected by the recall. To date, there has been no evidence indicating the recalled products do not meet specifications, according to a press release.

The recalled products are sold over the counter at pharmacies and retail stores throughout the United States, and can be identified by the words "Made in Vietnam" on the side carton panel under the company name and address information as well as on the back label of the bottle. Lot numbers for the recalled products contain the letter "V." Distributors and retailers are being notified by letter to stop distributing the products and to follow the recall instructions provided by the company. Questions about the recall can be directed to The Mentholatum Company at 877/636-2677, Monday through Friday, 9 AM to 5 PM Eastern Time. FDA urges consumers and health care providers to report any adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program. More information is available at *www.fda.gov/Safety/Recalls/ucm382076.htm.*

FDA Provides Compounding Law Implementation Information

FDA has provided implementation information on Title I of the recently passed Drug Quality and Security Act – known as the Compounding Quality Act – through its website.

Of note, FDA specifies that compounding entities may register as an outsourcing facility, which, under certain conditions, may be exempt from the Federal Food, Drug, and Cosmetic Act's (FD&C Act) approval and labeling requirements. Drugs produced by compounders that are not registered as outsourcing facilities must meet the conditions of Section 503A of the FD&C Act, which was amended by the new law, to qualify for certain exemptions.

The document adds, "If a compounded drug does not qualify for exemptions under either section 503A or 503B of the [FD&C Act], the compounded drug would be subject to all of the requirements of the [FD&C Act] that are applicable to drugs made by conventional manufacturers, including the new drug approval and adequate directions for use requirements." FDA also notes it will provide additional information about how the agency will interpret certain provisions of Section 503A at a later date.

The implementation information may be viewed at *www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm.*

New e-LTP Fees Effective July 1, 2014

Supporting ongoing efforts to protect the integrity of its licensure transfer programs and to support the expansion of new technologies that are being implemented to enhance the program, the National Association of Boards of Pharmacy® (NABP®) is adjusting the fees for the Electronic Licensure Transfer Program® (e-LTP™).

Beginning July 1, 2014, the e-LTP fees will be adjusted as follows:

- The preliminary application and first state transfer fee will increase from $350 to $375
- Each additional state transfer will increase from $50 to $75
- Change of states will increase from $50 to $75
- Time extensions will increase from $50 to $75

The fees for e-LTP were last adjusted in 2010. More information about e-LTP is available in the Programs section of the NABP website at *www.nabp.net.* Additional questions about the fee adjustment may be directed to Neal Watson, licensure programs manager, at 847/391-4406, or at nwatson@nabp.net.

Collaborative Pharmacy Practice Adopted as Law in Tennessee

With an overwhelming House vote of 98-0 and Senate vote of 32-0, the Tennessee General Assembly voted unanimously to give Tennessee-licensed pharmacists the ability to enter into collaborative pharmacy practice agreements with prescribers to improve the health, safety, and quality of care for their patients.

According to the Tennessee Pharmacists Association, studies have consistently shown that patient health improves significantly when pharmacists work in collaboration with physicians and other health care providers to manage the care of patients. In the past, the Pharmacy Practice Act has included the ability to obtain a "medical order" for vaccines, medication therapies, and other patient care services. On April 29, 2014, Governor Bill Haslam signed this bill into law as Public Chapter (PC) 832. PC 832 becomes effective on July 1, 2014, and it defines collaborative pharmacy practice as follows.

Section 3. Tennessee Code Annotated, Section 63-10-204, in part:

> . . . [amended]( ) "Collaborative pharmacy practice" is the practice of pharmacy whereby one (1) or more licensed pharmacists licensed in this state, jointly and voluntarily work with one (1) or more prescribers licensed in this state, under a collaborative pharmacy practice agreement to provide patient care services, to achieve optimal medication use and desired patient outcomes. . .

Furthermore, collaborative pharmacy practice agreement is defined as follows.

