# Advisory Board on Physician Assistants

Virginia Board of Medicine

February 1, 2018
1:00 p.m.

# Advisory Board on Physician Assistants

Board of Medicine
Thursday, February 1, 2018, 1:00 PM
9960 Mayland Drive, Suite 201
Henrico, Virginia

**PERIMETER CENTER CONFERENCE CENTER**
**EMERGENCY EVACUATION OF BOARD AND TRAINING ROOMS**
(Script to be read at the beginning of each meeting.)

## Training Room 2

Exit the room using one of the doors at the back of the room. **(Point)** Upon exiting the doors, turn **LEFT.** Follow the corridor to the emergency exit at the end of the hall.

Upon exiting the building, proceed straight ahead through the parking lot to the fence at the end of the lot. Wait there for further instructions.

# ADVISORY BOARD ON PHYSICIAN ASSISTANTS

October 5, 2017, 1:00 PM
9960 Mayland Drive, Suite 201
Richmond, VA
Training Room 2

The Advisory Board on Physician Assistants met Thursday, October 5, 2017, at 1:00 p.m. at the Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Richmond, Virginia.

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| **MEMBERS PRESENT:** | Thomas Parish PA-C, Chair<br>Portia Tomlinson, PA-C, Vice-Chair<br>Rachel Carlson, PA-C |
| **MEMBERS ABSENT:** | James Potter, MD<br>Citizen member-vacant |
| **STAFF PRESENT:** | William L. Harp, MD, Executive Director<br>R. Alan Heaberlin, Deputy for Licensure<br>Elaine Yeatts, DHP Senior Policy Analyst<br>ShaRon Clanton, Licensing Specialist<br>Colanthia Morton Opher, Operations Manager |
| **GUESTS PRESENT:** | David Falkenstein, VAPA<br>Robert Glasgow, PA-C, VAPA<br>W. Scott Johnson, MSV<br>Jeremy Welsh, VAPA |

## Call to Order

Mr. Parish called the meeting to order at 1:00 pm.

## Emergency Egress Procedures

Mr. Heaberlin provided the emergency egress instructions.

## Roll Call

Ms. Clanton called the roll, and a quorum was declared.

## Approval of the Minutes from June 8, 2017

Ms. Tomlinson moved to adopt the minutes. The motion was seconded and carried.

**Adoption of Agenda**

Ms. Tomlinson moved to adopt the agenda. The motion was seconded and carried.

**Public Comment on Agenda Items**

Mr. Falkenstein discussed actions to amend 18VAC85-50-10, 18VAC85-50-101 and 18VAC50-110.

**NEW BUSINESS**

1. The Advisory Board discussed revising the different types of supervision as currently defined in the regulations. It recommended removing Direct Supervision, General Supervision and Personal Supervision from Section 18VAC85-50-10. Revisions were recommended in Section 18VAC85-50-101(B) to remove (i.e. "direct," "personal," or "general"), and in Section 18VAC85-50-110(2)(a) "Under general supervision", and in Section (2)(b), edits were recommended regarding direct supervision of invasive procedures.

   Ms. Carlson moved to approve the recommended amendments. The motion was seconded and carried.

2. The Advisory Board reviewed 18VAC85-50-181 and recommended revision, noting that not all pharmacies are filling prescriptions written by physician assistants for weight loss. The Advisory Board recommended adding *"C. If specifically authorized in his practice agreement with a supervising or collaborating physician, a physician assistant or nurse practitioner may perform the physical examination, review tests, and prescribe Schedules III through VI controlled substances for treatment of obesity, as specified in subsection B of this section"*, basically the language from 18VAC85-20-90 of the Medicine and Surgery Regulations. It was thought that adding this would remove any confusion pharmacists might have regarding physician assistants writing prescriptions for weight loss medications.

   Ms. Tomlinson moved to approve importing subsection C from the Medicine and Surgery Regulations with the exception of "or nurse practitioner" to 18VAC85-50-181 of the Regulations Governing the Practice of Physician Assistants.

   The motion was seconded and carried.

3. Discussion of Student Exemption and License Applicant Status-Dr. Harp

   Dr. Harp reviewed the student exemption and license applicant status for respiratory therapy and occupational therapy. The Advisory Board did not think a change was necessary for physician assistants. No action was taken.

4. Approval of 2018 Meeting Calendar-Alan Heaberlin

   Ms. Tomlinson moved to accept the dates. The motion was seconded and approved unanimously.

5. Election of Officers-Thomas Parish, PA-C

   Mr. Parish moved to appoint Portia Tomlinson as Chair and Rachel Carlson as Vice-Chair. The motion was seconded and carried.

**ANNOUNCEMENTS:**

Mr. Heaberlin informed the Advisory Board that there are currently 3,596 active and 51 inactive Physician Assistants. The members were informed of the $50.00 per diem that is now being paid to those advisory board members who are not state employees.

**NEXT MEETING DATE**

February 1, 2018 @ 1:00 p.m.

**ADJOURNMENT**

The meeting of the Advisory Board was adjourned at 1:52 p.m.

_____
Thomas Parish, PA-C, Chair

_____
William L. Harp, M.D., Executive Director

_____
ShaRon Clanton, Licensing Specialist

# Report of 2018 General Assembly

**HB 132 Controlled substances containing opioids; limits on prescription.**

*Chief patron:* Bell, John J.

*Summary as introduced:*
**Limits on prescription of controlled substances containing opioids.** Prohibits a prescriber providing treatment for a patient in an emergency department of a corporation, facility, or institution licensed to provide health care from prescribing a controlled substance containing an opioid in a quantity greater than a 10-day supply, as determined in accordance with the prescriber's directions for use. The bill also prohibits a pharmacist from dispensing a controlled substance containing an opioid pursuant to a prescription issued by a prescriber providing treatment to a patient in the emergency department of a corporation, facility, or institution licensed to provide health care unless the prescription complies with the requirements of the bill.

