April 2021

Virginia Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

Perimeter Center • 9960 Mayland Dr, Suite 300 • Henrico, VA 23233
Phone: 804/367-4456 • *www.dhp.virginia.gov/pharmacy*

Emergency Regulation Requires Registration of Pharmacy Technician Trainees

Effective January 3, 2021, emergency regulation 18 Virginia Administrative Code (VAC) 110-20-111(C) requires anyone enrolled in a pharmacy technician training program and performing the duties of a pharmacy technician to obtain registration as a pharmacy technician trainee. To be registered as a pharmacy technician trainee, a person will need to submit an application and fee to the Virginia Board of Pharmacy prior to performing the duties of a pharmacy technician. The registration will be valid for no more than two years provided the trainee is enrolled in a pharmacy technician training program and actively progressing toward completion. The regulations also require the pharmacy technician trainee to be directly supervised by a pharmacist who holds a current active license and assumes full responsibility for the supervision of the trainee. To obtain a registration, the applicant will need to apply online at *https://www.license.dhp.virginia.gov/apply.* The applicant must provide the information regarding their enrollment in a pharmacy technician training program and pay the associated fee for the registration.

Pharmacies allowing persons to perform the duties of a pharmacy technician without holding a pharmacy technician registration or pharmacy technician trainee registration may be subject to possible disciplinary action beginning July 1, 2021.

COVID-19 Vaccine

As more and more pharmacists are administering vaccines to combat the coronavirus disease 2019 (COVID-19), practitioners should be aware that error reporting for therapeutic products under an Emergency Use Authorization (EUA) is **mandatory.** For errors related to COVID-19 vaccines that are available under an EUA, reports must be sent to the Vaccine Adverse Event Reporting System. This reporting requirement includes vaccine administration errors, whether or not the error is associated with an adverse event.

Additionally, Centers for Disease Control and Prevention (CDC) reminds providers that the "COVID-19 Vaccine is Provided at 100% No Cost to Recipients," providers "must administer COVID-19 vaccine at no out-of-pocket cost to the recipient," and providers "may not charge an office visit or other fee if COVID-19 vaccination is the sole medical service provided."

The Virginia Department of Health is continuously updating important information on its website for health care professionals, including reimbursement guidance, vaccine clinic resources, provider resources, and patient education.

Alternate Delivery Requires Identification of All Pharmacies Involved in the Filling and Dispensing of Prescriptions

At its September 9, 2020 meeting, the Board voted 6:3 to withdraw its proposal for intended regulatory action, which would have eliminated a requirement for a pharmacy that is only holding a prescription for pickup or delivery to a consumer to be identified on the prescription label. Therefore, the current requirements in Regulations Governing the Practice of Pharmacy 18VAC110-20-275(B)(2) apply, which requires the identity of all pharmacies involved in the filling and dispensing to be captured on the prescription label. This includes a pharmacy that may only be holding the prescription for pickup or delivery to the consumer. The identity of the pharmacies on the prescription label shall be recorded in a manner that can be easily read and understood by the patient. Please refer to the regulation for other subjects that must be captured in the policy and procedure manual for each pharmacy participating in such a drug delivery system.

National Pharmacy Compliance News

April 2021

NABPF
National Association of Boards of Pharmacy Foundation

Guidelines, Materials Available to Health Care Providers for Safely Administering COVID-19 Vaccines

Guidelines and materials are available to support health care providers with safely administering the coronavirus disease 2019 (COVID-19) vaccine, including safe practice recommendations from the Institute for Safe Medication Practices (ISMP) and a United States Pharmacopeia (USP) toolkit.

After numerous reports of errors or hazards associated with the administration of COVID-19 vaccines, ISMP is sharing safe practice recommendations.

A new USP toolkit is also available to facilitate operational efficiencies that can help accelerate delivery and support safe handling of COVID-19 vaccines while maintaining quality and ultimately the public's trust. Download the USP toolkit.

FDA Issues Guidance to Protect Consumers From Methanol Poisoning

Food and Drug Administration (FDA) has issued guidance for industry, *Policy for Testing of Alcohol (Ethanol) and Isopropyl Alcohol for Methanol, Including During the Public Health Emergency (COVID-19).* The guidance is intended to help pharmaceutical manufacturers and pharmacists who engage in drug compounding to avoid using pharmaceutical alcohol contaminated with or substituted with methanol in drug products. FDA noted that methanol is not an acceptable ingredient for any drug product and should not be used. The guidance is available on the FDA website.

