



Virginia Board of Pharmacy

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Pharmacy-Related Legislation Passed by the 2018 General Assembly

The following is a summary of select pieces of legislation passed by the 2018 Virginia General Assembly affecting the profession of pharmacy.

House Bill (HB) 322: Naloxone or other opioid antagonist; possession & administration. This bill amended §54.1-3408 to add employees of the Virginia Department of Corrections who are designated as probation and parole officers or correctional officers to the list of individuals who may possess and administer naloxone or other opioid antagonist, provided they have completed a training program. This section of law was amended during the 2017 General Assembly session to add 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 authorized individuals who may possess and administer naloxone or other opioid antagonist. Once this bill becomes effective on July 1, 2018, the Virginia Board of Pharmacy protocol (Guidance Document 110-44) will be amended with the new language.

HB 501: Home hospice programs; disposal of drugs. This bill requires every hospice to develop policies and procedures for the disposal of drugs dispensed as part of the hospice plan of care for a patient, which shall include requirements that such disposal be: (i) performed in a manner that complies with all state and federal requirements for the safe disposal of drugs by a licensed nurse, physician assistant, or physician who is employed by or has entered into a contract with the hospice program; (ii) witnessed by a member of the patient's family or a second employee of the hospice program who is licensed by a health regulatory board within the Virginia Department of Health Professions (DPH); and (iii) documented in the patient's medical record.

HB 520: Nonresident warehousemen and nonresident third-party logistics providers. Requires warehousemen or third-party logistics providers that are located outside the

Commonwealth and ship prescription drugs or devices into the Commonwealth to register with the Board. This bill requires such nonresident warehousemen and nonresident third-party logistics providers to maintain a license, permit, or registration in the resident state and to retain records in a certain manner. The Board will promulgate regulations related to the storage, handling, and distribution of prescription drugs or devices by nonresident warehousemen and nonresident third-party logistics providers.

HB 793: Nurse practitioners; practice agreements. This bill eliminates the requirement for a practice agreement with a patient-care team physician for a licensed nurse practitioner who has met several conditions for this allowance, to include having obtained five or more years of clinical experience. The Virginia Board of Medicine and Board of Nursing will develop joint regulations on this subject.

HB 842: Controlled paraphernalia; possession or distribution, hypodermic needles and syringes, naloxone. This bill authorizes REVIVE! trainers pursuant to §54.1-3408(Y) to dispense hypodermic needles and syringes for the administration of naloxone. The dispensing shall be performed in accordance with the naloxone protocol approved by the Board of Pharmacy (Guidance Document 110-45, found at www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm), which was amended at the March 2018 full Board meeting.

HB 1251/Senate Bill (SB) 726: CBD oil and THC-A oil; certification for use, dispensing. These identical bills expanded the use of cannabidiol (CBD) oil or THC-A oil and made amendments to the current law. A practitioner may now issue a written certification for the use of CBD oil or THC-A oil for the treatment or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use. The bill increases the supply of CBD oil or THC-A oil that a pharmaceutical processor may dispense from a 30-day supply to a 90-day supply.

SB 330: THC-A oil; dispensing, tetrahydrocannabinol levels. Adds CBD oil or THC-A oil to the list of covered

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National Pharmacy Compliance News

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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 Requires Labeling Update on Opioid-Containing Cough and Cold Medicines

In January 2018, Food and Drug Administration (FDA) announced that the agency is requiring safety labeling changes to limit the use of prescription opioid cough and cold medicines containing codeine or hydrocodone in children younger than 18 years old because the serious risks of these medicines outweigh their potential benefits in this population. After safety labeling changes are made, these products will no longer be indicated for use to treat cough in any pediatric population and will be labeled for use only in adults aged 18 years and older. In addition, labeling for the medications will be updated with additional safety information for adult use. This update will include an expanded Boxed Warning notifying consumers about the risks of misuse, abuse, addiction, overdose and death, and slowed or difficult breathing that can result from exposure to codeine or hydrocodone. Additional information is available in FDA's news release at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592109.htm.

Latest NDTA Shows Opioids Pose Significant Impact to Public Health

Drug Enforcement Administration (DEA) indicates a significant shift in the overall drug threat reported by law enforcement over the last 10 years with opioids (including controlled prescription drugs, fentanyl and other synthetic opioids, and heroin) reaching epidemic levels and impacting significant portions of the United States. According to the *2017 National Drug Threat Assessment (NDTA)* report, every year since 2001, controlled prescription drugs, specifically opioid analgesics, have been linked to the largest number of overdose deaths of any illicit drug class, outpacing those for cocaine and heroin combined.