01/23/18 House: Subcommittee recommends striking from docket (10-Y 0-N)

**HB 137 Marijuana; possession or distribution for medical purposes.**

*Chief patron:* Levine

*Summary as introduced:*
**Possession or distribution of marijuana for medical purposes; affirmative defense for treatment of cancer.** Provides an affirmative defense to prosecution for possession of marijuana if a person has a valid written certification issued by a practitioner for cannabidiol oil or THC-A oil for treatment of, or to alleviate the symptoms of, cancer. Under current law, only the treatment of intractable epilepsy is covered by the affirmative defense.

01/23/18 House: Assigned Courts sub: Subcommittee #1

**HB 148 Prescription Monitoring Program; requirements of prescribers, prescriptions for opioids.**

*Chief patron:* Rasoul

*Summary as introduced:*
**Prescription Monitoring Program; requirements of prescribers; prescriptions for opioids.** Requires a prescriber to request and review information from the Prescription Monitoring Program prior to issuing a prescription for opioids, including a refill of an existing prescription for opioids. Currently, a prescriber is only required to request information from the Prescription Monitoring Program prior to initiating a new course of treatment that includes the prescribing of opioids anticipated at the onset to last more than seven consecutive days.

01/23/18 House: Subcommittee recommends striking from docket (10-Y 0-N)

**HB 157 Right to Treat Act; requirement of Maintenance of Certification prohibited, etc.**

*Chief patron:* Rasoul

*Summary as introduced:*
**Right to treat; requirement of Maintenance of Certification prohibited.** Prohibits hospitals and other entities that have organized medical staff or a process for credentialing physicians as members of staff or employ or enter into contracts for employment with physicians and are required to be licensed from requiring any Maintenance of Certification or Osteopathic Continuous Certification, as defined in the bill, as a condition of granting or continuing staff membership or professional privileges to a licensed physician. The bill prohibits accident and sickness insurance plans, health services plans, and health maintenance organizations from requiring any Maintenance of Certification or Osteopathic Continuous

Certification as a condition of participation or reimbursement for a physician licensed by the Board of Medicine; and prohibits the Board of Medicine from requiring any Maintenance of Certification or Osteopathic Continuous Certification as a condition of licensure to practice medicine in the Commonwealth.

01/17/18 House: Assigned C & L sub: Subcommittee #2

**HB 169 Lyme disease; information disclosure requirement, sunset.**

*Chief patron:* Murphy

*Summary as introduced:*
**Lyme disease information disclosure requirement; sunset.** Extends to July 1, 2023, the sunset of the provision requiring disclosure of certain information to a patient when a Lyme disease test is ordered. Under current law, the disclosure requirement will expire on July 1, 2018.

01/18/18 House: Stricken from docket by Health, Welfare and Institutions (21-Y 0-N)

**HB 184 Drug Control Act; dispensing drugs without a prescription.**

*Chief patron:* Hayes

*Summary as introduced:*
**Dispensing drugs without a prescription.** Authorizes a pharmacist to dispense up to a five-day supply of a Schedule VI drug to an individual who has been displaced from his residence by a natural or man-made disaster; has had his supply of the drug lost, destroyed, or otherwise rendered unusable as a consequence of the disaster; and is unable to tell the pharmacist the identity of the prescriber or his regular pharmacist or pharmacy. The bill also requires the individual to present evidence sufficient to establish, among other things, that the individual had been in lawful possession of the drug pursuant to a prescription provided to another pharmacist and that his health would be in danger without the benefits of the drug. Before prescribing the drug, the pharmacist is required to determine with a reasonable degree of certainty that the requested drug and dosage level are consistent with the drug and its dosage level that had been prescribed to the individual at the time of his displacement from his residence. During the period for which the drug has been dispensed, the pharmacist is required to diligently attempt to ascertain the identity of the prescriber and the identity of the pharmacist or pharmacy in possession of the prescriber's prescription. Upon obtaining such information, the pharmacist is required to take such additional reasonable action as will permit the individual to obtain a new or renewal prescription and resume obtaining the drug pursuant to his prescription.

01/17/18 House: Assigned HWI sub: Subcommittee #1

**HB 197 Prescription monitoring program; definitions, requirement for filling prescriptions.**

*Chief patron:* Mullin

*Summary as introduced:*
**Prescription monitoring program.**

01/23/18 House: Subcommittee recommends striking from docket (10-Y 0-N)

**HB 226 Patients; medically or ethically inappropriate care not required.**

*Chief patron:* Stolle

*Summary as introduced:*
**Medically or ethically inappropriate care not required.** Establishes a process whereby a physician may cease to provide health care that has been determined to be medically or ethically inappropriate for a patient.

01/22/18 House: Assigned HWI sub: Subcommittee #3

**HB 298 Birth control; definition.**

*Chief patron:* Watts

*Summary as introduced:*
**Definition of birth control.** Defines "birth control" as contraceptive methods that are approved by the U.S. Food and Drug Administration and provides that birth control shall not be considered abortion for the purposes of Title 18.2.

01/03/18 House: Referred to Committee for Courts of Justice

**HB 313 Prescription Monitoring Program; notification of top prescribers by quantity covered substances.**

*Chief patron:* Head

*Summary as introduced:*
**Prescription Monitoring Program; notification of top prescribers.** Provides that the Director of the Department of Health Professions shall annually review data collected by the Prescription Monitoring Program to identify those prescribers who, based on such data, fall within the top 10 percent of prescribers by quantity of covered substances prescribed and shall notify such prescribers thereof.

01/23/18 House: Subcommittee recommends reporting with substitute (10-Y 0-N)

**HB 322 Naloxone or other opioid antagonist; possession & administration.**

*Chief patron:* Bourne

*Summary as introduced:*
**Possession and administration of naloxone.** Adds employees of the 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 that they have completed a training program.

01/24/18 House: VOTE: BLOCK VOTE PASSAGE (98-Y 0-N)

**HB 333 Prescription Monitoring Program; requirements of prescribers, exceptions.**

*Chief patron:* Yancey

*Summary as introduced:*
**Prescription Monitoring Program; requirements of prescribers; exceptions.** Provides that a prescriber initiating a new course of treatment to a human patient that includes the prescribing of opioids, anticipated at the onset of treatment to last more than seven consecutive days, shall not be required to request information about the patient from the Prescription Monitoring Program if the purpose of the prescription is the management of pain associated with cancer.