> ( )"Collaborative pharmacy practice agreement" is a written and signed agreement entered into voluntarily between one (1) or more licensed pharmacists in this state, and one (1) or more prescribers licensed in this state, each of whom is in active practice in this state providing patient care services in this state, that provides for collaborative pharmacy practice, as defined by law. . .

Furthermore, according to Section 4, Tennessee Code Annotated, Title 63, Chapter 10, Part 2 (amended), the Board will promulgate rules as stated in part:

> . . . 63-10-217 (g) The board of pharmacy, in collaboration with the board of medical examiners and board of osteopathic examination, shall promulgate rules establishing appropriate minimum standards applicable for provisions to be contained in any collaborative practice agreement, including, but not limited to, provisions regarding drugs or drug categories such as controlled substances covered under the collaborative pharmacy practice agreement. . .

For the complete amendment and PC, see the next article (below) for instructions.

New Restrictions on Pseudoephedrine Set to Take Effect on July 1, 2014

After a long and spirited debate between members of the House and the Senate relative to increased regulations on ephedrine- and pseudoephedrine-containing products (House Bill No. 1574/Senate Bill No. 1751), both houses remained divided regarding this legislation. The House and Senate appointed a Conference Committee pursuant to motions to resolve these differences. The Conference Committee recommended an amended piece of legislation, which was then passed by both the House and the Senate and signed by Governor Haslam on May 14, 2014.

Just recently posted as PC 906, this legislation amends Section 39-17-431(c), and becomes effective on July 1, 2014. Furthermore, it mandates the following changes to quantity limits for behind-the-counter sales of pseudoephedrine and implements these new age restrictions:

1. Restricts behind-the-counter sales of ephedrine or pseudoephedrine base, or their salts, isomers, or salts of isomers to the same person to 5.76 grams in any period of 30 consecutive days, or 28.8 grams in any one-year period.
2. Prohibits an individual from purchasing products containing ephedrine or pseudoephedrine base, or their salts, isomers, or salts of isomers in an amount more than 5.76 grams per person in any period of 30 consecutive days, or 28.8 grams in any one-year period. (Therefore, if a person wants to buy 5.76 grams every month, he or she will only be able to purchase this amount five months out of any one-year period.)

Note: Be advised that the federal daily limit of 3.6 grams per day and 9 grams per month is still in place as found in the following web link: *http://thomas.loc.gov/cgi-bin/cpquery/?&dbname=cp109&sid=cp109djs6R&refer=&r_n=hr333.109&item=&sel=TOC_358801&>.*

These quantity restrictions:

- **Apply** to pharmacist-generated prescription orders of the product pursuant to §63-10-206. The provision of patient education and counseling as a part of the practice of pharmacy shall be required when any product is issued under this subsection (c).
- **Apply** to the total amount of base ephedrine and pseudoephedrine contained in the products and not the overall weight of the products.
- **Apply** regardless whether one form of identification required in this subsection (d) is used to make the purchase or if two or more forms of identification required in this subsection (d) are used to purchase the products.
- **Do not apply** to a person who obtains the product or products pursuant to a valid prescription issued by a licensed health care practitioner authorized to prescribe by the laws of the state.

This new law also specifies that there shall be no protocol or procedure mandated by any individual or corporate entity that interferes with the pharmacist's professional duty to counsel and evaluate the patient's appropriate pharmaceutical needs and the exercise of the pharmacist's professional judgment as to whether it is appropriate to dispense medication as set forth in the law.

3. Age Restrictions: No person under 18 years of age may purchase a product that contains any immediate methamphetamine precursor, except pursuant to a valid prescription issued by a licensed health care practitioner authorized to prescribe by the law of the state or a pharmacist-generated prescription issued pursuant to §63-10-206.

Note: Any prescription issued from a pharmacist is subject to the limits described above. A person over the age of 18 can continue to make a purchase for an individual 18 years of age or younger, such as a parent purchasing for a child.