Standardize Concentrations for Oral Liquid Preparations

ISMP Institute for Safe Medication Practices An ECRI Affiliate

This column was prepared by ISMP, an ECRI affiliate. Have you experienced a medication error or close call? Report such incidents in confidence to ISMP's National Medication Errors Reporting Program online at www.ismp.org *or by email to ismpinfo@ismp.org to activate an alert system that reaches manufacturers, the medical community, and FDA. To read more about the risk reduction strategies that you can put into practice today, subscribe to the ISMP Medication Safety Alert! newsletters at* www.ismp.org.

Few would disagree that standardizing the concentrations of drugs has enormous potential for increasing safety, especially in pediatric care. Standardization limits the risk of variation, especially when patients are transitioned from hospital to home or have prescriptions filled at different pharmacies. However, ISMP has learned of multiple instances in which unrecognized differences or changes in drug concentrations led to confusion and dosing errors.

In one example, a patient was prescribed hydroxyurea, an antineoplastic agent. The community pharmacy compounded a 50 mg/mL suspension for the patient with instructions to take 13 mL (650 mg) for each dose. When the patient was later admitted to the hospital, the inpatient pharmacy prepared their standard concentration of 100 mg/mL, but the same dose volume of 13 mL was ordered. As a result, the patient received doses of 1,300 mg for several days before the error was recognized. It is unclear why the community pharmacy prepared a 50 mg/mL concentration. Perhaps the prescriber ordered that concentration or that was the concentration with which the pharmacist was most familiar.

Similar concentration mix-ups have been reported in literature. In one case, the oral class 1c antiarrhythmic medication flecainide was involved. The parents of a nine-month-old infant were told to increase the child's dose volume of flecainide to 4 mL, assuming the concentration was 5 mg/mL as in the original prescription.[1] However, the parents refilled the prescription at a different pharmacy and received the drug in a 20 mg/mL concentration. The patient received 80 mg/4 mL, a fourfold overdose, resulting in wide complex tachycardia and QRS prolongation.

There have been efforts, including those by a collaborative led by the University of Michigan[2]and the American Society of Health-System Pharmacists (ASHP)[3], to publish lists of consensuses and literature-based standard concentrations. In fact, for the medications involved in the cases above, both the University of Michigan and ASHP standard recommendations are in alignment – hydroxyurea 100 mg/mL and flecainide 20 mg/mL. However, the outreach and communication of these standardization efforts do not appear to be reaching prescribers and pharmacists. Both inpatient and outpatient practitioners need to get on the same set of standard concentrations for compounded oral liquids. It is imperative that both medical and pharmacy professional organizations develop and implement effective strategies to reach and influence practitioners to use the published standard concentrations. ISMP urges prescribers and pharmacists to review the University of Michigan and

ASHP lists and consider adopting the proposed standard concentrations. Your efforts can help reduce the risk of medication errors.

It is also important for pharmacists to provide patients or caregivers with appropriately sized metric-only dosing devices (eg, oral syringes) to measure and administer doses. Label directions for patients and caregivers should include the dose in terms of mL (not teaspoonfuls), matching the dosing device. The community pharmacy label should also include the concentration next to the drug name. To be sure patients or caregivers are able to use the dosing device and measure the proper dose, use the teach-back method to demonstrate how to measure and administer prescribed amounts. This also gives pharmacists, patients, and caregivers an opportunity to catch an error.

References

1. Wang GS, Tham E, Maes J, et al. Flecainide toxicity in a pediatric patient due to differences in pharmacy compounding. Int J Cardiol. 2012;161(3):178-9.
2. *www.mipedscompounds.org/*
3. *www.ashp.org/-/media/assets/pharmacy-practice/s4s/docs/Compound-Oral-Liquid.ashx*

Opioid Use Disorder Educational Programs, Resources Available for Pharmacists

Through its Opioid Use Disorder (OUD) Education Program, the College of Psychiatric and Neurologic Pharmacists (CPNP) provides educational programs and resources that can help pharmacists during the ongoing opioid epidemic. These educational opportunities include Accreditation Council for Pharmacy Education-approved, on-demand programs covering subjects such as pharmacotherapy for OUD, comorbid disorders, and chronic pain and OUD. Toolkits and guides are available to assist pharmacists in the areas of intervention, medication management, and naloxone access.

These educational materials and resources can be accessed through the CPNP website.

National Diabetes Prevention Program – How Pharmacists Can Get Involved

Pharmacists can play a key role in preventing type 2 diabetes by helping to expand the reach of the National Diabetes Prevention Program (National DPP) – a program led by the Centers for Disease Control and Prevention (CDC) that makes it easier for patients with prediabetes or who are at risk for type 2 diabetes to participate in evidence-based lifestyle changing programs to reduce their risk and improve overall health. CDC offers an action guide for community pharmacists that outlines ways pharmacies can raise awareness of prediabetes. The National DPP is a partnership among private and public organizations to screen and test for prediabetes and refer people with prediabetes to a CDC-recognized lifestyle change program participating in the National DPP, and deliver the National DPP lifestyle change program. More information about how pharmacists can participate is available on the CDC website.