01/23/18 House: Subcommittee recommends passing by indefinitely (10-Y 0-N)

**HB 363 Sexual orientation change efforts; prohibited as training for certain health care providers, etc.**

*Chief patron:* Hope

*Summary as introduced:*
**Sexual orientation change efforts prohibited.** Prohibits any health care provider or person who performs counseling as part of his training for any profession licensed by a regulatory board of the Department of Health Professions from engaging in sexual orientation change efforts with any person under 18 years of age. The bill defines "sexual orientation change efforts" as any practice or treatment that seeks to change an individual's sexual orientation or gender identity, including efforts to change behaviors or gender expressions or to eliminate or reduce sexual or romantic attractions or feelings toward individuals of the same gender. "Sexual orientation change efforts" does not include counseling that provides assistance to a person undergoing gender transition or counseling that provides acceptance, support, and understanding of a person or facilitates a person's coping, social support, and identity exploration and development, including sexual-orientation-neutral interventions to prevent or address unlawful conduct or unsafe sexual practices, as long as such counseling does not seek to change an individual's sexual orientation or gender identity. The bill provides that no state funds shall be expended for the purpose of conducting sexual orientation change efforts, referring a person for sexual orientation change efforts, extending health benefits coverage for sexual orientation change efforts, or awarding a grant or contract to any entity that conducts sexual orientation change efforts or refers individuals for sexual orientation change efforts.

01/05/18 House: Referred to Committee on Health, Welfare and Institutions

**HB 385 Health care providers; meeting, trial, and deposition charges.**

*Chief patron:* Habeeb

*Summary as introduced:*
**Health care providers; meeting, trial, and deposition charges.** Provides that, in any case, a health care provider may only charge a patient or the patient's attorney, executor or administrator, or authorized insurer a reasonable fee on an hourly basis for such health care provider's actual time spent at or preparing for (i) a meeting related to pending or probable litigation, (ii) a trial, or (iii) a deposition. The bill further specifies that such fee shall not be more than the amount of actual lost revenue incurred due to such time spent at or preparing for such meeting, trial, or deposition.

01/16/18 House: Assigned Courts sub: Subcommittee #2

**HB 450 Abortion; informed written consent.**

*Chief patron:* Rodman

*Summary as introduced:*
**Abortion; informed written consent.** Repeals the statutory requirements that a physician obtain a pregnant woman's informed written consent and perform fetal transabdominal ultrasound imaging before performing an abortion.

01/06/18 House: Referred to Committee for Courts of Justice

**HB 452 Prescription Monitoring Program; requirements of prescribers, exceptions.**

*Chief patron:* Yancey

*Summary as introduced:*
**Prescription Monitoring Program; requirements of prescribers; exceptions.** Provides that a prescriber initiating a new course of treatment to a human patient that includes the prescribing of opioids, anticipated at the onset of treatment to last more than seven consecutive days, shall not be required to request information about the patient from the Prescription

Monitoring Program if the purpose of the prescription is the management of pain associated with fibromyalgia, provided that management of the patient's pain through means other than the prescription of opioids has been unsuccessful.

01/23/18 House: Subcommittee recommends passing by indefinitely (10-Y 0-N)

**HB 458 CBD oil and THC-A oil; certification for use, dispensing.**

*Chief patron:* Filler-Corn

*Summary as introduced:*
**CBD oil and THC-A oil; certification for use; dispensing.** Provides that a practitioner may issue a written certification for the use of cannabidiol oil or THC-A oil for the treatment or to alleviate the symptoms of any diagnosed condition or disease. Under current law, a practitioner may only issue such certification for the treatment or to alleviate the symptoms of intractable epilepsy. The bill increases the supply of CBD oil or THC-A oil a pharmaceutical processor may dispense from a 30-day supply to a 90-day supply. The bill reduces the minimum amount of cannabidiol or tetrahydrocannabinol acid per milliliter for a dilution of the Cannabis plant to fall under the definition of CBD oil or THC-A oil, respectively. The bill provides that any agent or employee of a pharmaceutical processor is authorized to deliver CBD oil or THC-A oil. Finally, the bill provides that no agent or employee of a pharmaceutical processor can be prosecuted for the possession or manufacture of marijuana or the possession, manufacture, or distribution of CBD oil or THC-A oil if such agent or employee is acting in accordance with certain statutes and regulations. Under current law, such agents and employees may be prosecuted but it is considered an affirmative defense if such agents or employees act in accordance with such statutes and regulations.

01/23/18 House: Assigned Courts sub: Subcommittee #1

**HB 503 Prescription Monitoring Program; disclosure of information, fitness to work evaluations.**

*Chief patron:* Mullin

*Summary as introduced:*
**Prescription Monitoring Program; disclosure of information; fitness to work and return to work evaluations.** Adds the following individuals to the list of individuals to whom the Director of the Department of Health Professions (the Director) may disclose information about a specific recipient contained in the Prescription Monitoring Program: (i) a physician licensed in the Commonwealth or another state who is performing an evaluation of the recipient's fitness for work or to return to work in a safety-sensitive position, as defined by the recipient's employer, at the request of the recipient's employer and (ii) a physician licensed in the Commonwealth or another state who is performing an evaluation of the recipient's fitness for work at a place of employment with a written drug-free workplace policy following an offer of employment but prior to hiring the recipient, upon request of the employer and when the request is consistent with the employer's written drug-free workplace policy. In both cases, the bill requires that the information be requested and released only for the purpose of establishing the recipient's treatment history and that notice be made, in a manner specified by the Director in regulation, to the recipient that information from the Prescription Monitoring Program may be requested and received by the physician performing the fitness for work or return to work evaluation.

