March 2016

Vermont Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

Vermont Secretary of State, Office of Professional Regulation, Board of Pharmacy
89 Main Street, Third Floor • Montpelier, VT 05620-3402 • *http://vtprofessionals.org*

CPE Monitor

CPE Monitor® is a collaborative service from the National Association of Boards of Pharmacy® (NABP®) and the Accreditation Council for Pharmacy Education (ACPE) that provides an electronic system for pharmacists and pharmacy technicians to track their completed continuing education (CE) credits. It also streamlines reporting and compliance verification for boards of pharmacy.

The Vermont Board of Pharmacy has access to information from registered users of CPE Monitor. Any pharmacist or pharmacy technician with an NABP e-Profile will automatically have information from ACPE-accredited programs uploaded to CPE Monitor. Effective with the July 1, 2017 licensing cycle, the Board will access CE information through the CPE Monitor system. What does this mean for licensees? If a licensee is randomly chosen by the Board for a CE audit, he or she will no longer need to provide copies of CE certificates to the Board, provided the CE programs are ACPE-accredited programs and tracked through CPE Monitor.

It is important to note that the Board also accepts programs approved for American Medical Association Category 1 CE as well as Board-approved programs. These CE programs do not upload to CPE Monitor. If a licensee has obtained credits from these providers, he or she will need to continue to provide the Board with copies of CE certificates.

Although the Administrative Rules of the Vermont Board of Pharmacy do not mandate CE requirements for technicians, CE credits are required by the Pharmacy Technician Certification Board (PTCB) for recertification. Pharmacy technicians may also register for CPE Monitor by creating an NABP e-Profile.

You may create your NABP e-Profile by visiting the NABP website at *www.MyCPEMonitor.net* and clicking on the link "Log in to Your e-Profile to Access CPE Monitor."

Technician Certification in Vermont

The latest administrative rules revision, effective September 15, 2015, includes significant changes to Part 5, Pharmacy Technicians. The technician rule change will be effective with the next biannual registration cycle on July 1, 2017.

The rules now make a distinction between a "pharmacy technician" and a "certified pharmacy technician," and outline the duties that may be performed by each technician category, as shown below.

A *certified pharmacy technician* may, under the supervision of a pharmacist:	**A *pharmacy technician* may, under the supervision of the pharmacist:**
Receive new written or electronic prescription drug orders, enter prescription data	Receive requests for refills of current prescriptions
Compound	Process medical coverage claims
Assist in the dispensing process	Perform inventory responsibilities
Perform all functions allowed to be performed by pharmacy technicians	Cashier

Effective July 1, 2017, each individual performing the activities listed under certified pharmacy technician must be registered with the Board as a "certified pharmacy technician." This will require the technician to have attained certification through a national pharmacy technician certification process. The Board will accept certification obtained through PTCB. All resources needed for this process can be found on the PTCB website at *https://www.ptcb.org*.

Any technician seeking to register as a "certified pharmacy technician" on July 1, 2017, who is not already

continued on page 4

Discontinue Use of Chen Shwezin Sterile Drug Products, FDA Warns

In October 2015, the United States Food and Drug Administration (FDA) issued a statement alerting health care providers and patients not to use drug products intended to be sterile that were made and distributed by Chen Shwezin, Inc, dba Park Compounding Pharmacy of Westlake Village, CA, because of lack of sterility assurance. Following an FDA inspection during which investigators observed unsanitary conditions, including poor sterile production practices, FDA recommended that Park Compounding Pharmacy cease sterile operations and recall all of its non-expired sterile drug products. However, the company had refused to recall its products, according to an FDA safety alert.

At this time, FDA has not received reports of any adverse events associated with the use of products from Park Compounding Pharmacy. FDA recommends that health care providers check their medical supplies, quarantine any sterile drug products from Park Compounding Pharmacy, and not administer them to patients.

More information is available in the FDA safety alert, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm465582.htm.*

Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!

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 Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

This is the final article of a three-part series on seven persistent safety gaffes of 2014.

6) Compounded Pain Creams: High Profit Margin and Danger

Some compounding pharmacies have been heavily marketing compounded pain creams directly to consumers via unsolicited calls, suggesting that the creams are more effective and safer than oral or injectable pain medications. Many of the creams contain drugs that can cause central nervous system depression or adverse cardiac effects, and most have not been FDA-approved for use in combination with each other or for topical use. Patients are charged per ingredient, with many creams containing numerous, expensive medications. Toxicity from the creams has been reported to poison control centers, including cases of accidental child exposures and intentional use for multiple family members. Patients are often unaware of the dangers with using the creams, which include unsafe packaging in containers without child-resistant closures. ISMP is specifically concerned about some statements that may be unproven, such as the products' safe use with children. Compounded pain creams need prominent warnings on labels that describe the potential for toxicity, and physicians and pharmacists who prescribe and dispense the creams must provide patients with instructions about possible adverse effects, safe storage, and proper use. ISMP believes regulatory or licensing oversight is necessary.

