



Tennessee Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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New Officers Are Elected for 2014 Term as Stephens Steps Down

During the January 2014 Tennessee Board of Pharmacy meeting, Dr Charles (Buddy) Stephens finished his term as president stating that “we’ve had a really good Board.” Stephens conveyed that it had been a memorable year and that Dr Terry Grinder (former acting director for the Board) said (laughingly) that “he talked to me more than all other presidents combined!” Stephens also stated that he thought the Board had made a very good choice in selecting Dr Reggie Dilliard as the new executive director for the Board, as well as in hiring three additional investigators to help increase regulation of sterile compounding pharmacies. Stephens thanked Assistant Commissioner Michelle Long for her assistance with these accomplishments.

As for his replacement, Dr Jason Kizer was voted as president and Dr Nina Smothers as vice president. Their terms started immediately, as Dr Kizer presided over the January meeting.

Board Promulgates Applicable USP Standards for Sterile Compounding While MWDs Are Licensed Separately

With emergency rules effective January 31, 2014, all Tennessee-licensed pharmacies and pharmacists are required to follow the most current version of applicable United States Pharmacopeia (USP) guidelines when compounding sterile products.

As revised, Rule 1140-01-.01 (39) states “. . . ‘USP standards’ means any applicable standard or standards published in the most current version of United States Pharmacopeia National Formulary [USP-NF] guidelines, to the extent that such guidelines do not conflict with state law, rules, or Board Policy Statements and as those guidelines may, from time to time, be amended. . . .”

Currently, Board investigators are utilizing USP-NF General Chapter <797>, Edition 2012, to reference and educate registrants on the new guidelines.

Also, as stated in emergency rule, the Board has designed an educational tool known as gap analysis, which will soon be available for pharmacists’ review. According to Board Vice President Nina Smothers, the analysis is designed to help pharmacy employees in assessing their sterile compounding pharmacy practice for strengths and weaknesses in regard to USP Chapter

<797> and other best practices. “We want the Gap Analysis to be an open book test for the pharmacist,” Smothers said. Board investigators plan to work from a modified form, built from questions used in the gap analysis, to inspect for sterile compounding regulation compliance.

The emergency rules, which also include fee increases for all Board registrants, and other pertinent rule changes may be viewed at http://state.tn.us/sos/rules_filings/01-17-14.pdf.

Fee increases are viewable on the Board website at http://health.state.tn.us/boards/pharmacy/PDFs/FeeIncrease_EffectiveJanuary31.pdf.

Modifier fees are added for pharmacies that are compounding sterile products and manufacturers and wholesalers/distributors (MWDs) that are manufacturing, wholesaling, or distributing sterile products.

Also included in the emergency rules, **the wholesaler/distributor is now being licensed separately from the manufacturer.**

In the next six months, final rules are to be promulgated by the Board, as the emergency rules will become replaced at that time.

Board and Department of Health Share Sterile Compounding Lessons Learned

Chief Medical Officer for the Tennessee Department of Health David Reagan, PhD, MD, and former Acting Director and current USP Sterile Compounding Investigator Trainer Terry Grinder, DPh, discussed lessons learned over the last year. Many of these same topics are covered in the USP 35 Chapter <797> sterile compounding section. This summary includes:

1. Sterile Process
 - a. The process to ensure appropriate sterile technique should be clearly documented, and staff authorized to perform sterile compounding should be appropriately trained and observed performing the standard process routinely as a part of their ongoing authorization to compound.
 - b. Protective apparel should be available and used appropriately to allow maintenance of sterility during operations; no makeup or jewelry should be worn.

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Changes to Fentanyl Pain Patch Warnings Required by FDA

To reduce the risk of accidental exposure, Food and Drug Administration (FDA) has announced new requirements that change the appearance of fentanyl pain patch warnings to make them more visible. The change also requires new language in the warning that emphasizes the risk of death from accidental exposure, particularly in children. The announcement coincided with a Consumer Update that stressed the potential danger of improperly discarded fentanyl patches to children and pets. FDA reminded consumers of the agency's previous advice for securely storing unused patches and disposing of used fentanyl patches by folding the sticky sides together and then flushing them down the toilet. The agency also advises patients to cover in-use patches with an adhesive film to keep them from coming loose, and to regularly check patches to ensure they are securely in place. FDA offers additional information for health care providers on the "Fentanyl Transdermal System (marketed as Duragesic) Information" page, available at www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm114961.htm. Consumer information about safe drug disposal methods is also available on the AWARE_xE[®] Web site at www.AWARERX.ORG.