01/23/18 House: Subcommittee recommends passing by indefinitely (8-Y 0-N)

**HB 533 Medicine and Dentistry, Boards of; acceptance of substantially equivalent military training, etc.**

*Chief patron:* Freitas

*Summary as introduced:*
**Professions and occupations; qualifications for licensure; acceptance of substantially equivalent military training, education, and experience.** Requires the Board of Medicine and the Board of Dentistry to accept the military training, education, or experience of a service member honorably discharged from active military service in the Armed Forces of

the United States, to the extent that such training, education, or experience is substantially equivalent to the requirements established by law and regulations of the respective board for the issuance of any license, permit, certificate, or other document, however styled or denominated, required for the practice of any business, profession, or occupation in the Commonwealth. Current law exempts the Board of Medicine and the Board of Dentistry from this requirement and provides that they may accept the military training, education, or experience of a service member under certain circumstances. The bill also directs the Department of Veterans Services to take steps to promote awareness among veterans of the acceptance of such substantially equivalent military training, education, or experience by the Department of Professional and Occupational Regulation, the Department of Health Professions, or any other board named in Title 54.1 (Professions and Occupations).

01/17/18 House: Assigned HWI sub: Subcommittee #1

**HB 621 Cobalt poisoning; notice to patients of risk.**

*Chief patron:* Bell, Robert B.

*Summary as introduced:*
**Notice to patients of risk of cobalt poisoning.**

01/18/18 House: Subcommittee recommends continuing to 2019

**HB 641 Prescription Monitoring Program; recipients of dispensed Schedule II drugs.**

*Chief patron:* Mullin

*Summary as introduced:*
**Prescription Monitoring Program; recipients of dispensed Schedule II drugs.** Requires pharmacists who dispense Schedule II drugs pursuant to a valid prescription to include the name, address, and government-issued identification number of the person to whom the covered substance was actually delivered in the report submitted to the Prescription Monitoring Program.

01/15/18 House: Assigned HWI sub: Subcommittee #2

**HB 793 Nurse practitioners; practice agreements.**

*Chief patron:* Robinson

*Summary as introduced:*
**Nurse practitioners; practice agreements.** Eliminates the requirement for a practice agreement with a patient care team physician for nurse practitioners who are licensed by the Boards of Medicine and Nursing and have completed at least 1,040 hours of clinical experience as a licensed, certified nurse practitioner. The bill replaces the term "patient care team physician" with the term "collaborating provider" and allows a nurse practitioner who is exempt from the requirement for a practice agreement to enter into a practice agreement to provide collaboration and consultation to a nurse practitioner who is not exempt from the requirement for a practice agreement. The bill establishes title protection for advanced practice registered nurses, nurse practitioners, certified registered nurse anesthetists, certified nurse midwives, and clinical nurse specialists. The bill contains technical amendments.

01/17/18 House: Assigned HWI sub: Subcommittee #1

**HB 842 Controlled paraphernalia; possession or distribution, hypodermic needles and syringes, naloxone.**

*Chief patron:* LaRock

*Summary as introduced:*
**Possession or distribution of controlled paraphernalia; hypodermic needles and syringes; naloxone.** Provides that 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 an opioid overdose or training in the administration of naloxone for overdose reversal and that has obtained a controlled substances registration from the Board of Pharmacy may dispense or distribute hypodermic needles and syringes in conjunction with such dispensing of naloxone and that a person to whom naloxone has been distributed by such individual may possess hypodermic needles and syringes in conjunction with such possession of naloxone.

01/23/18 House: Subcommittee recommends reporting with amendments (10-Y 0-N)

**HB 854 Polysomnographic technology; students or trainees, licensure.**

*Chief patron:* Peace

*Summary as introduced:*
**Practice of polysomnographic technology; licensure; students or trainees.** Provides that a student enrolled in an educational program in polysomnographic technology or a person engaged in a traineeship does not require a license to practice polysomnographic technology, provided that such student or trainee is under the direct supervision of a licensed polysomnographic technologist or a licensed doctor of medicine or osteopathic medicine. The bill requires any such student or trainee to be identified to patients as a student or trainee in polysomnographic technology. The bill also provides that any such student or trainee is required to have a license to practice after18 months from the start of the educational program or traineeship or six months from the conclusion of such program or traineeship, whichever is earlier.

01/23/18 House: Assigned HWI sub: Subcommittee #1

**HB 860 Prescription drugs; delivery of orders.**

*Chief patron:* Peace

*Summary as introduced:*
**Delivery of prescription drug orders.** Provides that whenever any pharmacy delivers a prescription drug order for which refrigeration is required by mail, common carrier, or delivery service, when the drug order is not personally hand delivered directly, to the patient or his agent at the person's residence or other designated location, the shipment shall include a means for the (i) detection of temperature variations that may cause chemical degradation of the drugs and (ii) notification of the patient of the variation.

01/17/18 House: Assigned HWI sub: Subcommittee #3

**HB 882 Prescribers; notice of administration of naloxone.**

*Chief patron:* Stolle

*Summary as introduced:*
**Prescribers; notice of administration of naloxone.** Requires every hospital that operates an emergency department to develop and implement a protocol for (i) identifying every prescriber who has prescribed opioids to a patient to whom naloxone is administered for the purpose of reversing an opioid overdose in the emergency department or by emergency medical services personnel or a law-enforcement officer prior to admission to the emergency department in the twelve month period immediately preceding the administration of naloxone and (ii) notifying each such prescriber that the patient has been treated with naloxone for the purpose of reversing an opioid overdose. Such notification shall be made in each case in which naloxone is administered for the purpose of reversing an opioid overdose by a health care provider in a

hospital emergency department, emergency medical services personnel, or a law-enforcement officer to a patient to whom opioids have been prescribed by a prescriber.

01/18/18 House: Impact statement from VDH (HB882)

**HB 884 Treatment pursuant to judicial order; when provider not liable.**

*Chief patron:* Stolle

*Summary as introduced:*
**Treatment pursuant to judicial order; when provider not liable.** Provides that a health care professional or licensed hospital shall not be liable for any cause of action arising from a claim that a person who received treatment pursuant to an emergency custody, temporary detention, or involuntary commitment order was not capable of consenting to such treatment or from a claim that a person who consented to treatment lacked the capacity to consent, if a judge or special justice has denied a petition for an emergency custody, temporary detention, or involuntary commitment order.

