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Virginia Board of Pharmacy News

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New Allowance for Partial Filling of Schedule II Prescriptions

The Comprehensive Addiction and Recovery Act (CARA), signed into federal law in July 2016, amends the Controlled Substances Act to allow for the partial filling of Schedule II prescriptions. CARA addresses many aspects of the opioid epidemic, including the prevention and education of opioid use and abuse. The new allowance for partial filling of Schedule II prescriptions is intended to decrease the amount of unwanted or unneeded controlled substances (CS) being dispensed. Regulation 18VAC110-20-310 was recently amended, as of September 7, 2017, to conform state regulation to the new federal allowance to allow the practice of partial filling of Schedule II prescriptions. Pharmacists should review Regulation 18VAC110-20-310 within the *Regulations Governing the Practice of Pharmacy,* found at *www.dhp.virginia.gov/pharmacy/pharmacy_laws_regs.htm,* to become familiar with how to comply with a patient's or prescriber's request to partially fill a Schedule II prescription. Additional information on CARA may be found at *https://www.congress.gov/bill/114th-congress/senate-bill/524/text.*

Potential Diversion of Promethazine With Codeine

Recently, the Virginia Board of Pharmacy has been alerted by law enforcement to the rapid increase in fraudulent prescriptions being phoned in for promethazine with codeine syrup. This diversion has generally been in the northern Virginia and Harrisonburg areas, but possibly may have spread to other areas in the state. Verbal orders are called to the pharmacy and the caller provides all of the correct information, such as Drug Enforcement Administration (DEA) and National Provider Identifier numbers. The prescriptions are called in under the names of several doctors, and the quantity is usually 473 ml. Invalid patient names and dates of birth are used. Pharmacists should be alert and use their professional judgment when receiving verbal orders for promethazine with codeine.

Compounding Pharmacies – Unlawful Activities

As a result of a report from the United States Department of Labor, Office of Inspector General – Office of Audit *(https://www.oig.dol.gov/public/reports/oa/2017/03-17-001-04-431.pdf)* highlighting the Office of Workers' Compensation Programs' need for better control over compounded drugs, the Board strongly urges pharmacists to be aware of activities that may violate law and result in disciplinary action. Schemes may involve: a prescriber writing a prescription for a compounded drug with questionable efficacy for patients who have workers' compensation; the prescriber receiving kickbacks from the compounding pharmacy; and the compounding pharmacy charging exorbitant prices for the compounded drugs to the payer. Board staff is also aware of other schemes that may involve a pharmacy partnering with a fulfillment entity that provides the compounding pharmacy with prescriptions that may not be valid, are often prescribed by prescribers located out-of-state, and were not requested by the patient. Please note that such fraudulent activity may constitute a violation of state and federal law and will subject a pharmacist to possible disciplinary action by the Board. Pharmacists should be alert to solicitations to partner with fulfillment entities and must not engage in fraudulent billing activity or violate requirements regarding kickbacks to prescribers.

Reminder – Discontinuation of the Virginia Pharmacy Technician Examination

As of September 1, 2017, the Board has discontinued offering the Virginia Pharmacy Technician Examination. Students who have successfully completed a Board-approved pharmacy technician training program must take either the Pharmacy Technician Certification Board (PTCB) examination or the Exam for the Certification of Pharmacy Technicians (ExCPT) prior to submitting an application to the Board for pharmacy technician registration. Information regarding the PTCB and ExCPT examinations may be

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.Pharmacy Domain Signals Safety on the Web

With only 4% of websites selling prescription drugs online following United States pharmacy laws and practice standards, consumers seeking medications online are faced with the daunting task of finding a safe site. To assist consumers and those legitimate pharmacies with an online presence, NABP has streamlined its website verification programs. As of September 1, 2017, NABP is only offering the .Pharmacy Verified Websites Program and the Verified Internet Pharmacy Practice Sites® (VIPPS®) program, providing an easy choice for safety-minded consumers and pharmacies alike. The .Pharmacy Program, which was launched in 2014, enables qualified pharmacies and pharmacy-related businesses to register a web address with the .pharmacy domain. A .pharmacy domain (pronounced "dot pharmacy") is part of a website's address like ".com" or ".biz": *www.safe.pharmacy.* It enables people to identify an online pharmacy or pharmacy-related website as safe and legitimate. Since .pharmacy is a verified domain, websites are evaluated against a set of safety standards before an applicant is approved to register the domain.