Surgery Patients Receive More Opioids in the US Than in Other Countries

Patients in the US are prescribed a disproportionally higher number of opioids after surgeries compared to surgery patients in other countries, according to a new study. The study, published in the *Journal of the American College of Surgeons,* reviewed data from 2,024 surgery patients and found that 83% of US patients without pain were prescribed opioids, compared with 8.7% of non-US patients without pain. The authors concluded that US patients are prescribed more amounts of opioids at higher rates regardless of the severeness of their post-surgical pain. The authors recommend that more efforts are made toward ensuring that opioid prescriptions are tailored to patients' needs.

The full text of the study can be accessed by visting *www.journalacs.org/article/S1072-7515(20)32336-X/fulltext.*

Study Finds 94% Drop in Symptomatic COVID-19 Cases With Pfizer's Vaccine

A study by Israel's largest health care provider, health maintenance organization Clalit, reported that there is a 94% drop in symptomatic COVID-19 cases with the Pfizer vaccine. The study represents 600,000 people who received two doses of the Pfizer COVID-19 vaccine in Israel. Clalit, which covers more than half of all Israelis, noted the same group who received the COVID-19 vaccine doses was also 92% less likely to develop serious illness from the virus. The study compared the vaccine recipient group to another group of the same size and medical history who had not received the vaccines. Read the full study here.

NABP Executive Director/Secretary Addresses Pharmacists' Involvement in COVID-19 Vaccination During FIP Webinar

NABP Executive Director/Secretary Lemrey "Al" Carter, PharmD, MS, RPh, presented during the International Pharmaceutical Federation's (FIP's) Regulators' Forum on pharmacists' involvement with COVID-19 vaccination on February 4, 2021. The webinar addressed a new regulatory vaccination preparedness self-assessment tool and risk assessment, the expanded roles for pharmacists, and data FIP has collected on vaccinations by pharmacists. View the webinar here.

Board Welcomes New Member

Bernard L. "Bernie" Henderson, Jr, of Henrico, VA, was appointed as a citizen member to the Board on November 6, 2020, by Governor Ralph Northam. Mr Henderson has a long history of involvement in state government, having served in the administrations of five governors, including serving as head of the Department of Health Professions (DHP) from 1986-1994. Mr Henderson is president emeritus and funeral celebrant of Woody and Nelsen Funeral Homes. He is filling the previously unexpired term held by Melvin Boone.

Emergency Regulations for Statewide Protocols for Initiation of Treatment Now in Place

House Bill (HB) 1506, which went into effect July 1, 2020, required statewide protocols to be developed by the Board of Pharmacy, in collaboration with the Board of Medicine and the Department of Health. Emergency regulations authorizing pharmacists to initiate treatment with certain drugs for patients 18 years of age or older became effective January 3, 2021. Pharmacists may now prescribe and dispense these drugs in accordance with the regulations and the statewide protocols. As authorized in the bill, the statewide protocols specifically address pharmacist initiation, dispensing, and administration of the following drugs to persons 18 years of age or older:

- epinephrine;
- injectables or self-administered hormonal contraceptives, including emergency contraceptives;
- prescription prenatal vitamins;
- naloxone or other opioid antagonists; and
- medications covered by the patient's insurance carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase the over-the-counter (OTC) equivalent of the same medication.

Although the bill also provides for a dietary fluoride supplement protocol, the American Dental Association does not recommend the prescribing of dietary fluoride supplements for persons 18 years of age or older.

The emergency regulations as well as the statewide protocols are available on the home page of the Board's website. The emergency regulations must be replaced with permanent regulations before they expire on July 2, 2022.

Recently signed into law by Governor Northam, HB 2079, introduced during the 2021 General Assembly session, authorizes the development of additional statewide protocols for persons 18 years of age or older for the following conditions: human immunodeficiency virus pre-exposure and post-exposure prophylaxis; tuberculin purified protein derivative tuberculosis testing; vaccines included on the Immunization Schedule published by CDC or that have a current EUA from United States Food and Drug Administration; and devices, controlled paraphernalia, or other supplies or equipment available OTC when covered by the patient's health insurance carrier. The bill would also require the Board to convene a stakeholder workgroup later this year to provide recommendations for statewide protocols for other medical conditions.