01/16/18 House: Assigned Courts sub: Subcommittee #2

**HB 915 Military medical personnel program; supervision of personnel by chief medical officer.**

*Chief patron:* Stolle

*Summary as introduced:*
**Military medical personnel program; supervision.** Provides that military medical personnel in a program, established by the Department of Veterans Services, who may perform certain delegated acts that constitute the practice of medicine while under the supervision of a physician or podiatrist may also perform such acts under the supervision of the chief medical officer, or his designee, of an organization participating in the program. In addition, the bill removes the designation of this program as a pilot program.

01/09/18 House: Referred to Committee on Health, Welfare and Institutions

**HB 974 Medical marijuana; written certification by physician for treatment.**

*Chief patron:* Guzman

*Summary as introduced:*
**Medical marijuana; written certification.** Allows a person to possess marijuana or tetrahydrocannabinol pursuant to a valid written certification issued by a physician for the treatment of any medical condition deemed terminal or debilitating by a licensed health care professional, pain management, cancer, glaucoma, intractable epilepsy, human immunodeficiency virus, osteoporosis, or arthritis. The bill allows a physician or pharmacist to distribute such substances without being subject to prosecution. Under current law, a person has an affirmative defense to prosecution for possession of marijuana if the marijuana is in the form of cannabidiol oil or THC-A oil and the person has been issued a written certification by a physician that such marijuana is for the purposes of treating or alleviating the person's symptoms of intractable epilepsy. The bill expands the authority for a pharmaceutical processor, after obtaining a permit from the Board of Pharmacy and under the supervision of a licensed pharmacist, to manufacture and provide marijuana in any form to be used for the treatment of any medical condition deemed terminal or debilitating by a licensed health care professional, pain management, cancer, glaucoma, intractable epilepsy, human immunodeficiency virus, osteoporosis, or arthritis, not just marijuana in the form of cannabidiol oil and THC-A oil to be used for the treatment of intractable epilepsy. Finally, the bill clarifies that the penalties for forging or altering a written certification for medical marijuana or for making or uttering a false or forged written certification are the same as the penalties for committing the same acts with regard to prescriptions.

01/09/18 House: Referred to Committee for Courts of Justice

**HB 1014 CBD oil and THC-A oil; certification for use, dispensing.**

*Chief patron:* Toscano

*Summary as introduced:*
**CBD oil and THC-A oil; certification for use; dispensing.** Provides that a practitioner may issue a written certification for the use of cannabidiol 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. Under current law, a practitioner may only issue such certification for the treatment or to alleviate the symptoms of intractable epilepsy.

01/23/18 House: Assigned Courts sub: Subcommittee #1

**HB 1037 Abortions; performance, eliminates certain requirement.**

*Chief patron:* Convirs-Fowler

*Summary as introduced:*
**Performance of abortions.** Eliminates the requirement that two other physicians certify that a third trimester abortion is necessary to prevent the woman's death or impairment of her mental or physical health.

01/09/18 House: Referred to Committee for Courts of Justice

**HB 1064 Medical marijuana; written certification issued by physician.**

*Chief patron:* Heretick

*Summary as introduced:*
**Medical marijuana; written certification.** Allows a person to possess marijuana or tetrahydrocannabinol pursuant to a valid written certification issued by a physician for the treatment of any medical condition and allows a physician or pharmacist to distribute such substances without being subject to prosecution. Under current law, a person has an affirmative defense to prosecution for possession of marijuana if the marijuana is in the form of cannabidiol oil or THC-A oil and the person has been issued a written certification by a physician that such marijuana is for the purposes of treating or alleviating the person's symptoms of intractable epilepsy. The bill expands the authority for a pharmaceutical processor, after obtaining a permit from the Board of Pharmacy and under the supervision of a licensed pharmacist, to manufacture and provide marijuana in any form to be used for the treatment of any medical condition, not just marijuana in the form of cannabidiol oil and THC-A oil to be used for the treatment of intractable epilepsy. Finally, the bill clarifies that the penalties for forging or altering a written certification for medical marijuana or for making or uttering a false or forged written certification are the same as the penalties for committing the same acts with regard to prescriptions.

01/10/18 House: Referred to Committee for Courts of Justice

**HB 1071 Health regulatory boards; electronic notice of license renewal.**

*Chief patron:* Heretick

*Summary as introduced:*
**Health regulatory boards; license renewal; electronic notice.** Provides that the Board of Funeral Directors and Embalmers, the Board of Medicine, and the Board of Nursing may send notices for license renewal electronically.

01/10/18 House: Referred to Committee on Health, Welfare and Institutions

**HB 1173 Controlled substances; limits on prescriptions containing opioids.**

*Chief patron:* Pillion

*Summary as introduced:*
**Limits on prescription of controlled substances containing opioids.** Eliminates the surgical or invasive procedure treatment exception to the requirement that a prescriber request certain information from the Prescription Monitoring Program (PMP) when initiating a new course of treatment that includes prescribing opioids for a human patient to last more than seven days. Under current law, a prescriber is not required to request certain information from the PMP for opioid prescriptions of up to 14 days to a patient as part of treatment for a surgical or invasive procedure. The provisions of the bill will expire on July 1, 2022.

01/18/18 House: Assigned HWI sub: Subcommittee #2
01/23/18 House: Subcommittee recommends reporting (10-Y 0-N)

**HB 1175 Prescribers; notice of administration of naloxone.**

*Chief patron:* Pillion

*Summary as introduced:*
**Prescribers; notice of administration of naloxone.** Requires every hospital that operates an emergency department to develop and implement a protocol for (i) identifying every prescriber who has prescribed opioids to a patient to whom naloxone is administered for the purpose of reversing an opioid overdose in the emergency department or by emergency medical services personnel or a law-enforcement officer prior to admission to the emergency department and (ii) notifying each such prescriber that the patient has been treated with naloxone for the purpose of reversing an opioid overdose. Such notification shall be made in each case in which naloxone is administered for the purpose of reversing an opioid overdose by a health care provider in a hospital emergency department, emergency medical services personnel, or a law-enforcement officer to a patient to whom opioids have been prescribed by a prescriber.