From 2007 to 2010, responses to the National Drug Threat Survey indicate cocaine was the greatest national drug threat, followed by a significant decline as the heroin threat increased between 2010 and 2016, eventually becoming the greatest national drug threat in 2015.

Illicit fentanyl and other synthetic opioids, primarily sourced from China and Mexico and shipped directly to the US or trafficked overland via Mexico and Canada, are contributing factors in the current synthetic opioid overdose epidemic. Traffickers in the US usually mix fentanyl into heroin products and sometimes other illicit

drugs or press it into counterfeit prescription pills, often without users' awareness, which leads to overdose incidents, notes the *2017 NDTA*. To access the *2017 NDTA*, visit www.dea.gov/divisions/hq/2017/hq102317.shtml.

FDA Recognizes Eight European Drug Regulatory Authorities Capable of Conducting Inspections

FDA has determined it will recognize eight European drug regulatory authorities as capable of conducting inspections of manufacturing facilities that meet FDA requirements. The eight regulatory authorities found to be capable are those located in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom. This achievement marks an important milestone to successful implementation and operationalization of the amended Pharmaceutical Annex to the 1998 US-European Union (EU) Mutual Recognition Agreement, which enables US and EU regulators to utilize each other's good manufacturing practice inspections of pharmaceutical manufacturing facilities. "By partnering with these countries, we can create greater efficiencies and better fulfill our public health goals, relying on the expertise of our colleagues and refocusing our resources on inspections in higher risk countries," said FDA Commissioner Scott Gottlieb, MD, in a news release located at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm583057.htm.

Incorrect Use of Insulin Pens at Home Can Cause Severe Hyperglycemia

The National Coordinating Council for Medication Error Reporting and Prevention has issued an alert on the incorrect use of insulin pens at home causing severe hyperglycemia in patients, including one reported fatality. The Institute for Safe Medication Practices National Medication Errors Reporting Program has received several reports of patients who failed to remove the inner cover of standard insulin pen needles prior to administering insulin. In the latest such event, a patient with type 1 diabetes did not know to remove the standard needle cover and was unaware she was using the pen incorrectly and had not been receiving any of the insulin doses; the patient developed diabetic ketoacidosis as a result and died.

Since insulin pens may differ between pens with automatic needle retraction devices and those with standard needle covers that require manual removal before administering insulin, it is imperative that removal of

needle covers be explained to patients who are issued standard insulin pens during their diabetes education. Pharmacists should verify that a patient understands the appropriate administration technique whenever pens and insulin needles are dispensed, notes the alert, which can be viewed at www.nccmerp.org/sites/default/files/nan-20171012.pdf.

FDA Advises on Opioid Addiction Medications and Benzodiazepines

Opioid addiction medications – buprenorphine and methadone – should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), advises FDA. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care providers can reduce these risks, notes a safety alert. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for minimizing the use of medication-assisted treatment drugs and benzodiazepines together.

Health care providers should take several actions and precautions and should develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. Additional information may be found at www.fda.gov/Drugs/DrugSafety/ucm575307.htm.

Only About 3% of Pharmacies and Other Entities Voluntarily Maintain a Prescription Drug Disposal Bin, GAO Reports

In response to the US Senate Judiciary Committee's request to review DEA's requirements for authorized collectors of prescription drugs and participation rates, the US Government Accountability Office (GAO) found that only about 3% of pharmacies and other entities eligible to collect unused prescription drugs for disposal have volunteered to do so. As of April 2017, 2,233 of the 89,550 eligible entities had registered with DEA to use disposal bins to collect unused prescription drugs. The majority of the authorized collectors were pharmacies, followed by hospitals or clinics. Factors that affected voluntary participation in maintaining disposal bins for the public included cost, uncertainty of proper implementation, and participation in other drug disposal efforts.

GAO found that participation rates varied by state. Connecticut, Missouri, and Maine had the lowest participation rates as of April 2017. North Dakota had the highest participation rate, followed by Alaska. The report, *Preventing Drug Abuse: Low Participation by Pharmacies and Other Entities as Voluntary Collectors of Unused*

Prescription Drugs, is located on the GAO website at www.gao.gov/products/GAO-18-25.

