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Virginia Board of Pharmacy News

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Changes to Issuances of Licenses, Registrations, and Permits

The Virginia Board of Pharmacy is implementing a process to cease mailing out on an annual basis the hard copy licenses, registrations, and permits that bear an expiration date. A final hard copy will be issued that contains no expiration date. Licensees must still continue to renew their licenses annually or as required, submit payment, and attest to compliance with obtaining any required continuing education. For more information, refer to the email notification sent to all licensees in June 2019 at *www.dhp.virginia.gov/pharmacy/newsletters/2019/PhamacyNews06262019.pdf.*

Board Elections

Congratulations to Cynthia Warriner, who was recently elected to serve as Board chairman for the term July 1, 2019, through June 30, 2020; and Kris Ratliff, who was elected vice chairman for the same term. The Board would also like to extend its appreciation to Rafael Saenz, who served as Board chairman from July 1, 2018, through June 30, 2019; and Ms Warriner, who served as vice chairman. Their leadership and expertise were greatly appreciated.

2019 Pharmacy-Related Legislation

The following bills were passed during the 2019 Virginia General Assembly Session.

House Bill (HB) 2557 Drug Control Act; classifies gabapentin as a Schedule V controlled substance. This bill classifies gabapentin as a Schedule V controlled substance (CS) as of July 1, 2019. For more information, refer to the email notification sent to all licensees in June 2019 at *www.dhp.virginia.gov/pharmacy/newsletters/2019/PhamacyNews06072019.pdf.*

HB 1839 Industrial hemp; federal Farm Bill. This bill contains several provisions, including a provision to conform Virginia law to the 2018 United States Farm Bill by amending the definitions of cannabidiol oil, marijuana, and tetrahydrocannabinol (THC) to exclude industrial hemp in the possession of a registered person, hemp products, or an oil containing no more than 0.3% THC. This bill became effective on March 21, 2019.

HB 1841 Pharmaceutical processors; employment, misdemeanors. This bill allows pharmaceutical processors to employ or permit to act as an agent of the pharmaceutical processor, individuals who have been convicted of certain drug and drug paraphernalia misdemeanors, except in cases where such a conviction occurred within the last five years. The bill also requires that pharmaceutical processors adopt policies for pre-employment drug screenings and regular, ongoing, and random drug screenings of employees. This bill became effective on July 1, 2019.

HB 2158 Naloxone; expands list of individuals who may dispense. This bill expands the list of individuals who may dispense naloxone, pursuant to a standing order, to include health care providers who provide services in hospital emergency departments and emergency medical services personnel. The bill eliminates certain requirements and establishes requirements for dispensing naloxone in an injectable formulation with a hypodermic needle or syringe. The bill also allows a person who dispenses naloxone on behalf of an organization to charge a fee for dispensing naloxone, provided that the fee is no greater than the cost to the organization of obtaining the dispensed naloxone. This bill became effective on July 1, 2019, and the Board is scheduled to amend the naloxone protocol at the September 2019 Board meeting.

HB 2228 Nursing and Psychology, Boards of; health regulatory boards, staggered terms. This bill provides a mechanism for evenly staggering the terms of members of

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National Pharmacy Compliance News

August 2019

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.

FDA Changes Opioid Labeling to Give Providers Better Information on Tapering

Noting that the agency remains focused on striking the right balance between policies that reduce the rates of opioid addiction while still allowing patients and health care providers access to appropriate pain treatments, Food and Drug Administration (FDA) has announced required changes to the prescribing information for all opioid analgesic medications used in the outpatient setting. The changes, announced in a Drug Safety Communication, provide expanded information to health care providers on how to safely decrease the dose in patients who are physically dependent on opioids. FDA intends for this information to be used when health care providers and patients have decided together that a decrease in dose or discontinuation of opioids is appropriate.