7) Clear Care: Still Causing Severe Eye Injuries Five Years Later

Since early 2010, ISMP has received scores of reports of painful eye injuries from patients using CLEAR CARE® Cleaning & Disinfecting Solution for contact lenses by Alcon (formerly CIBA VISION), a Novartis company, and similar store-brand products. Hundreds more can be found on Internet listservs. Located on store shelves near other lens disinfectants and solutions, these disinfecting products differ from other commonly used solutions in that they must be used with a special lens case in order to neutralize the 3% hydrogen peroxide component of the solution over at least six hours before putting the lenses back into the eyes. However, many patients have inadvertently used the solution to soak their lenses in a standard lens case, or thought the solution was saline and instilled it directly into their eyes. This has caused severe eye burning, leading many to seek out emergency medical care for corneal burns. In 2012, Alcon made a label enhancement to warn customers to use the special lens case, but the label change has been ineffective. Neither the company nor FDA's Medical Devices division have been persuaded to make effective label improvements before permanent eye injury or blindness occurs. If the labeling and packaging cannot be improved to reduce the harm being reported, perhaps these products should be pulled from the market or available only behind the pharmacy counter.

Risk of Dose Confusion and Medication Errors With Avycaz, FDA Cautions

Confusion about the drug strength displayed on the vial and carton labels has led to some dosing errors with the intravenous antibacterial drug Avycaz™ (ceftazidime and avibactam), warned FDA in September 2015. The agency explained that Avycaz was initially approved with the vial and carton labels displaying the individual strengths of the two active ingredients (2 g/0.5 g); however, the product is dosed based on the sum of the active ingredients (2.5 g). To prevent medication errors, FDA revised the labels to indicate that each

vial contains Avycaz 2.5 g, equivalent to ceftazidime 2 g and avibactam 0.5 g, according to an FDA safety alert.

As of September 2015, FDA had received reports of three medication error cases related to confusion on how the strength was displayed on the Avycaz vial and carton labels. Two cases stated that the errors occurred during preparation of the dose in the pharmacy. The third case described concern about the potential for confusion because the strength displayed for Avycaz differs from how the strength is displayed for other beta-lactam/beta-lactamase drugs. Based on the information provided in the reports, FDA is aware that at least one of the patients received a higher-than-intended dose of Avycaz. As of September 2015, no adverse events were reported.

More details are included in the FDA safety alert, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463595.htm.*

US Compounding, Inc, Recalls All Lots of Sterile Compounded Products

In September 2015, US Compounding, Inc, of Conway, AR, issued a voluntary recall of all lots of sterile products aseptically compounded and packaged by the company, and that remain within expiry, because of a lack of sterility assurance. The affected sterile products were distributed nationwide to patients, providers, hospitals, and clinics between March 14, 2015, and September 9, 2015. The recall does not apply to any nonsterile compounded medications prepared by US Compounding. Providers are advised to discontinue use of the products, quarantine any unused product, and contact US Compounding to arrange the return of any unused sterile compounded products using the information provided in the FDA press release, available at *www.fda.gov/Safety/Recalls/ucm464071.htm.*

The company issued this recall out of an abundance of caution. Providers who have dispensed any sterile product distributed by US Compounding should contact patients to whom product was dispensed and notify them of this recall. A list of all sterile compounded products that have been recalled is provided on FDA's website at *www.fda.gov/Safety/Recalls/ucm464072.htm.*

FDA Investigates the Risks of Using Pain Medicine Tramadol in Young Patients

As of September 2015, FDA is investigating the use of the pain medicine tramadol in young patients because of the rare but serious risk of slowed or difficult breathing. This risk may be increased in patients treated with tramadol for pain after surgery to remove their tonsils and/or adenoids. Tramadol is not FDA-approved for use in patients aged 17 years or younger; however, data show it is being used "off-label" in the pediatric population, according to the safety alert on FDA's website, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463499.htm.*

FDA is evaluating all available information and will communicate final conclusions and recommendations to the public when the review is complete. Health care providers are encouraged to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Decreased Potency Reported in Drugs Stored in Becton-Dickinson Syringes

