August 2018

News

Massachusetts Board of Registration in Pharmacy

Published to promote compliance of pharmacy and drug law

239 Causeway Street, 5th Floor • Boston, MA 02114 • *www.mass.gov/dph/boards/pharmacy*

Pharmacy Technicians-in-Training

As many of you are already aware, all pharmacy technicians-in-training are now required to have a license **before** working in a pharmacy. Regulation 247 Code of Massachusetts Regulation 8.00 was updated to track all persons training to become pharmacy technicians, and this new license type is generating a high volume of applications. Massachusetts Board of Registration in Pharmacy staff has been working diligently to process them in a timely manner, and the Board wants to assure its licensees that it will always do its best to expedite the process.

Until the trainee license has been obtained, new technician trainees may undertake training fundamentals as long as they do not require access to drugs or assist in the prescription filling process.

For example, in a retail setting, neither a license nor being counted in the staffing ratio is required while learning how to operate the cash register. Other potential actions that can be completed while awaiting a license would be learning the computer system, becoming familiar with company policies, Health Insurance Portability and Accountability Act training, and other company "start-up" procedures.

The Board apologizes in advance if the wait for any license is longer than expected. If an applicant has not received license verification after 7-10 days, please do not hesitate to contact the Board so that we can investigate your inquiry. As a reminder, technician trainees may take the licensure exam and apply for licensure after 500 hours, but must do so before the license expires. The technician-in-training license is valid for one year or 1,500 hours, whichever comes first.

Compounding of Copies of a Commercially Available Drug Product

Massachusetts General Law Chapter 112 Section 39D defines "compounding" as the preparation, mixing, assembling, packaging, or labeling of one or more active ingredients with one or more other substances in order to create a final drug preparation that meets a unique medical need of an individual patient. That compounded drug preparation must demonstrate a significant difference from the comparable commercially available drug and is required to meet a documented medical need as determined by the prescriber. This medical need must be noted on the prescription. Cost saving is not considered a "significant difference" to justify compounding. One example of permitted compounding would be a product that must be compounded without a preservative or other allergen for a specific patient's use.

Federal guidance, "Compounded Drug Products That Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act" also restricts the compounding of drug products that are essentially copies of a commercially available drug product. Food and Drug Administration (FDA) considers a compounded drug product to be essentially a copy of a commercially available drug product if:

1. The compounded drug product has the same active pharmaceutical ingredient(s) (API) as the commercially available drug product;
2. The API(s) have the same, similar, or an easily substitutable dosage strength; and
3. The commercially available drug product can be used by the same route of administration as prescribed for the compounded drug.

FDA does not consider a drug product to be commercially available if the approved product is no longer marketed or the drug product appears on the FDA drug shortage list. If the drug must be compounded due to one of these circumstances, the compounder should note on the prescription the reason for compounding as well as the date the shortage list was consulted.

Board staff has recently received inquiries on the compounding of oral vancomycin solution from injectable vials. Now that oral vancomycin suspension has been FDA approved and is a commercially available product, oral vancomycin should no longer be compounded.

Power Loss

It is advisable to establish and implement a contingency plan in the event of a power loss in the pharmacy. The plan should entail preventative measures and action plans to manage the power loss in order to facilitate a quick return to normal operation. Items to address include how to maintain critical operations (eg, computer systems), minimize inventory damage or

Continued on page 4

National Pharmacy Compliance News

August 2018

NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

DEA Launches New Tool to Help Distributors Make Informed Decisions About Customers

In February 2018, Drug Enforcement Administration (DEA) launched a new tool to assist drug manufacturers and distributors with their regulatory obligations under the Controlled Substances Act. The agency added a new feature to its Automation of Reports and Consolidated Orders System (ARCOS) Online Reporting System, a comprehensive drug reporting system that monitors the flow of controlled substances (CS) from their point of manufacture through commercial distribution channels to the point of sale at the dispensing/retail level. This newly added function will allow the more than 1,500 DEA-registered manufacturers and distributors to view the number of registrants who have sold a particular CS to a prospective customer in the last six months.