Board Staff News

Longtime DHP and Board staff member **J. Samuel "Sammy" Johnson, Jr, RPh,** retired from the Board effective April 1, 2021. Mr Johnson came to DHP in 1999, where he served for 12 years as the deputy director of enforcement. He joined the Board in 2011 as a deputy executive director. Many of you have interacted with Mr Johnson in person and on the telephone throughout the years, and have benefited from his vast knowledge of pharmacy laws and regulations. He will be greatly missed, and the Board wishes him all the best in his retirement!

Caroline D. Juran, BSPharm, DPh (Hon), executive director of the Board, will assume the position of president of the National Association of Boards of Pharmacy® (NABP®) at the 117th NABP Annual Meeting in May 2021. Ms Juran is currently completing her term as president-elect of the Association, after having served on the Executive Committee as the District 2 representative from 2013-2016. Under her leadership, the Virginia Board of Pharmacy received NABP's Fred T. Mahaffey Award for contributions to the regulation of the practice of pharmacy and its efforts to ensure that compounding is performed in a safe and compliant manner. The Board congratulates Ms Juran for her outstanding pharmacy leadership at both the state and national level.

Pharmaceutical Processor – Cannabis Oil

The pharmaceutical processor program, originally approved by the Virginia General Assembly during the 2015 legislative session, has evolved significantly since its inception. Originally developed as a low-tetrahydrocannabinol (THC) program to treat pediatric epilepsy, each general assembly session has brought new advancements to the program.

Currently, four of the allowable five pharmaceutical processor permits have been awarded. The four pharmaceutical processors, which cultivate, process, and dispense cannabis oil formulations, are in Bristol, VA (Dharma Pharmaceuticals, LLC); Richmond, VA (Green Leaf Medical of Virginia, Inc); Portsmouth, VA (Columbia

continued on page 5

continued from page 4

Care Eastern Virginia, LLC); and Manassas, VA (Dalitso, LLC). Each pharmaceutical processor may also establish up to five cannabis dispensing facilities in their health service area. These facilities will dispense the cannabis oil formulations produced by the pharmaceutical processors. A pharmacist-in-charge is required for the operations of both the pharmaceutical processors and the cannabis dispensing facilities. Additional pharmacists may staff the dispensaries to provide patient consultations to determine appropriate product selection.

To become a registered patient for cannabis oil, a patient must first be evaluated by a practitioner licensed by the Board who will provide the individual with a written certification for the use of cannabis oil if the practitioner feels the individual may benefit from the use of cannabis oil products for the treatment of any diagnosed disease or condition. The patient must then submit an application to the Board, along with a copy of the written certification and proof of age, identity, and residency. Once approved by the Board, the patient will be provided with a registration card that they will take along with the written certification to the dispensary. The dispensary staff will verify the patient's registration, provide consultation on product choices, and enter dispensed product information into the Virginia Prescription Monitoring Program (PMP). Once a patient has been to the dispensary to verify identity and eligibility, they may access home delivery of cannabis oil products if desired.

Cannabis oil products are currently available in any formulation except botanical flower. Additionally, there is no cap on the total percent of THC that may be in the extracted products; however, the THC cannot exceed 10 mg per dose. Products currently available include tinctures, lotions, edibles, nasal sprays, suppositories, and vape inhalants. Total THC content ranges from less than 1% to over 80%. Each product must be tested by a third-party lab and submitted to the Board for review and approval before being dispensed. To date, the Board has approved over 150 products.

HB 2218, passed by the 2021 Virginia General Assembly, includes the allowance for botanical cannabis, an expansion of telemedicine for use in both accessing a practitioner for a written certification and the pharmacist at the dispensary, and expanded product access options. While the Board currently oversees the medical cannabis program, HB 2312, authorizing an adult-use retail cannabis program under the oversight of a new state agency, was also passed by the General Assembly. To learn more about the pharmaceutical processor program, please visit *https://www.dhp.virginia.gov/Pharmacy/PharmaceuticalProcessing/default.htm.*

Promethazine With Codeine Prescriptions and Pharmacy Robberies

Because of the increase in pharmacy robberies, pharmacists are asked to notify the Virginia State Police or local law enforcement agency of any counterfeit/fraudulent prescriptions received for promethazine with codeine. Fraudulent prescriptions have been received in person, faxed, and called in over the telephone. If asked by an individual if the pharmacy stocks this drug, use extreme caution. Not all pharmacy robberies were preceded by fraudulent prescriptions. All pharmacists are reminded to be cognizant of "red flags" related to prescriptions received. Pharmacists are strongly encouraged to access the Virginia PMP and to verify validity of suspicious prescriptions directly with the prescriber's office.

The *Virginia Board of Pharmacy News* is published by theVirginia 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.

Caroline Juran, Executive Director - State News Editor
Lemrey "Al" Carter, PharmD, MS, RPh - National News Editor & Executive Editor
Amy Sanchez - Publications and Editorial Manager