For complete PC information on both of these bills, visit the Tennessee Department of State, Division of Publications website at *http://tnsos.org/acts/PublicActs.108.php?showall.* To access the final versions of these bills, follow the link. Once on the page, locate the box at the top left of the

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screen entitled "Look for," enter the bill number (Collaborative Practice: SB1992, or Pseudoephedrine: HB1574), choose "Bill Number" in the "Select Field" drop-down box, and click "Search."

Attention Stakeholders! Comments Requested for USP Chapter Regarding the Handling of Hazardous Drugs

According to United States Pharmacopeia (USP) website information, USP General Chapter <800> Hazardous Drugs–Handling in Healthcare Settings, has been drafted and is now open for comments. All stakeholders are urged to read and respond before the closing date of July 31, 2014. This chapter addresses many aspects of compounding hazardous medications, including sterile/nonsterile preparations, dispensing, storing, and facility design. Several Tennessee pharmacies are currently remodeling compounding areas to meet USP standards. This chapter may cause those plans to be adjusted.

Please navigate to the following websites for additional information: *www.usp.org/sites/default/files/usp_pdf/EN/m7808.pdf* and *www.usp.org/usp-nf/notices/compounding-notice.*

Compounding Sterile Fee Modifier Now Due for Some

As noted in the previous Board *Newsletter,* and located on the Board website, a sterile compounding fee is now in effect. If a registrant is currently practicing sterile compounding, and the pharmacy license is due to renew in the year 2015 or later, the $250 fee is due now. If the pharmacy renewal is to take place this year (2014), the fee is due at the time of renewal. Send payment to: HRB/Tennessee Board of Pharmacy, 665 Mainstream Drive, Nashville, TN 37243.

Compounding Sterile Product Mandated Quarterly Reporting Sample and Gap Analysis Tool Now Available on Board Website

In the emergency Board rules, quarterly reports are required for Tennessee licensed pharmacies practicing sterile compounding. Exemptions are noted in the rule below.

Furthermore, the Board has adopted a gap analysis to be used as a tool to help all sterile compounding sites better understand their strengths and weaknesses and to help these sites educate themselves for Board inspections to applicable USP and best practice standards. Pharmacy investigators are currently educating and informing registrants of the gap analysis on an annual basis as part of the inspection process. It may be downloaded from the following web link: *http://health.state.tn.us/boards/pharmacy/PDFs/GAP%20analysis%2003122014.pdf.*

As stated in Tennessee Board of Pharmacy Emergency Rule 1140-07-.02, in part,

> (4) Any licensed pharmacy which compounds sterile products, except hospital pharmacies compounding for inpatients of a hospital, shall submit to the Board of Pharmacy, on a quarterly basis, a report listing the quantity of sterile products compounded and dispensed during the previous quarterly period and any other information as required by USP standards.
>
> (a) Quarterly reports submitted pursuant to this paragraph shall be submitted by the 15th day of the month following the end of each calendar quarter.
>
> (b) In any calendar year where any one of the above dates fall on a weekend or official state holiday, all quarterly reports due on that date shall be submitted on the following business day.
>
> (c) The format for reports submitted pursuant to this paragraph shall be determined by the Board of Pharmacy through policy and made available to the public on the Board of Pharmacy's website.

To view the sample report, navigate to the following site: *http://health.state.tn.us/boards/pharmacy/PDFs/Sample%20Interim%20Product%20Reporting%20for%20Drug%20Compounding%20Facilities.pdf.*

The information may be mailed directly to the Board office or attached and e-mailed to Investigator Terry Grinder at Terry .Grinder@tn.gov.

Board 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 reminds licensees that the Mandatory Practitioner Profile Questionnaire for Licensed Health Care Providers must be completed and updated as information changes. A copy of the Mandatory Practitioner Profile Questionnaire may be found at *http://health.state.tn.us/Downloads/g6019027.pdf.*

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

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 bi-monthly meetings in Nashville, TN. The following dates are scheduled for 2014 (The address is 665 Mainstream Drive, Nashville, TN 37243):

- July 7, 2014, Iris Room
- July 30-31, 2014, Iris Room
- September 10-11, 2014, Poplar Room
- November 5-6, 2014, Iris Room

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

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