New: Free ISMP Medication Safety Alert! Newsletter for LTC Facilities

 *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 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 July, ISMP began publishing *Long-Term Care Advise-ERR*, a new *ISMP Medication Safety Alert!* newsletter for nurses and administrators in long-term care (LTC) facilities. ISMP receives error reports that have occurred in LTC facilities. The newsletter is provided free to LTC facilities in the United States thanks in part to corporate sponsorship from Lilly and for a nominal sub-

scription fee for pharmacies that service LTC facilities and others. Please visit ISMP's Web site at www.ismp.org/Newsletters/longtermcare for more information, and let your LTC facilities know about this free offer.

Here are a few excerpts from a recent issue.

Immediate Vs Extended Release Error

A physician called a LTC facility to change a resident's oxycodone order from an extended-release formulation to an immediate release formulation at the same dose and frequency. The nurse receiving the verbal order transcribed it as "Discontinue OxyContin 10 mg BID, Start OxyContin 10 mg IR BID," with "IR" meant to represent immediate release. Although OxyContin[®] is a brand of oxycodone, it is only available as an extended-release tablet. The pharmacy had previously been dispensing OxyContin for the resident, so the nurse thought she could communicate the prescriber's order by discontinuing the current OxyContin order and then ordering OxyContin as an immediate-release product. The pharmacy continued dispensing OxyContin. The differences between these products and formulations were brought to the attention of nursing staff via an in-service. To minimize the risk of confusion, do not attach modifiers such as "IR" for immediate-release or "RS" for regular strength unless it is part of the official drug name.

Errors Occur During Transitions of Care

A pharmacist reported the following hazardous situation that can occur during a hospital to LTC transfer. Residents are often admitted to a LTC facility with a list of medications printed from the hospital pharmacy computer. On these printouts, doses are expressed along with the number of tablets. For example, the printout may list hydrochlorothiazide 50 mg/2 tablets daily for an order in which the total dose was 50 mg because the hospital only stocks the 25 mg tablets. During hospitalization the patient required two tablets for each dose; however, the LTC nurse may misinterpret the order to mean two 50 mg tablets, making the total dose 100 mg, or two times more than prescribed. This issue arises every time the resident's total dose in the hospital requires more than one tablet or capsule. Discharge medication summaries and transfer orders should only list the total dose in mg or mcg and other directions for use (ie, frequency, route, drug name) to avoid misinterpretation.

2013 USP Chapter <797> Compliance Survey Shows Compliance Trends Unchanged From 2012

The 2013 United States Pharmacopoeia (USP) Chapter <797> Compliance Survey, the third annual report released since 2011, shows that the overall compliance rate of 77.2% remains nearly unchanged from the 2012 rate. Budgetary restrictions and physical plant limitations were among the top challenges to compliance by survey respondents. The report also details the



Compliance News to a particular state or jurisdiction should not be assumed as representing the law of such state or jurisdiction.)

survey's findings on what types of facilities are participating in compounding, and compliance in specific domain areas such as environmental sampling and gloved fingertip sampling. Of the survey's 1,045 participants, 97% of the survey's respondents said that USP Chapter <797> "has had a positive influence on patient safety." The report notes National Association of Boards of Pharmacy® (NABP®) efforts to assist state boards of pharmacy in evaluating pharmacy compliance with USP Chapter <797> requirements for sterile compounding in their states. The report also noted that those who participated in the 2011 survey had a higher compliance score than those who did not. The survey's authors encouraged pharmacy owners with multiple areas of noncompliance to target one or two areas to improve. They also encouraged organizations that participated in the survey to make use of the free Action Plan – generated upon completion of the survey – and other free resources to "reshape" their sterile compounding practices. The full report on the survey's results is available in the October 2013 issue of *Pharmacy Purchasing & Products Magazine* and on the magazine's Web site at www.pppmag.com/article/1403.

FDA Recommends Schedule II Classification for Hydrocodone Combination Products

FDA planned to submit a formal recommendation to reclassify hydrocodone combination products as Schedule II controlled substances to the Department of Health and Human Services by early December 2013. FDA expects the National Institute on Drug Abuse to concur with the recommendation, indicates a statement on the FDA Web site. FDA also indicates that while "the value of and access to these drugs has been a consistent source of public debate," the agency has "been challenged with determining how to balance the need to ensure continued access to those patients who rely on continuous pain relief while addressing the ongoing concerns about abuse and misuse." Drug Enforcement Administration makes the final decision about the appropriate scheduling of these drugs. In January 2013, FDA's Drug Safety and Risk Management Advisory Committee made a recommendation that hydrocodone combination products be classified as Schedule II drugs following a 19-to-10 vote that concluded a two-day meeting during which members discussed the potential for abuse and misuse of the medications and the potential impact of rescheduling the drug products. FDA's statement on the recommendation is available at www.fda.gov/Drugs/DrugSafety/ucm372089.htm.