DEA regulations require distributors to both "know their customer" and to develop a system to identify and report suspicious orders. Manufacturers and distributors have asked DEA for assistance in fulfilling these obligations and have requested ARCOS information to help them determine if new customers are purchasing excessive quantities of CS. This new tool will provide valuable information for distributors to consider as part of their assessment. More details are available in a news release at *www.dea.gov/divisions/hq/2018/hq021418.shtml.*

PTCB Launches Certified Compounded Sterile Preparation Technician Program

In January 2018, the Pharmacy Technician Certification Board (PTCB) launched the PTCB Certified Compounded Sterile Preparation Technician (CSPT) Program. To be eligible to apply, a technician must:

- Be a PTCB certified pharmacy technician (CPhT) in good standing; and
- Have completed either a PTCB-recognized sterile compounding education/training program and one year of continuous full-time compounded sterile preparation work experience, or three years of continuous full-time compounded sterile preparation work experience.

To earn CSPT Certification, eligible CPhTs are required to pass the CSPT Exam and submit competency attestation documentation from a qualified supervisor. The two-hour, 75-question CSPT Exam covers hazardous and nonhazardous compounded sterile products in the four domains of:

- Medications and components (17%);
- Facilities and equipment (22%);
- Sterile compounding procedures (53%); and
- Handling, packaging, storage, and disposal (8%).

The purpose of the Attestation Form is to document the candidate's completion of required training and certain skill and competency assessments in such areas as aseptic technique, equipment cleaning, and use of personal protective equipment. More details about the CSPT Program are available on PTCB's website at *www.ptcb.org.*

DEA Enables Mid-level Practitioners to Prescribe and Dispense Buprenorphine

In January 2018, DEA announced a deregulatory measure that will make it easier for residents of underserved areas to receive treatment for opioid addiction. Nurse practitioners and physician assistants can now become Drug Addiction Treatment Act-Waived qualifying practitioners, which gives them authority to prescribe and dispense the opioid maintenance drug buprenorphine from their offices. This final rule took effect January 22, 2018. More details about DEA's amendments are available in a Federal Register notice titled "Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder" (Document Number: 2018-01173).

New CDC Training Offers CPE on Antibiotic Stewardship

The Centers for Disease Control and Prevention's (CDC's) Office of Antibiotic Stewardship is offering free continuing education opportunities for health care professionals. Focused on judicious antibiotic prescribing and antibiotic resistance, the online training is offered in four sections, each with multiple modules. Section 1 of the "CDC Training on Antibiotic Stewardship" is open now and can be accessed at *www.train.org/cdctrain/course/1075730/compilation*. Additional sections will be released throughout 2018. More information and resources about CDC's national effort to help fight antibiotic resistance and improve antibiotic prescribing and use are available on CDC's website at *www.cdc.gov/antibiotic-use/index.html.* CDC is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). This program meets the criteria for 0.258 CEUs of CPE credit. The ACPE Universal Activity Number is 0387-0000-18-031-H05-P.

Walmart to Provide Free Solution to Dispose of Medications With Schedule II Prescriptions

In partnership with Walmart, DisposeRx will provide a safe and easy way to neutralize unused, unwanted, or expired prescription opioids. DisposeRx developed a powdered product, also called DisposeRx, that permanently dissolves when mixed with water and sequesters excess opioids and other

drugs in a stiff, biodegradable gel that can be safely thrown in the trash. Walmart will provide a free packet of DisposeRx with every new Schedule II prescription filled at its 4,700 pharmacies nationwide. "This partnership with DisposeRx is an exciting opportunity for Walmart to protect the safety of its customers and public health. Unwanted or expired prescription medications left inside consumers' medicine cabinets can be an easy source for those seeking to misuse or abuse a prescription drug," said Pharmacy Clinical Services Manager for WalMart Health and Wellness and NABP Past President Jeanne D. Waggener, RPh, DPh. "We're not just making it easy for patients to safely dispose of their medications, but we're also helping prevent abuse before it starts." Additional information is provided in a January 17, 2018 news release titled "Walmart Launches Groundbreaking Disposal Solution to Aid in Fight Against Opioid Abuse and Misuse."