"Rapid discontinuation can result in uncontrolled pain or withdrawal symptoms. In turn, these symptoms can lead patients to seek other sources of opioid pain medicines, which may be confused with drug-seeking for abuse," the agency said in the communication. "Patients may attempt to treat their pain or withdrawal symptoms with illicit opioids, such as heroin, and other substances."

In addition to these changes, an FDA press release also announced that additional policies related to the opioid crisis are forthcoming. These include a requirement for immediate-release formulations of opioids to be made available in fixed-quantity packaging that contain doses more typical of what patients may need for common acute pain conditions and procedures. The full press release is available in the News and Events section of the FDA website.

DEA Warns of Scam Calls Targeting Pharmacists and Other DEA-Registered Providers

Health care providers and other members of the public have reported receiving phone calls from people claiming to represent Drug Enforcement Administration (DEA), and threatening legal action against them if a large fine is not paid immediately over the phone. According to a DEA press release, this scam used fake names and badge numbers, or the names of well-known senior officials with DEA, and threatened victims with arrest, prosecution, imprisonment, and revocation of their DEA numbers. The agency emphasizes that DEA will never contact practitioners by phone to demand money or any form of payment. DEA will not request any personal or sensitive information by phone, and notification of legitimate investigation or legal action is made via official letter or in person.

DEA asks anyone who receives a call from a person purporting to be a DEA special agent or other law enforcement official asking for money to refuse the demand and report the threat using the online form or by calling 877/792-2873. Reporting these calls will assist DEA in investigating and stopping this activity.

FDA Officials Outline 2019 Efforts to Improve Quality of Compounded Drugs

Recognizing the important roles compounded drugs can play in patient care, FDA plans to continue its efforts to improve the quality of compounded drugs. According to a statement posted to the FDA website, these priorities include:

- maintaining quality manufacturing compliance,
- strengthening and refining regulations on compounding from bulk drug substances,
- finalizing the agency's memorandum of understanding with the states, and
- issuing revised draft guidance for compounding by hospital and health systems.

"We've worked to refine our existing practices, shape new policies and increase the frequency of our communications with industry, Congress, states and patients concerning our programs," then-Commissioner Scott Gottlieb, MD, and Deputy Commissioner Anna Abram said in a statement published on the FDA website. "We anticipate that 2019 will be an equally productive year for the FDA's compounding program, with better quality continuing to be our top priority as part of our ongoing effort . . . to improve the quality of compounded products for consumers . . ."

In addition, Gottlieb and Abram's statement notes that the agency will continue to work closely with stakeholders on these steps and any other compounding-related measures not outlined in the statement.

China Agrees to Stricter Fentanyl Production Laws Following Pressure From US Lawmakers

China has announced that all variations of the powerful opioid product, fentanyl, will be treated as controlled substances (CS). According to a press release from Senator Tom Cotton, the announcement came after a bipartisan group of United States lawmakers, including Cotton, introduced Senate Bill 1044, a bill designed to apply pressure to the Chinese government to make all forms of synthetic opioids illegal and to provide US law enforcement with more tools and resources to go after illicit traffickers in China, Mexico, and other countries.

"Combating the flow of illicit fentanyl into our country is imperative in the fight to save American lives from the opioid crisis," Senate Minority Leader Chuck Schumer said in the press release. "We must hold China accountable for their role in the fentanyl trade. China's new regulation to make all fentanyl categories illegal is an important step and the administration deserves praise for their efforts to secure this change. However, we have to demonstrate that we will demand China enforce these laws and take strong action against opioid traffickers."

In a December meeting with President Donald Trump, China's President Xi Jinping promised to classify fentanyl as a CS following a 2018 report by the US-China Economic and Security Review Commission that found China to be "the largest source of illicit fentanyl and fentanyl-like substances" in the US, according to a report from NPR. The latest increase in opioid-related overdose deaths has been largely attributed to the availability of illegally manufactured fentanyl.