In addition to showing patients that they operate a safe website, the .pharmacy domain allows pharmacies and related entities to advertise online through Google, Bing, and Yahoo! The .Pharmacy Program replaces the e-Advertiser Approval℠ and Veterinary-VIPPS® programs for those entities that are not eligible to apply for VIPPS but want to advertise with the search engines.

For more information about the .Pharmacy Program, including the application and domain name registration process and fees, visit *www.safe.pharmacy/apply.*

Quality Processes, Risk Management, and Culture: HR-Related Policies That Conflict With a Just Culture

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.*

As health care organizations move toward a "Just Culture," one of the areas potentially overlooked is human resource (HR)-related policies and procedures. Because these policies and procedures typically describe staff expectations, individual accountability, and disciplinary processes, they must be reviewed and often revised to ensure alignment with the tenets of a Just Culture. Otherwise, the journey will be long and unsuccessful if the policies are in conflict with a Just Culture.

In a Just Culture, HR-related policies and procedures regarding safety should hold all individuals equally accountable for the quality of their behavioral choices and should not focus on errors (which are not a behavioral choice), except for the expectation to report them. Policies and procedures should reflect a tone that is proactive toward risk identification, rather than reactive to errors and adverse outcomes. They should define human error as inadvertent, with a response of consoling individuals and conducting an investigation to determine how to redesign systems to prevent errors or detect them before reaching the patient. Policies and procedures should describe how to investigate a procedural violation to determine its causes and scope, and how to coach staff who have engaged in at-risk behaviors under the mistaken, but good faith, belief that the risks were insignificant or justified. For outcome-based duties related to a business code of conduct, such as arriving to work on time and wearing identification badges, policies should be clear about expectations and the actions that will be taken when they are not met. When describing reckless behavior (actions involving a conscious disregard of what an individual knows is a substantial and unjustifiable risk), remove any reference to "negligent" or "criminal" conduct as the basis for disciplinary action. Regrettably, mere human error can result in legal action (criminal negligence), but human error is never reckless behavior. Also ensure that event reporting and investigation policies and procedures support the tenets of a Just Culture.

While HR-related policies and procedures cannot guarantee that the desired actions will be realized in practice, they are a critical step for building an organizational foundation for success. Old punitive policies risk slipping back into an unjust culture. As organizations align actual practice with a Just Culture, they also need to align supporting policies and procedures.

AMA Task Force to Reduce Opioid Abuse Promotes Safe Storage, Disposal of Opioids

The American Medical Association (AMA) Task Force to Reduce Opioid Abuse released a resource document that urges physicians and other health care providers to promote safe storage and disposal of opioids and all medications. The AMA document indicates physicians and other providers need to:

- educate patients about safe use of prescription opioids;
- remind patients to store medications out of children's reach in a safe place; and
- talk to patients about the most appropriate way to dispose of expired, unwanted, and unused medications.

The AMA resource document and additional information can be found at *www.ama-assn.org/opioids-disposal.* Options for disposing of medications safely are available in the Initiatives section of the NABP website at *www.nabp.pharmacy* under AWAR$_X$E®.

CDC Guide Shows Importance of Physicians, Pharmacists Working Together

Collaborative care by at least two practitioners working together with the patient to accomplish shared goals has been shown to improve hypertension control and cholesterol management, especially when the team involves a physician or nurse and a pharmacist, notes a new guide developed by the Centers for Disease Control and Prevention (CDC) Division for Heart Disease and Stroke Prevention, in collaboration with the American Pharmacists Association and AMA. The guide,

Creating Community-Clinical Linkages Between Community Pharmacists and Physicians, discusses the importance of community-clinical linkages specific to community pharmacists and physicians and provides a framework for how community pharmacists and physicians might approach the development of a link to help patients. In addition, the guide provides examples of existing community-clinical linkages between community pharmacists and physicians and discusses common barriers to and potential solutions for creating community-clinical linkages. The guide is available at *www.cdc.gov/dhdsp/pubs/docs/ccl-pharmacy-guide.pdf.*

FIP Report Shows Value of Pharmacists' Role in Consumers' Self-Care

Support from pharmacists will assist consumers in better health maintenance and greater health system efficiency, indicates a recently released report from the International Pharmaceutical Federation (FIP). The report, *Pharmacy as a gateway to care: Helping people towards better health,* discusses the various factors involved in individual self-care and the evidence that pharmacists can increase value for those individuals through many opportunities because informed, engaged, and educated consumers will play a greater and critical role in caring for themselves. The definition of self-care this report adopts is that of the World Health Organization: "the ability of individuals, families and communities to promote health, prevent disease, and maintain health, and to cope with illness and disability with or without the support of a health care provider."