New FDA Drug Info Rounds Training Videos Available

FDA Drug Info Rounds, a series of online 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 two Drug Info Rounds videos, pharmacists discuss the review and approval of new drug names and the review of marketing and advertising materials for new drugs. The videos can be viewed at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm368620.htm and www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm371785.htm, respectively. 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.

CPPA Developing Specialty Pharmacy Accreditation Program

The Center for Pharmacy Practice Accreditation® (CPPA) has announced the development of a new accreditation program for specialty pharmacy practices. CPPA Executive Director Lynnae Mahaney, MBA, RPh, FASHP, VHA-CM, indicates that "CPPA will be able to develop the new specialty pharmacy standards quickly and efficiently with the existing standards development methodology, infrastructure, and network of specialty pharmacy expertise."

CPPA is a partnership between the American Pharmacists Association, the American Society of Health-System Pharmacists, and NABP. CPPA develops and implements comprehensive programs of pharmacy practice site accreditation, including the promotion, development, and maintenance of principles, policies, and standards. CPPA offers the general public and users of pharmacy services a means of identifying those pharmacies that satisfy the accreditation criteria and are focused on advancing patient care, safety, and quality.

More information may be found in the press release, available at www.pharmacypracticeaccredit.org/news/2013/10/cppa-to-develop-specialty-pharmacy-accreditation-program.



Pharmacists & Technicians:
Don't Miss Out on Valuable CPE Credit.
Set Up Your NABP e-Profile and Register for CPE Monitor Today!

Continuing pharmacy education (CPE) providers who are accredited by the Accreditation Council for Pharmacy Education (ACPE) have integrated CPE Monitor® into their systems and are requiring pharmacists and pharmacy technicians to provide a National Association of Boards of Pharmacy® (NABP®) e-Profile ID number and date of birth (MMDD) in order to process ACPE-accredited CPE credit.

Visit www.MyCPEmonitor.net to set up your NABP 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.

- c. Equipment coming in contact with sterile product must be sterile. Careful attention to sterile surfaces, including gloves, hoods, and other equipment, is essential.
 - d. Sterile equipment or supplies are usually supplied in packaging whose outside is nonsterile. Proper handling of the nonsterile packaging is essential to maintenance of a sterile field.
 - e. Manipulation of compounded sterile products following any sterilization step(s) should be minimized so as to not to introduce any risk of contamination. Final product sterilization should be the last step in the compounding process, or as close to the last step in product preparation as possible.
 - f. Careful attention is needed to environmental control measures and should include ongoing monitoring and recording of pressure differentials from the cleanest to clean to dirty rooms as applicable.
2. Labeling, Storage, and BUD
- a. Product should be clearly labeled with beyond-use dates (BUD) and storage specifications, based on USP Chapter <797> risk levels and the appropriate storage conditions (room temperature, refrigerated, or frozen) as well as product testing (unless product is prepared in batches of 25 or less).
 - b. Sterile products may not be packaged in a manner labeled or implied as multi-patient use. The term “multi-dose vial,” when applied to injectable medication, is reserved for Food and Drug Administration (FDA)-approved manufactured products using FDA-approved labels.
 - c. Repackaging of manufactured injectable medications (eg, dividing a manufacturer-supplied single-dose or single-use vial into syringes) requires clear labeling and packaging to facilitate product trace-back.
 - d. Lot numbers should be specific for product, product formulation, date, and batch.
3. Preservative-Free Medication Formulation Considerations
- a. Preservative-free medication should only be used for a single patient (ie, single package, single-dose vial)
 - b. Please refer to USP Chapter <797> to determine BUDs, but for high-risk preservative-free medication, the BUD established should not exceed three days when sterility testing is not performed.
4. Quality Assurance and Equipment Maintenance
- a. Thoroughly document successful completion of sterilization steps, such as use of an autoclave.
 - b. Autoclaves should have documentation of load configuration studies, biological indicators, and parameters (temperature, time, and pressure).
 - c. For those compounding over 25 doses of medication in a batch, testing of sterility of product that has been formulated for distribution is needed, with a clear documentation chain.
- d. A clearly documented process should be in place to guide and monitor equipment cleaning, maintenance, and use.
 - e. Quality control information falling outside of expected values must be immediately assessed and remedied, including removal of unused product from all potentially affected lot(s) from distribution.
 - f. Media-fill test procedures should be performed under conditions that closely simulate the most challenging or stressful conditions encountered when compounding high-risk products.
 - g. Procedures for receiving and investigating complaints must be in place, operating in a timely way, and well documented.
 - h. Rejected components or products should be sequestered from other components.
5. Record Keeping
- a. All relevant information regarding the compounded product should be well documented. Such records should be easily retrievable (and preferably electronically maintained) for at least two years from the last date dispensed.
 - b. Linkage between lot numbers and distribution (eg, invoices) and significant process records (eg, autoclave, sterility testing records, and operator) must be created, maintained, and easily retrievable.
- Pharmacies operating outside FDA registration as manufacturers are not permitted to supply compounded sterile product (including repackaged products) to a third party such as a distributor or sales agent.