Two Lots of Transdermal Fentanyl Patches Recalled Due to Product Mislabeling

Alvogen, Inc, of Pine Brook, NJ, is recalling two lots of Fentanyl Transdermal System 12 mcg/h transdermal patches to the consumer level after a small number of cartons were found to contain 50 mcg/h patches. Though the 50 mcg/h patches are individually labeled correctly, accidental application of the higher dosage patch instead of the prescribed 12 mcg/h patch could result in serious, life-threatening, or fatal respiratory depression. The company has not received any reports of adverse events related to this issue.

The company is notifying its distributors and direct customers by certified letter and is arranging for the return and replacement of all recalled products. Pharmacies are asked to stop dispensing any product subject to the recall. Consumers that have affected products should immediately remove any patch currently in use and contact their health care provider. Patients with unused product should return it to the point of purchase for replacement.

Additional information on the recall, including the affected lot numbers and customer service contact information, is available in a press release posted to the FDA website. Adverse reactions and quality problems can be reported to the FDA MedWatch Safety Information and Adverse Event Reporting Program.

FDA Releases Toolkit to Help Promote Safe Opioid Disposal

FDA has made a new resource available for consumers and health care providers to help promote and educate individuals about how to safely dispose of unused opioids. The free Safe Opioid Disposal – Remove the Risk Outreach Toolkit includes video, radio, and print public service announcements, social media graphics and posts, fact sheets, drop-in content, and website badges that health care providers and other interested individuals and organizations can use to promote the message of opioid safety. The toolkit and its resources can be accessed on the Ensuring Safe Use of Medicine section of the FDA website.

An additional resource available to help consumers find disposal kiosks available year round is the National Association of Boards of Pharmacy® (NABP®) Drug Disposal Locator Tool, available in the AWAR$_X$E® Prescription Drug Safety section of the NABP website, *www.nabp.pharmacy/initiatives/AWARxE.* With more than 6,500 disposal sites in the continually updated database, consumers can enter location information to find the nearest disposal sites to them using a map.

Additional information about the FDA campaign can be found at *https://www.fda.gov/drugs/buying-using-medicine-safely/ensuring-safe-use-medicine.*

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the following health regulatory boards, without affecting the terms of current members:

- Virginia Board of Nursing
- Virginia Board of Psychology
- Virginia Board of Dentistry
- Virginia Board of Long-Term Care Administrators
- Virginia Board of Medicine
- Virginia Board of Veterinary Medicine
- Virginia Board of Audiology and Speech-Language Pathology
- Virginia Board of Pharmacy
- Virginia Board of Counseling

Specifically, appointments to the Virginia Board of Pharmacy that are set to begin July 1, 2022, require one citizen member and one pharmacist member to be appointed for terms of three years, and that any remaining appointments shall be for terms of four years. Thereafter, all appointments to the Virginia Board of Pharmacy shall be for terms of four years, as provided in §54.1-3305 of the Code of Virginia. This bill became effective on July 1, 2019.

HB 2318 Naloxone; possession and administration by school nurses and local health department employees. This bill adds school nurses, local health department employees assigned to a public school pursuant to an agreement between the local health department and the school board, and other school board employees or individuals contracted by a school board to provide school health services to the list of individuals who may possess and administer naloxone or another opioid antagonist, provided that they have completed a training program. This bill became effective on July 1, 2019.

HB 2559 Electronic transmission of certain prescriptions; exceptions. This bill provides certain exceptions, effective July 1, 2020, to the requirement that any prescription for a CS that contains an opioid be issued as an electronic prescription. The bill requires the licensing health regulatory board of a prescriber to grant such prescriber a waiver of the electronic prescription requirement for a period not to exceed one year. The waiver may be granted due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the prescriber, or under exceptional circumstances demonstrated by the prescriber. The bill provides that a dispenser is not required to verify whether one of the exceptions applies when he or she receives a non-electronic prescription for a CS containing an opioid. The bill requires the Virginia Boards of Medicine, Nursing, Dentistry, and Optometry to promulgate regulations to implement the prescriber waivers. Finally, the bill requires the secretary of the Virginia Department of Health and Human Resources to convene a work group to identify successes and challenges of the electronic prescription requirement and offer possible recommendations to increase electronic prescribing of CS that contain an opioid, and to report to the chairs of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by November 1, 2022. This bill became effective on July 1, 2019.