The report is available at *www.fip.org/files/fip/publications/2017-04-Pharmacy-Gateway-Care.pdf.*

FDA Restricts Use of Codeine and Tramadol Medicines in Children; Recommends Against Use in Breastfeeding Women

As of April 2017, Food and Drug Administration (FDA) is restricting the use of codeine and tramadol medicines in children. FDA is also recommending against the use of these medicines in breastfeeding mothers due to possible harm to their infants. Codeine and tramadol medicines carry serious risks, including slowed or difficult breathing and death, which appear to be a greater risk in children younger than 12 years, and should not be used in this age group. These medicines should also be limited in some older children. Single-ingredient codeine and all tramadol-containing products are FDA-approved only for use in adults.

As indicated in the FDA Drug Safety Communication available at *www.fda.gov/Drugs/DrugSafety/ucm549679.htm,* FDA is requiring several changes to the labels of all prescription medicines containing these drugs. These new actions further limit the use of these medicines beyond their 2013 restriction of codeine use in children younger than 18 years to treat pain after surgery from removal of tonsils and/or adenoids. FDA is now adding:

- A *Contraindication* to the drug labels of codeine and tramadol, alerting that codeine should not be used to treat pain or cough and tramadol should not be used to treat pain in children younger than 12 years.
- A new *Contraindication* to the tramadol label, warning against its use in children younger than 18 years to treat pain after surgery from removal of tonsils and/or adenoids.
- A new *Warning* to the drug labels of codeine and tramadol to recommend against their use in adolescents between 12 and 18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems.
- A strengthened *Warning* to mothers that breastfeeding is not recommended when taking codeine or tramadol medicines due to the risk of serious adverse reactions in breastfed infants.

FDA urges health care providers to report side effects involving codeine- and tramadol-containing medicines to the FDA MedWatch program at *www.fda.gov/safety/medwatch.*

AVMA Warns Pharmacists and Pet Owners About Xylitol Pharmaceutical Products

Pharmaceutical products containing xylitol may be dangerous and fatal to dogs, warns the American Veterinary Medical Association (AVMA). Xylitol stimulates an insulin release that can result in severe hypoglycemia and fatal liver damage. Pharmacists and pet owners need to be aware of and protect against xylitol toxicoses, indicates AVMA. FDA-approved gabapentin capsules and tablets do not contain xylitol, but the liquid form does. In addition, xylitol-containing media might be used in compounding products if the pharmacist is uninformed about not using it.

AVMA urges pharmacists to not use xylitol-containing products when compounding for canine patients and to contact the veterinarian if a prescribed product contains xylitol. The veterinarian may be unaware that this sweetener is in the product. AVMA also encourages pet owners and caretakers to verify with the pharmacist when picking up their dog's medication at a human pharmacy that the medication does not contain xylitol. Xylitol-containing peanut butter should not be used to help a dog take its medication.

For more information, visit *atwork.avma.org/2017/05/30/eliminate-xylitol-from-canine-prescriptions.*

CDC Publishes Guide to Help Pharmacists Initiate CPAs With Prescribers

CDC published a guide that provides pharmacists with information and resources to empower them to initiate collaborative practice agreements (CPAs) with collaborating prescribers. The guide, *Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team,* contains a sample CPA and sample language that can be customized by pharmacists and prescribers using their specific state laws to create a CPA. The guide includes an overview of state laws, including which states currently allow CPAs. The guide is available at *www.cdc.gov/dhdsp/pubs/docs/CPA-Team-Based-Care.pdf.*

DEA Releases New Edition of Drugs of Abuse Resource Guide

Drug Enforcement Administration (DEA) released the 2017 edition of *Drugs of Abuse, A DEA Resource Guide,* which serves as a resource on the most commonly abused and misused drugs in the US. The latest edition, which is an update to the 2015 publication, describes the consequences of drug use, a drug's effects on the body and mind, overdose potential, origin, legal status, and other key facts. It also includes the most current information on new and emerging trends in drug misuse and abuse, including fentanyl, other opioids, and synthetic drugs. The 2017 edition can be found at *www.dea.gov/pr/multimedia-library/publications/drug_of_abuse.pdf.*