01/18/18 House: Assigned HWI sub: Subcommittee #1

**HB 1182 Perinatal hospice and palliative care; notice to woman of agencies.**

*Chief patron:* LaRock

*Summary as introduced:*
**Perinatal hospice and palliative care; notice.** Requires every health care provider that diagnoses a fetus with a profound and irremediable congenital or chromosomal anomaly that is incompatible with sustaining life after birth to provide the pregnant women with geographically indexed materials prepared by the Department of Health that are designed to inform the woman of public and private agencies providing perinatal hospice and palliative care services available to the woman if she chooses to continue the pregnancy, and requires the Department of Health to make such information available both to health care providers and on a website maintained by the Department. The bill also requires health care providers to annually report data and information about cases in which information regarding perinatal hospice and palliative care services is provided.

01/10/18 House: Referred to Committee on Rules

**HB 1194 Schedule I controlled substances; adds various drugs to list.**

*Chief patron:* Garrett

*Summary as introduced:*
**Schedule I controlled substances.** Adds drugs to the list of Schedule I controlled substances.

01/10/18 House: Referred to Committee on Health, Welfare and Institutions

**HB 1231 Abortion; a pregnant person has a fundamental right to obtain.**

*Chief patron:* Boysko

*Summary as introduced:*
**Right to abortion; provision of abortion.** Provides that a pregnant person has a fundamental right to obtain a lawful abortion and that no statute or regulation shall be construed to prohibit the performance of an abortion prior to viability or if necessary to protect the life or health of the pregnant person. The bill also provides that any statute that places a burden on a pregnant person's access to abortion without conferring any legitimate health benefit is unenforceable. The bill expands who can perform first trimester abortions to include, in addition to physicians, physician's assistants and midwives licensed by the Board of Medicine, nurse practitioners or certified nurse midwives jointly licensed by the Board of Medicine and the Board of Nursing, and persons acting pursuant to orders and under the appropriate supervision of a physician. The bill also expands who can perform second trimester abortions to include persons acting pursuant to orders and under the appropriate supervision of a physician. The bill eliminates the requirement that second trimester abortions be performed in a licensed hospital. The bill eliminates the requirement that two other physicians certify that a third trimester abortion is necessary to prevent the pregnant person's death or impairment of her mental or physical health as well as the need to find that the pregnant person's health would be substantially and irremediably impaired. The bill permits a third trimester abortion if the pregnancy is not viable. The bill eliminates all the procedures and processes, including the performance of an ultrasound, required to effect a pregnant person's informed written consent to the performance of an abortion; however, the bill does not change the requirement that a pregnant person's informed written consent first be obtained. The bill removes language classifying facilities that perform five or more first trimester abortions per month as hospitals for the purpose of complying with regulations establishing minimum standards for hospitals. The bill also removes the prohibition on the sale of health insurance policies that provide coverage for abortions through an exchange established or operating in the Commonwealth pursuant to the federal Patient Protection and Affordable Care Act. The bill eliminates the crime, punishable as a Class 4 felony, of administering a drug or other thing to a pregnant person or using other means with the intent to destroy such person's unborn child or to produce an abortion or miscarriage.

01/10/18 House: Referred to Committee for Courts of Justice

**HB 1251 CBD oil and THC-A oil; certification for use, dispensing.**

*Chief patron:* Cline

*Summary as introduced:*
**CBD oil and THC-A oil; certification for use; dispensing.** Provides that a practitioner may issue a written certification for the use of cannabidiol 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. Under current law, a practitioner may only issue such certification for the treatment or to alleviate the symptoms of intractable epilepsy. This bill is a recommendation of the Joint Commission on Health Care.

01/18/18 House: Referred to Committee for Courts of Justice
01/23/18 House: Assigned Courts sub: Subcommittee #1

**HB 1295 Prescription Monitoring Program; disclosure of info to a public institution of higher education.**

*Chief patron:* Rasoul

*Summary as introduced:*
**Prescription Monitoring Program; disclosure of information; public institution of higher education.** Allows the Director of the Department of Health Professions to disclose certain information included in the Prescription Monitoring Program to a public institution of higher education for the purpose of bona fide research or education.

01/18/18 House: Assigned HWI sub: Subcommittee #2
01/23/18 House: Subcommittee recommends passing by indefinitely (5-Y 4-N)

**HB 1303 Prescribing controlled substances; veterinarian-client-patient relationship.**

*Chief patron:* Garrett

*Summary as introduced:*
**Prescribing controlled substances; veterinarian-client-patient relationship.** Provides that a veterinarian shall not prescribe medication unless a bona fide veterinarian-client-patient relationship exists and establishes the requirements for a bona fide veterinarian-client-patient relationship.

01/19/18 House: Assigned HWI sub: Subcommittee #1

**HB 1377 Epinephrine; possession and administration at outdoor educational programs.**

*Chief patron:* Torian

*Summary as introduced:*
**Possession and administration of epinephrine; outdoor educational programs.** Provides that an employee of an organization that provides outdoor educational experiences or programs for youth who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

01/19/18 House: Assigned HWI sub: Subcommittee #2

**HB 1378 Surgical assistants; renewal of registration.**

*Chief patron:* Robinson

*Summary as introduced:*
**Registration of surgical assistants; renewal of registration.** Requires proof of a current credential as a surgical assistant or surgical first assistant issued by the National Board of Surgical Technology and Surgical Assisting, the National Surgical Assistant Association, or the National Commission for the Certification of Surgical Assistants or their successors for renewal of registration as a surgical assistant.

01/19/18 House: Assigned HWI sub: Subcommittee #1

**HB 1422 CBD oil and THC-A oil; certification for use, dispensing.**

*Chief patron:* Marshall

*Summary as introduced:*
**CBD oil and THC-A oil; certification for use; dispensing.** Provides that a practitioner may issue a written certification for the use of cannabidiol oil or THC-A oil for the treatment or to alleviate the symptoms of any diagnosed condition or disease, including epilepsy, cancer, glaucoma, human immunodeficiency virus, acquired immunodeficiency syndrome, amyotrophic lateral sclerosis, multiple sclerosis, post-traumatic stress disorder, traumatic brain injury, chronic pain, or other chronic or terminal condition or disease. Under current law, a practitioner may issue such certification only for the treatment or to alleviate the symptoms of intractable epilepsy.