One in Five Drivers Uses a Prescription Drug That Can Impair Driving Despite Receiving Warnings

A new study that analyzes data from the National Roadside Survey of Alcohol and Drug Use, 2013-2014, found that one in five drivers has taken prescription drugs that could impair driving despite having been warned about the risks. The authors of the study, "Receipt of Warnings Regarding Potentially Impairing Prescription Medications and Associated Risk Perceptions in a National Sample of U.S. Drivers," indicate that of the 7,405 random drivers who completed the prescription drug portion of the survey, almost 20% reported recent use (within the past two days) of a potentially impairing prescription drug.

Compared to people who were prescribed antidepressants (62.6%) and stimulants (57.7%), those who were prescribed sedatives (85.8%) and narcotics (85.1%) were most likely to report receiving warnings about the potential of these drugs to affect driving from their health care provider, pharmacy staff, or medication label.

Several European countries have introduced color-coded categories (ie, no, minor, moderate, and major influence on driving) to drug labeling to increase patient safety. Beyond labeling, the authors of the study note it is important that health care providers consistently communicate with patients about their medications' driving-related risks. The study was published online in the *Journal of Studies on Alcohol and Drugs* on October 31, 2017, and can be found at <https://doi.org/10.15288/jsad.2017.78.805>.

PTCB CPhT Program Earns Accreditation From the American National Standards Institute

The Pharmacy Technician Certification Board's (PTCB's) Certified Pharmacy Technician (CPhT) Program has earned accreditation from the American National Standards Institute (ANSI) Personnel Certification Accreditation Program through December 2022. ANSI is the first personnel certification accreditation body in the US to meet internationally accepted practices for accreditation. "We were the first pharmacy technician certification program to receive accreditation by the National Commission for Certifying Agencies (NCCA) in 2006, and now we are the first and only program to achieve ANSI accreditation," said PTCB Executive Director and Chief Executive Officer William Schimmel in a news release. More details are available in PTCB's December 18, 2017 news release, which can be found in the News Room section of www.ptcb.org.

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substances the dispensing of which must be reported to the Virginia Prescription Monitoring Program (PMP). The bill requires a practitioner, prior to issuing a written certification for CBD oil or THC-A oil to a patient, to request information from the director of the DPH for the purpose of determining what other covered substances have been dispensed to the patient.

The bill requires the Board to (i) promulgate regulations that include a process for registering CBD oil and THC-A oil products, and (ii) require an applicant for a pharmaceutical processor permit to submit to fingerprinting and provide personal descriptive information to be forwarded through the Virginia Central Criminal Records Exchange to the Federal Bureau of Investigation for a criminal history record search. The bill requires a pharmacist or pharmacy technician, prior to the initial dispensing of each written certification, to:

- (a) make and maintain for two years a paper or electronic copy of the written certification that provides an exact image of the document that is clearly legible;
- (b) view a current photo identification of the patient, parent, or legal guardian; and
- (c) verify current board registration of the practitioner and the corresponding patient, parent, or legal guardian.

The bill requires that, prior to any subsequent dispensing of each written certification, the pharmacist, pharmacy technician, or delivery agent view the current written certification; a current photo identification of the patient, parent, or legal guardian; and the current board registration issued to the patient, parent, or legal guardian.

Finally, the bill requires a pharmaceutical processor to ensure that the percentage of tetrahydrocannabinol in any THC-A oil on site is within 10% of the level of tetrahydrocannabinol measured for labeling, and to establish a stability testing schedule of THC-A oil.

HB 1177/SB 933: Health insurance; contracts with pharmacies and pharmacists, etc. These identical bills state that no provider contract between a health carrier or its pharmacy benefits manager (PBM) and a pharmacy or its contracting agent shall contain a provision (i) authorizing the carrier or its PBM to charge, (ii) requiring the pharmacy or pharmacist to collect, or (iii) requiring an enrollee to make a copayment for a covered prescription drug in an amount that exceeds the least of the applicable copayment for the prescription drug that would be payable in the absence of this section or the cash price the enrollee would pay for the prescription drug if the enrollee purchased the prescription drug without using the enrollee's health plan. The measure requires provider contracts between a health carrier or its PBM and a pharmacy or contracting agent to contain specific provisions that allow a pharmacy to (a) disclose to an enrollee information relating to the provisions

of this section and the availability of a more affordable therapeutically equivalent prescription drug; (b) sell a more affordable therapeutically equivalent prescription drug to an enrollee if one is available; and (c) offer and provide direct and limited delivery services to an enrollee as an ancillary service of the pharmacy. This measure applies to provider contracts entered into, amended, extended, or renewed on or after January 1, 2019.