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accessed at *www.ptcb.org* and *www.nhanow.com,* respectively. It is important to note that discontinuation of the Virginia Pharmacy Technician Examination only affects prospective applicants who have completed a Board-approved pharmacy technician training program. Those pharmacy technicians who are currently registered with the Board are not affected by this change. Furthermore, those prospective applicants who maintain a current PTCB certification may simply apply for a pharmacy technician registration; completion of a Board-approved pharmacy technician training program is not required for those who have recently obtained or maintain a current PTCB certification. Those persons interested in taking the ExCPT must complete a Board-approved pharmacy technician training program prior to submitting an application to the Board for pharmacy technician registration. Information regarding the current registration process may be accessed on the Board's website under the Frequently Asked Questions section related to Pharmacy Technician Registration, found at *www.dhp.virginia.gov/pharmacy/pharmacy_faq.htm#TechRegistration.*

New Laws Affecting Pharmacy

The following is a summary of select pieces of legislation passed by the Virginia General Assembly in 2017 affecting pharmacies and pharmacists:

House Bill (HB) 1453: Amended §§8.01-225 and 54.1-3408 of the Code of Virginia. Allows a person who is authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone for use in opioid overdose reversal, and who is acting on behalf of an organization that provides services to individuals at risk of experiencing opioid overdose or training in the administration of naloxone for overdose reversal and that has obtained a CS registration from the Board pursuant to §54.1-3423, to dispense naloxone to a person who has completed a training program on the administration of naloxone for opioid overdose reversal, provided that such dispensing is (i) pursuant to a standing order issued by a prescriber, (ii) in accordance with protocols developed by the Board in consultation with the Virginia Board of Medicine and the Department of Health, and (iii) without charge or compensation. The bill also provides that dispensing may occur at a site other than that of the CS registration, provided that the entity possessing the CS registration maintains records in accordance with regulations of the Board of Pharmacy. The bill further provides that a person who dispenses naloxone shall not be liable for civil damages of ordinary negligence for acts or omissions resulting from the rendering of such treatment if he or she acts in good faith and that a person to whom naloxone has been dispensed pursuant to the provisions of the bill may possess naloxone and may administer naloxone to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose.

HB 1642: Amended §54.1-3408 of the Code of Virginia. Adds employees of the Department of Forensic Science, the Office of the Chief Medical Examiner, and the Department of General Services Division of Consolidated Laboratory Services to the list of individuals who may possess and administer naloxone or other opioid antagonist, provided that they have completed a training program.

HB 2165: Amended §§54.1-3401, 54.1-3408.02, and 54.1-3410 of the Code of Virginia. Requires a prescription for any CS containing an opiate to be issued as an electronic prescription as of July 1, 2020. The bill requires the Secretary of Health and Human Resources to convene a work group to review actions necessary for the implementation of the bill's provisions and evaluate hardships on prescribers and the inability of prescribers to comply with the deadline for electronic prescribing and to make recommendations for any extension or exemption processes relative to compliance or disruptions due to natural or man-made disasters or technology gaps, failures, or interruptions of service.

Senate Bill 1027: Amended §§18.2-250.1 and 54.1-3408.3; created 54.1-3442.5 through 54.1-3442.8. Authorizes a pharmaceutical processor, after obtaining a permit from the Board and under the supervision of a licensed pharmacist, to cultivate cannabis for the purpose of producing and dispensing cannabidiol oil and THC-A oil for the treatment of intractable epilepsy. The bill sets a limit on the number of permits that the Board may issue and requires that the Board adopt regulations establishing health, safety, and security requirements for permitted processors. The bill provides that only a licensed practitioner of medicine or osteopathy who is a neurologist or who specializes in the treatment of epilepsy may issue a written certification to a patient for the use of cannabidiol oil or THC-A oil. The bill also requires that the practitioner who issues the written certification for cannabidiol oil or THC-A oil, the patient issued such certification, and, if the patient is a minor or incapacitated, the patient's parent or legal guardian register with the Board. Finally, the bill provides an affirmative defense for agents and employees of pharmaceutical processors in a prosecution for the manufacture, possession, or distribution of marijuana.