ASHP Research and Education Foundation Predicts Trends to Affect Pharmacy in 2018

In the 2018 Pharmacy Forecast: Strategic Planning Advice for Pharmacy Departments in Hospitals and Health Systems, the American Society of Health-System Pharmacists (ASHP) Research and Education Foundation provides guidance on eight topics that will challenge pharmacy practice leaders in hospitals and health systems. Published in the January 15, 2018 issue of American Journal of Health-System Pharmacy, the new report focuses on the following areas:

- Therapeutic innovation;
- Data, analytics, and technology;
- Business of pharmacy;
- Pharmacy and health-system leadership;
- Advanced pharmacy technician roles;
- Population health management;
- Public health imperatives; and
- Coping with uncertainty and chaos.

The 2018 report is available at *www.ajhp.org/content/75/2/23.*

USP Encourages Pharmacists to Help Patients Find Quality Dietary Supplements

Recall announcements, enforcement actions, and reports challenging the quality of dietary supplements are problematic issues facing pharmacists who want to ensure that the over-the-counter (OTC) products they are recommending to patients are of good quality. Many consumers purchase OTC dietary supplements and herbal products, often assuming they are regulated like prescription medications. While the law requires pharmaceuticals to meet specific quality standards set by the United States Pharmacopeial Convention (USP), the same requirements do not apply to supplements. For this reason, USP has created quality standards and a verification process specifically for these health products. Brands displaying the USP Verified Mark signal to the public that "what's on their label is what's in the bottle." Health care practitioners can learn more about USP's efforts at *www.usp.org/dietary-supplements-herbal-medicines.*

Further, USP Dietary Supplement Verification Services are available to manufacturers and brands worldwide. They include Good Manufacturing Practice facility auditing, product quality control and manufacturing product documentation review, and product testing. Manufacturers that are participating in USP's verification program for dietary supplements can be found at *www.usp.org/verification-services/program-participants.*

New CPE Monitor Subscription Plan Helps Pharmacists Track Compliance Via Mobile App

To help pharmacists easily monitor their CPE compliance, NABP partnered with the Accreditation Council for Pharmacy Education (ACPE) to develop CPE Monitor Plus, a subscription service for CPE Monitor®. Launched in April 2018, the new subscription service enables pharmacists to perform a variety of advanced functions beyond the basic CPE Monitor service, including:

- viewing CPE credit status by state to verify at a glance how much CPE credit must be earned to satisfy license renewal requirements;
- uploading certificates from non-ACPE CPE courses and applying them to relevant state licenses;
- receiving email alerts when CPE cycle deadlines are approaching;
- viewing all transcripts and individual courses and generating simplified, automated reports;
- searching for additional ACPE activities via ACPE P.L.A.N. (Pharmacists' Learning Assistance Network); and
- accessing ACPE CPD (Continuous Professional Development) via single sign on.

CPE Monitor Plus is available for an annual, renewable subscription fee of $29.95, regardless of how many licenses a pharmacist has or adds at a later date. CPE Monitor Plus is only available via NABP's new mobile app. Search for NABP e-Profile in Google Play Store (Android) or the App Store (iPhone).

The standard CPE Monitor service is still available for free and can also be accessed via the app or a desktop by signing in with NABP e-Profile login credentials.

For more information, visit *www.nabp.pharmacy/CPE.*

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their CPE credit electronically

Continued from page 1

loss (refrigerated/frozen products), as well as staff education on these procedures. The pharmacist manager of record should review the plan with all relevant staff and post it in an easily accessible location. Pharmacies should also develop a communication plan with other pharmacies, prescribers, and caregivers to maintain continuity of care during this time period.