Senate Bill (SB) 1289 Pharmacy, Board of; seizure of controlled substances and prescription devices. This bill clarifies the process by which the Board, an authorized agent of the Board, or law enforcement can seize and place CS and prescription devices under seal if they are owned or possessed by a person or entity whose registration, license, permit, or certificate authorizing such ownership or possession is suspended or revoked. The bill also provides procedures and requirements for the transfer and disposal of sealed CS and prescription devices, if they are subject to forfeiture. The bill provides that the period of time in which the director of the Virginia Department of Health Professions, his or her authorized agent, or a law enforcement officer may properly dispose of the seized drugs and devices, in the event that the owner has not claimed and provided for the proper disposition of the property, is 60 days from the notice of seizure. This bill became effective on July 1, 2019.

SB 1557 Pharmacy, Board of; cannabidiol oil and tetrahydrocannabinol oil, regulation of pharmaceutical. This bill authorizes licensed physician assistants and licensed nurse practitioners to issue a written certification for use of cannabidiol oil and tetrahydrocannabinolic acid (THC-A) oil. The bill requires the Board to promulgate regulations establishing dosage limitations, which shall require that each dispensed dose of cannabidiol oil or THC-A oil not exceed 10 milligrams of THC. The bill requires the secretary of the Virginia Department of Health and Human Resources and the secretary of the Virginia Department of Agriculture and Forestry to convene a work group to review and recommend an appropriate structure for an oversight organization in Virginia, and report its findings and recommendations to the chairs of the Senate Committee on Agriculture, Conservation and Natural Resources; the Senate Committee on Education and Health; the House Committee on Agriculture, Chesapeake and Natural Resources; and the House Committee

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on Health, Welfare and Institutions by November 1, 2019. This bill became effective on July 1, 2019.

SB 1632 Cannabidiol oil and THC-A oil; possession or distribution at public school. This bill provides that no school nurse employed by a local school board, person employed by a local health department who is assigned to the public school pursuant to an agreement between the local health department and the school board, or other person employed by or contracted with a local school board to deliver health-related services shall be prosecuted for possession or distribution of cannabidiol oil or THC-A oil for storing, dispensing, or administering cannabidiol oil or THC-A oil, in accordance with a policy adopted by the local school board, to a student who has been issued a valid written certification for the use of cannabidiol oil or THC-A oil. The bill also provides that the Virginia Department of Health Professions, in coordination with the Virginia Department of Education, shall develop and make available to school boards, a standardized form that is to be completed by the practitioner who issues a written certification and the pharmaceutical processor that dispenses the cannabidiol oil or THC-A oil to a student. The bill also provides that no school board shall be required to suspend or expel any student who holds a valid written certification for the use of cannabidiol oil or THC-A oil issued by a practitioner for the possession or use of such oil in accordance with the student's individualized health plan and in compliance with a policy adopted by the school board. This bill is identical to HB 1720 and became effective on July 1, 2019.

SB 1719 Cannabidiol oil and THC-A oil; registered agents and pharmaceutical processors. This bill authorizes a patient, or if such patient is a minor or an incapacitated adult, such patient's parent or legal guardian, to designate an individual to act as his or her registered agent for the purposes of receiving cannabidiol oil or THC-A oil pursuant to a valid written certification. Such a designated individual is required to register with the Board. The bill authorizes the Board to set a limit on the number of patients for whom any individual is authorized to act as a registered agent.

The bill directs the Board to promulgate regulations regarding the wholesale distribution and transfer of cannabidiol oil or THC-A oil between pharmaceutical processors. This bill also removes a requirement that a pharmaceutical processor may only dispense cannabidiol oil or THC-A oil that is cultivated and produced on site. This bill became effective on July 1, 2019.

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