01/23/18 House: Assigned Courts sub: Subcommittee #1

**HB 1440 Schedule I and Schedule II drugs; adds various drugs to lists.**

*Chief patron:* Garrett

*Summary as introduced:*

**Schedule I and Schedule II drugs.** Adds MT-45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine) to Schedule I of the Drug Control Act and Dronabinol [(-)-delta-9-*trans* tetrahydrocannabinol] in an oral solution in a drug product approved for marketing by the U.S. Food and Drug Administration to Schedule II of the Drug Control Act and removes naldemedine from Schedule II of the Drug Control Act.

01/16/18 House: Referred to Committee on Health, Welfare and Institutions

**HB 1524 Medicine, Board of; regulations related to retention of patient records, minimum time for retention.**

*Chief patron:* Ingram

*Summary as introduced:*
**Board of Medicine; regulations related to retention of patient records; time.** Directs the Board of Medicine to amend regulations governing retention of patient records by health practitioners to require health care providers to maintain patient records (i) for a minimum of 10 years from the date the record was created for an adult patient and (ii) until the patient reaches the age of 18 or becomes emancipated, with a minimum time for record retention of 10 years from the date the record was created, for records of a minor child patient. Currently, patient records must be maintained (a) for a minimum of six years from the date of the last patient encounter for adult patients and (b) until the patient reaches the age of 18 or becomes emancipated, with a minimum time for record retention of six years from the date of the last patient encounter, for minor child patients.

01/22/18 House: Assigned HWI sub: Subcommittee #1

**SB 25 Drug Control Act; dispensing drugs without a prescription.**

*Chief patron:* Spruill

*Summary as introduced:*
**Dispensing drugs without a prescription.** Authorizes a pharmacist to dispense up to a five-day supply of a Schedule VI drug to an individual who has been displaced from his residence by a natural or man-made disaster; has had his supply of the drug lost, destroyed, or otherwise rendered unusable as a consequence of the disaster; and is unable to tell the pharmacist the identity of the prescriber or his regular pharmacist or pharmacy. The bill also requires the individual to present evidence sufficient to establish, among other things, that the individual had been in lawful possession of the drug pursuant to a prescription provided to another pharmacist and that his health would be in danger without the benefits of the drug. Before prescribing the drug, the pharmacist is required to determine with a reasonable degree of certainty that the requested drug and dosage level are consistent with the drug and its dosage level that had been prescribed to the individual at the time of his displacement from his residence. During the period for which the drug has been dispensed, the pharmacist is required to diligently attempt to ascertain the identity of the prescriber and the identity of the pharmacist or pharmacy in possession of the prescriber's prescription. Upon obtaining such information, the pharmacist is required to take such additional reasonable action as will permit the individual to obtain a new or renewal prescription and resume obtaining the drug pursuant to his prescription.

01/22/18 Senate: Assigned Education sub: Health Professions

**SB 293 Controlled substances and devices, certain; dispensing.**

*Chief patron:* McClellan

*Summary as introduced:*
**Dispensing of certain controlled substances and devices.** Authorizes a prescriber to dispense controlled substances and devices without obtaining a license from the Board of Pharmacy, provided that such controlled substances and devices have been prescribed for the purposes of reproductive health and are dispensed in good faith within the course of his professional practice. The bill provides that facilities from which prescribers dispense only such controlled substances and devices are not required to obtain a permit from the Board. The bill requires the Board to establish a list of controlled substances and devices that may be so dispensed that includes controlled substances and devices used for contraception, maternal health, hormone replacement therapy, and sexually transmitted and reproductive tract infections.

01/16/18 Senate: Assigned Education sub: Health Professions

**SB 330 THC-A oil; dispensing, tetrahydrocannabinol levels.**

*Chief patron:* Dunnavant

*Summary as introduced:*
**THC-A oil; dispensing.** Requires the Board of Pharmacy to promulgate regulations that (i) ensure the percentage of tetrahydrocannabinol in dispensed THC-A oil is within 10 percent of the level of tetrahydrocannabinol measured for labeling and (ii) require stability testing of any pharmaceutical processor producing THC-A oil.

01/17/18 Senate: Read third time and passed Senate (40-Y 0-N)

**SB 357 Death certificates; electronic filing required.**

*Chief patron:* McClellan

*Summary as introduced:*
**Death certificates; electronic filing required.** Requires a death certificate, for each death that occurs in the Commonwealth, to be electronically filed with the State Registrar. Under current law, death certificates may be filed electronically or nonelectronically.

01/16/18 Senate: Assigned Education sub: Health

**SB 436 Schedule I drugs; classification for fentanyl derivatives.**

*Chief patron:* Wexton

*Summary as introduced:*
**Schedule I drugs; classification for fentanyl derivatives.** Adds to Schedule I of the Drug Control Act a classification for fentanyl derivatives.

01/09/18 Senate: Referred to Committee on Education and Health

**SB 505 Doctorate of medical science; establishes requirements for licensure and practice.**

*Chief patron:* Carrico

*Summary as introduced:*
**Doctorate of medical science; licensure and practice.** Establishes requirements for licensure and practice as a doctorate of medical science. The bill provides that it is unlawful to practice as a doctorate of medical science unless licensed by the Board of Medicine (Board) and requires that an applicant for licensure, among other requirements, (i) hold an active unrestricted license to practice as a physician assistant in the Commonwealth or another jurisdiction and be able to demonstrate engagement in active clinical practice as a physician assistant under physician supervision for at least three

years and (ii) be a graduate of at least a two-year doctor of medical science program or an equivalent program that is accredited by a regional body under the U.S Department of Education and an accrediting body approved by the Board. The bill provides that doctorates of medical science can practice only as part of a patient care team at a hospital or group medical practice engaged in primary care and are required to maintain appropriate collaboration and consultation, as evidenced in a written or electronic practice agreement, with at least one patient care team physician. The bill requires the Board to establish the scope of practice for doctorates of medical science and to promulgate regulations regarding collaboration and consultation among a patient care team and requirements for the practice agreement. The bill outlines the prescriptive authority of doctorates of medical science. The bill also authorizes various powers and requires various duties of a doctorate of medical science where such powers and duties are, under current law, given to and required of physician assistants and nurse practitioners.