Reminder – Required CE for Pharmacists in 2017

Pursuant to §54.1-3314.1(J) of the Code of Virginia and to address Virginia's opioid abuse crisis, which the state health commissioner recently declared a public health emergency, the Board determined at its December 2016 meeting that all pharmacists must obtain at least one hour of continuing education (CE) in 2017 in any of the following subject areas: proper opioid use, opioid overdose prevention, or naloxone administration. The one-hour minimum requirement is part of the required 15 hours of CE that must be obtained during 2017 and is not in addition to the required 15 hours. This is a one-time requirement; further action of the Board would be required to mandate CE in a specific topic in future years. This requirement applies

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only to pharmacists, not pharmacy technicians. Please note that this requirement does not identify specific objectives that must be included in the selected CE program, nor has a list of approved CE programs been identified from which pharmacists must choose. The requirement is intended to be general to allow each pharmacist the flexibility in choosing an appropriate CE program that focuses on the proper use of opioids, opioid overdose prevention, or naloxone administration. The CE must be obtained between January 1 and December 31, 2017, and prior to renewing the pharmacist's license.

USP Chapter <800> Postponed Until December 1, 2019

During the September 2017 full Board meeting, the Board discussed time frames for enforcing United States Pharmacopeia (USP) Chapter <800>. Subsequent to the meeting, USP announced its intent to delay the effective date of Chapter <800> until December 1, 2019. USP stated, "The purpose of this postponement is to align the official date of General Chapter <800> with the official date of the next revision of General Chapter <797> *Pharmaceutical Compounding — Sterile Preparations,* to provide a unified approach to quality compounding." As a result, the Board will reconsider the time frames for enforcing compliance with Chapter <800>. Please note that the Board cannot enforce the standards prior to the chapter officially becoming effective.

Transfer of Unfilled Schedule II-V CS Prescriptions

DEA has recently clarified the conditions under which an unfilled prescription for a Schedule II-V CS may be transferred. The following is an excerpt from an email from Loren T. Miller, associate section chief, Liaison and Policy Section of DEA, to Carmen Catizone, executive director/secretary of the National Association of Boards of Pharmacy®:

> The Controlled Substances Act and its implementing regulations outline what can take place regarding prescriptions for controlled substances. In Title 21, Code of Federal Regulations, Section 1306.25 the DEA made a specific exception so that a DEA registered pharmacy can, once it has filled an original prescription for a controlled substance in Schedules III-V, transfer the original prescription information to another DEA registered pharmacy for the purpose of allowing that second pharmacy to then dispense any remaining valid refills still permitted by law and the prescriber's authorization. With one exception, such an allowance currently does not exist for the forwarding of an unfilled prescription from one DEA registered retail pharmacy so that it may be filled at another DEA registered retail pharmacy.
>
> Prescriptions can take the form of paper (including fax), call-in, or electronic prescription for controlled substances (EPCS). The DEA has addressed the forwarding of an EPCS prescription. The DEA published information in the preamble of the notice of proposed rulemaking (NPRM) on EPCS, 73 FR 36722, and the preamble of the interim final rule (IFR) on EPCS, 75 FR 16235. Note, because this was in the preamble and not in the EPCS regulations, it represents the DEA's policy. As posted in the preambles of the NPRM and the IFR, an unfilled original EPCS prescription can be forwarded from one DEA registered retail pharmacy to another DEA registered retail pharmacy, and this includes Schedule II controlled substances.

While the Board condones a pharmacist transferring an unfilled or on-hold prescription from one pharmacy to another, it appears DEA does not support this action. While DEA condones the "forwarding" of an unfilled or on-hold EPCS from one pharmacy to another, it is unclear at this time how a pharmacist "forwards" a prescription. Such an ability may be included in a future National Council for Prescription Drug Programs version utilized to transmit EPCS.

New Allowance for Prescribing Buprenorphine Without Naloxone

Please be aware that the Virginia Board of Medicine recently amended emergency regulation 18VAC85-21-150 to include an additional exception for when a prescriber may issue a prescription for buprenorphine without naloxone. For patients who have a demonstrated intolerance to naloxone, such prescriptions for the mono-product shall not exceed 3% of the total prescriptions for buprenorphine written by the prescriber and the exception shall be clearly documented in the patient's medical record. The Board of Medicine intends to use data from the prescription monitoring program to identify any noncompliance on this issue. Pharmacists are reminded that the Board of Medicine's regulations do not place additional requirements on pharmacists. Pharmacists should continue to evaluate the validity of prescriptions by ensuring that the prescription was issued for a legitimate medical purpose.

Board Election Results

Congratulations to Ryan K. Logan and Michael I. Elliott who were recently elected by the Board of Pharmacy to serve as chairman and vice chairman of the Board, respectively. Additionally, the Board extends appreciation to Rebecca Thornbury and Mr Logan for their dedication and leadership during the previous year while serving as chairman and vice chairman, respectively.

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.

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