In September 2015, FDA expanded its alert regarding compounded or repackaged drugs stored in Becton-Dickinson (BD) general use syringes to include certain additional syringe sizes including 1 mL, 10 mL, 20 mL, and 30 mL BD syringes, and BD oral syringes. FDA's original alert applied to compounded or repackaged drugs that have been stored in 3 mL and 5 mL BD syringes. The agency expanded the alert based on BD reports that an interaction with the rubber stopper in certain lots of these syringes can cause some drugs stored in these syringes to lose potency if filled and not used immediately. BD reports that the following drugs in particular can be affected by the stoppers, but it does not know whether other drugs can be affected: fentanyl, rocuronium, neostigmine, morphine, midazolam, methadone, atropine, hydromorphone, cisatracurium, and remifentanil. This safety alert does not pertain to BD prefilled, prefillable, heparin flush, saline flush, or insulin syringes, indicates BD in an alert notice. Further, BD's alert notice also has a search tool to assist customers in determining if their lots are affected. FDA advises hospital pharmacies and staff to contact any outsourcers to determine if affected lots of BD syringes were used for compounded or repackaged products. Hospital pharmacies and staff should not administer compounded or repackaged drugs that have been stored in any of these syringes unless there is no suitable alternative available. Adverse reactions may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program.

More details are included in the FDA Safety Alert, available at *www.fda.gov/Drugs/DrugSafety/ucm458952.htm.*

MediStat Pharmacy Issues Recall of Sterile Drug Products

MediStat Pharmacy, a 503B outsourcing facility in Foley, AL, has initiated a national recall of all sterile injectable products distributed between November 1, 2014, and September 3, 2015. The recall is based on the identification of various pathogens within the compounding environment. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from MediStat, and not administer them to patients. FDA has received reports of several adverse events that are potentially associated with the drug products made by MediStat. MediStat voluntarily ceased sterile compounding operations in September 2015. FDA asks health care providers and patients to report adverse reactions or quality problems experienced with the use of these products to the FDA's MedWatch Adverse Event Reporting program.

More details are included in an FDA press release, available at *www.fda.gov/Safety/Recalls/ucm461939.htm.*

National Association of Boards of Pharmacy Foundation
1600 Feehanville Drive
Mount Prospect, IL 60056

VERMONT BOARD OF PHARMACY

Presorted Standard
U.S. Postage
PAID
Chicago, Illinois
Permit No. 5744

continued from page 1

certified should initiate the certification process at this time in order to allow for study time and time for taking the examination.

Grandfather Clause

Based on feedback received by the Board during the rules revision process, an alternate and temporary route to certification has been established in the rules revision. This transitional process, or "grandfather clause," allows for a technician who has not completed a national certification to be registered as a certified pharmacy technician in Vermont, provided that:

a. As of July 1, 2017, the technician has been a Vermont-registered pharmacy technician in good standing with an unencumbered registration continuously since July 1, 2014;
b. The technician currently engages in the tasks reserved for certified pharmacy technicians under Rule 5.2(b); and
c. The technician applicant pays the applicable fee and submits an application. This application is to include:
    1. A detailed description of the certified pharmacy technician tasks that the applicant has engaged in, signed by both the applicant and the pharmacist manager or supervising pharmacist.
    2. Verification by the pharmacist manager or supervising pharmacist that the applicant currently performs those certified pharmacy technician tasks competently.

An important note: An individual who becomes a Vermont-certified pharmacy technician under the grandfather clause may continue to practice as a certified pharmacy technician only in that person's current pharmacy practice location and for that person's current employer. Registration with the Board as a Vermont-certified pharmacy technician under this rule will terminate with the cessation of practice at the registrant's current practice location or with the registrant's current employer.

You may access the administrative rules on the Board website at *https://www.sec.state.vt.us/media/702345/5-RX-Rules-2015-Final-Adopted-August-24-2015.pdf.*

Board Updates

Board Meetings

The Board meets on the fourth Wednesday morning of each month, with the exception of holiday periods, at the Office of Professional Regulation in Montpelier, VT. Board agendas and minutes are posted to the Board's website.

Board meetings are open to the public. The Board would particularly like to encourage any pharmacist or technician to attend. This is an excellent opportunity to share information and provide feedback on issues that are important to your practice. Reservations are not required. Upcoming meeting dates for 2016 are:

- ♦ March 23
- ♦ April 27
- ♦ May 25
- ♦ June 22
- ♦ July 27
- ♦ August 24

Administrative Rules Update

The most recent version of the administrative rules, effective September 15, 2015, is posted in the Statutes & Rules section of the Board's website at *https://www.sec.state.vt.us/professional-regulation/list-of-professions/pharmacy.aspx*. An annotated version of the rules is also posted on the website. The annotated version highlights the changes in the rules from the previous version (June 1, 2014).

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

Robert Enos, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Deborah Zak - Communications Manager