Compounding Sterile Product Inspections Bring ‘Ah Ha’ Moments

While learning USP standards, a few other “ah ha” moments were discovered by Board investigators. These tips might be helpful for the sterile compounder to review.

- ◆ When compounding sterile products, **sterile** gloves are to be used as opposed to simply spraying with isopropyl alcohol (IPA).
- ◆ Alcohol is to be **sterile** IPA.
- ◆ The waterless alcohol-based surgical hand scrub, used to disinfect hands during the hand hygiene process, should have “persistent activity.”
- ◆ Straight from USP 35 Chapter <797> Appendices, “. . . Sterile 70% IPA wetted gauze pads or other particle-generating material **shall not** be used to disinfect the sterile entry points of packages and devices. . .”
- ◆ When cleaning and disinfecting the compounding area, eg, laminar flow hoods, etc, “items shall be removed from all areas to be cleaned, and surfaces shall be cleaned by removing loose material and residue from spills, e.g.,

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water-soluble solid residue are removed with **Sterile Water (for injection or irrigation) and low-shedding wipes. . .**”

- ◆ And last but not least, regarding bulk or unformulated drug substances and added substances or excipients (also known as API or active pharmaceutical ingredient), compounding facility personnel shall mark **the date received on the packaged ingredient**. And, if a package does not have a supplier’s expiration date listed on the package, the product is only to be used for **one year** from the date received unless tested for purity and quality as stated in USP Chapter <797>.

MWDs Will Soon Report ARCOS Data to the Board

Pursuant to Public Chapter 430, which was signed into law by Governor Bill Haslam on May 16, 2013, all Tennessee-licensed MWDs of controlled substances (CS) must regularly submit a report in Automation of Reports and Consolidated Orders System (ARCOS) format to the Board. This data report includes all Schedule II through V CS distributed to Tennessee licensees. **Be advised that this law does not apply to a pharmacy unless it also holds a separate MWD license.**

MWD licensees seeking instructions on how to comply with this new law and other information about Public Chapter 430 can send an e-mail to tn.arcos@tn.gov. Additional instructions detailing reporting procedures will be sent via e-mail to the responsible party identified on the account registration form once the reporting system is in place.

MWDs that do not wholesale or distribute CS (including tramadol-containing products) to a licensee of the Tennessee Department of Health should complete an exemption form found at http://health.tn.gov/apps/ARCOS/ARCOS_%20Exemption_Form.pdf and return via e-mail to tn.arcos@tn.gov. Questions may be answered by sending an e-mail to tn.arcos@tn.gov.

Pharmacies Are Reminded to Complete Bedside Delivery Attestation if in Business Model

As more questions arise in regard to bedside delivery of medications to hospital rooms, it is important to remember Board policy and to fill out the attestation form located at <http://health.state.tn.us/boards/Pharmacy/PDFs/PH-4201.pdf>, also located on the Board website.

The Board has voted to allow bedside delivery of medications to patients of a hospital when the following conditions are met and approval has been received from Board staff:

1. 100% of patients are counseled (two-way video technology is acceptable, but a backup plan must be in place for technology failure to maintain compliance with this requirement);
2. Patient choice of pharmacy provider must be maintained;
3. Delivery must occur by certified pharmacy technician, pharmacist, or pharmacy intern;
4. Chain of custody must be direct from pharmacy to patient (may not be left with hospital staff);

5. CS prescriptions must be transmitted to the pharmacy by the hospital
 - ◆ The certified pharmacy technician must transport the hard-copy prescription to the pharmacy unless a properly formatted, Drug Enforcement Administration compliant e-prescription is transmitted
 - ◆ The pharmacy may not dispense until the hard copy is compared to the transmitted copy; and
6. A process must be in place to handle patient complaints.

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 must be completed and updated as information changes. The website to obtain a copy of the Mandatory Practitioner Profile may be found at <http://health.state.tn.us/Downloads/g6019027.pdf>.

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

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 2014 (address is 665 Mainstream Drive, Nashville, TN 37243):

- ◆ March 11-12, 2014, Iris Room
- ◆ May 28-29, 2014, Poplar 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.

Tennessee Board of Pharmacy Members

Dr Jason S. Kizer – President
Dr Nina Smothers – Vice President
Dr William J. Bunch – Board Member
Dr Mike Dickenson – Board Member
Dr Kevin Eidson – Board Member
Dr Charles Stephens – Board Member
Ms Joyce McDaniel – Public Board Member

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