HB 1556/SB 832: Prescription Monitoring Program; adds controlled substances included in Schedule V and naloxone. These identical bills require the dispensing of Schedule V drugs dispensed pursuant to a prescription and naloxone to be reported to the PMP. This reporting requirement is effective July 1, 2018.

SB 226: Prescription Monitoring Program; veterinarians. Requires veterinarians who dispense controlled substances (CS) to report certain information about the animal and the owner to the PMP. The bill requires veterinarians to register with the PMP and, when issuing a prescription to an animal for opiates that will last more than seven days, to request certain information from the PMP regarding both the animal and the owner of the animal.

SB 544: Prescription drugs; donation of used medicines. This bill clarifies that prescription drug donation programs may accept eligible prescription drugs from individuals, including those residing in nursing homes, assisted living facilities, or intermediate care facilities established for individuals with intellectual disability; licensed hospitals; any facility operated by the Department of Behavioral Health and Developmental Services; an agent pursuant to a power of attorney; a decedent's personal representative; a legal guardian of an incapacitated person; or a guardian ad litem donated on behalf of the represented individual. Such donations of eligible drugs may be redispensed to indigent patients in compliance with Regulations 18VAC110-20-740 through 18VAC110-20-800. Eligible drugs are those in which official compendium storage requirements are assured and the drugs are in manufacturers' original sealed containers or in sealed individual dose or unit-dose packaging that meets official compendium Class A or B container requirements or better, as set forth in §54.1-3411.1(A)(2) of the Code of Virginia. The drugs must also bear an expiration date that is not less than 90 days from the date the drug is donated and must not have been adulterated or misbranded. The following drugs shall not be accepted for donation:

- ◆ Schedule II-V CS or any other drug if such return is inconsistent with federal law;
- ◆ drugs determined to be hazardous for donation based on:
 - (i) the pharmacist's professional judgment, experience, or knowledge, or
 - (ii) available reference materials;

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- ◆ drugs that may only be dispensed to a patient registered with the drug manufacturer under a restricted distribution system; and
- ◆ drugs that have been previously compounded.

SB 882: Prescription refill; approval. Provides that a prescriber may authorize a registered nurse or licensed practical nurse to approve additional refills of a prescribed drug for no more than 90 consecutive days, provided that (i) the drug is classified as a Schedule VI drug; (ii) there are no changes in the prescribed drug, strength, or dosage; (iii) the prescriber has a current written protocol, accessible by the nurse, that identifies the conditions under which the nurse may approve additional refills; and (iv) the nurse documents in the patient's chart any refills authorized for a specific patient pursuant to the protocol and the additional refills are transmitted to a pharmacist in accordance with the allowances for an authorized agent to transmit a prescription orally or by facsimile pursuant to current law and regulations.

Animal Prescriptions – Information Required

The PMP often receives inquiries and incorrect data from pharmacies when reporting the dispensing of a covered substance for an animal. §54.1-3409, Professional use by veterinarians, of the Code of Virginia states:

A veterinarian may not prescribe controlled substances for human use and shall only prescribe, dispense or administer a controlled substance in good faith for use by animals within the course of

his professional practice. He may prescribe, on a written prescription or on oral prescription as authorized by §54.1-3410. He may administer drugs, and he may cause them to be administered by an assistant or orderly under his direction and supervision. Such a prescription shall be dated and signed by the person prescribing on the day when issued, and shall bear the full name and address of the owner of the animal, and the species of the animal for which the drug is prescribed and the full name, address and registry number, under the federal laws of the person prescribing, if he is required by those laws to be so registered.

The date of birth is a required reporting field for the PMP. **When dispensing a prescription for an animal, the date of birth to be reported is that of the owner of the animal. As a reminder, as of July 1, 2017, the species code is a required data element. The animal species code is "02."** Questions regarding the reporting of covered substances to the PMP should be emailed to pmp@dhp.virginia.gov, or you may call the PMP at 804/367-4566.

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