If the power loss is relatively short in duration and the temperature of the room is not extreme, staff should refrain from opening the refrigerator and freezer units. Once power is restored, it is imperative to monitor temperature readings to determine if the stored medications have been exposed to out of range temperatures. If refrigerator/freezer storage conditions have been compromised and damage to the contents is suspected, the drug inventory must be evaluated for continued product integrity according to United States Pharmacopeia (USP) standards and Board policy.

The power loss may affect other systems and appliances within the pharmacy including the information technology system, telephones, automated dispensing systems, heating/air-conditioning, diagnostic equipment, and alarm systems. It is strongly advised to utilize a portable generator or a backup generator and verify which automated devices and equipment are supported by that generator. Generators should be tested monthly and maintained on a regular basis.

Pharmacies that engage in sterile compounding are advised to provide an uninterruptible source of power or backup generator for the clean room air handlers and primary engineering controls. CriticalPoint, LLC, recommends having previously established baseline and excursion levels for temperature, humidity, and nonviable particle count. The pharmacy should note the time of the power loss, limit access to the ISO controlled environments, and prevent introduction of additional sources of contamination to the compromised airflow. Once power is restored, the particulate counts should return to acceptable levels within 30 minutes, but pharmacies should maintain compliance with USP Chapter <797> requirements in regard to returning buffer rooms to 30 air changes per hour and temperature, humidity, and pressure differentials to acceptable ranges. A thorough cleaning of primary engineering controls as well as environmental monitoring should be performed in accordance with USP standards before resuming compounding activities.

Permitted Prescription Changes

The joint policy between the Drug Control Program and the Board that provides a list of changes and additions that pharmacies are permitted to make on prescriptions was updated in March 2018. Although the majority of information has stayed the same, a few additions and clarifications have been made.

After consultation with the **prescriber,** information that may be changed or added to **Schedule II** prescriptions now includes the supervising physician's name of a mid-level prescriber, "no substitution" language, and "partial fill upon patient request" language.

After consultation with the **prescriber or authorized agent,** information that may be changed or added to **Schedule III-VI** prescriptions now includes the supervising physician's name of a mid-level prescriber and "no substitution" language. Additionally, the days supply (eg, 30-day versus 60-day supply) may be changed after authorization, but only for Schedule VI drugs that do not require prescription monitoring program reporting.

Learn more about the policy.

Lau Kwan's Retirement

After 34 years of service, Lau Kwan, the Board's beloved administrative assistant, has retired. Her last day with the Board was May 31, 2018. As an important contributor to many of the Board's operations, Lau will be sorely missed around the office. In addition to her hard work, she was always friendly, helpful, and dedicated, and the Board will miss her pleasant disposition. Thank you and good luck, Lau!

Inquiries Received by the Board

In 2017, a total of 1,422 documented inquiries were received from stakeholders and the public. The average time of response to the inquirer, excluding outliers, was 40.31 hours and the median time was 24.26 hours. In addition to time required for research, the response times included non-business hours such as nights and weekends. The majority of the inquiries fell under the categories of licensing, nonresident licensing, controlled substances, continuing education, and general prescription questions.

Did You Know?

A quality-related event is defined as an improperly dispensed prescribed medication that includes any deviation from the prescription, including quantity errors. Incorrectly dispensed quantities of medications, including those of Schedule II drugs, should be added to the pharmacy's continuous quality improvement program for analysis.

Board Staff

David Sencabaugh, RPh.....Executive Director
Monica Botto, CPhT ..... Associate Executive Director
William Frisch, Jr, RPh..... Director of Pharmacy Compliance
Michelle Chan, RPh.....Quality Assurance Pharmacist
Heather Engman, JD, MPH ..... Counsel to the Board
Joanne Trifone, RPh ..... Director of Pharmacy Investigations
Ed Taglieri, RPh.....Pharmacy Substance Use Disorder Program Supervisor

The *Massachusetts Board of Registration in Pharmacy News* is published by the Massachusetts Board of Registration in 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.

David Sencabaugh, RPh - Executive Director
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Amy Suhajda - Communications Manager