01/09/18 Senate: Referred to Committee on Education and Health

**SB 511 Optometry; scope of practice.**

*Chief patron:* Suetterlein

*Summary as introduced:*
**Optometry; scope of practice.** Provides that the practice of optometry includes the evaluation, examination, diagnosis, and treatment of abnormal or diseased conditions of the human eye and its adnexa by the use of medically recognized and appropriate devices, procedures, or technologies but that it does not include treatment by laser surgery; treatment by surgery except for treatment of styes, chalazia, or anterior segment lesions that does not require the use of general anesthesia or sutures; or the use of injections, including venipuncture and intravenous injections, except for certain injections by TPA-certified optometrists and for the treatment of emergency cases of anaphylactic shock with intramuscular epinephrine.

01/09/18 Senate: Referred to Committee on Education and Health

**SB 544 Prescription drugs; donation of used medicines.**

*Chief patron:* Obenshain

*Summary as introduced:*
**Prescription drug donation program.** Requires that the existing prescription drug donation program regulated by the Board of Pharmacy accept eligible unused drugs from individuals, manufacturers, nursing homes, assisted living facilities, intermediate care facilities established for individuals with intellectual disability (ICF/IID), licensed hospitals, or any facility operated by the Department of Behavioral Health and Developmental Services. The bill also provides that pharmacies may re-dispense such drugs to the indigent. Under the current program, only hospitals and indigent care clinics may re-dispense such drugs to the indigent. The bill also provides liability protection for those who donate, accept, and dispense such unused drugs.
01/22/18 Senate: Assigned Education sub: Health Professions

**SB 597 Marijuana; possession or distribution for medical purposes.**

*Chief patron:* Vogel

*Summary as introduced:*
**Possession or distribution of marijuana for medical purposes; affirmative defense for treatment of certain conditions.** Provides an affirmative defense to prosecution for possession of marijuana if a person has a valid written certification issued by a practitioner for cannabidiol oil or THC-A oil for treatment of, or to alleviate the symptoms of, cancer, glaucoma, human immunodeficiency virus, acquired immune deficiency syndrome, hepatitis C, amyotrophic lateral sclerosis, Crohn's disease, Alzheimer's disease, nail patella, cachexia or wasting syndrome, multiple sclerosis, or

complex regional pain syndrome. Under current law, only the treatment of intractable epilepsy is covered by the affirmative defense.

01/09/18 Senate: Referred to Committee for Courts of Justice

**SB 632 Controlled substances; limits on prescriptions containing opioids.**

*Chief patron:* Dunnavant

*Summary as introduced:*
**Limits on prescription of controlled substances containing opioids.** Eliminates the surgical or invasive procedure treatment exception to the requirement that a prescriber request certain information from the Prescription Monitoring Program (PMP) when initiating a new course of treatment that includes prescribing opioids for a human patient to last more than seven days. Under current law, a prescriber is not required to request certain information from the PMP for opioid prescriptions of up to 14 days to a patient as part of treatment for a surgical or invasive procedure. The provisions of the bill will expire on July 1, 2022.

01/10/18 Senate: Referred to Committee on Education and Health
01/22/18 Senate: Assigned Education sub: Health Professions

**SB 726 CBD oil and THC-A oil; certification for use, dispensing.**

*Chief patron:* Dunnavant

*Summary as introduced:*
**CBD oil and THC-A oil; certification for use; dispensing.** Provides that a practitioner may issue a written certification for the use of cannabidiol 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. Under current law, a practitioner may only issue such certification for the treatment or to alleviate the symptoms of intractable epilepsy. This bill is a recommendation of the Joint Commission on Health Care.

01/22/18 Senate: Assigned Education sub: Health Professions

**SB 728 Prescription Monitoring Program; prescriber and dispenser patterns.**

*Chief patron:* Dunnavant

*Summary as introduced:*
**Prescription Monitoring Program; prescriber and dispenser patterns.** Requires the Director of the Department of Health Professions to annually review controlled substance prescribing and dispensing patterns. The bill requires the Director to conduct such review in consultation with an advisory panel consisting of representatives from the relevant health regulatory boards, the Department of Health, the Department of Medical Assistance Services, and the Department of Behavioral Health and Developmental Services. The bill requires the Director to make any necessary changes to the criteria for unusual patterns of prescribing and dispensing and report any findings and recommendations for best practices to the Joint Commission on Health Care by November 1 of each year.

01/22/18 Senate: Assigned Education sub: Health Professions

**SB 735 Prescription Monitoring Program; disclosure of information; Department of Medical Assistance.**

*Chief patron:* Dunnavant

*Summary as introduced:*
**Prescription Monitoring Program; disclosure of information; Department of Medical Assistance Services.** Allows the Director of the Department of Health Professions to disclose information about a specific recipient of covered substances who is a recipient of medical assistance services to a physician or pharmacist licensed in the Commonwealth or his designee who holds a multistate licensure privilege to practice nursing or a license issued by a health regulatory board within the Department of Health Professions and is employed by the Department of Medical Assistance Services, for the purpose of determining eligibility for and managing the care of the recipient in a Patient Utilization Management Safety or similar program.

01/22/18 Senate: Assigned Education sub: Health Professions

**SB 795 CBD oil and THC-A oil; certification for use; dispensing.**

*Chief patron:* Dunnavant

*Summary as introduced:*
**CBD oil and THC-A oil; certification for use; dispensing.** Provides that a practitioner may issue a written certification for the use of cannabidiol 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. Under current law, a practitioner may only issue such certification for the treatment or to alleviate the symptoms of intractable epilepsy. The bill also reduces the minimum amount of cannabidiol or tetrahydrocannabinol acid per milliliter for a dilution of the Cannabis plant to fall under the definition of CBD oil or THC-A oil, respectively.

01/22/18 Senate: Assigned Education sub: Health Professions

**SB 832 Prescription Monitoring Program; adds controlled substances included in Schedule Vaud naloxone.**

*Chief patron:* Carrico

*Summary as introduced:*
**Prescription Monitoring Program; covered substances.** Adds controlled substances included in Schedule V for which a prescription is required and naloxone to the list of covered substances the dispensing of which must be reported to the Prescription Monitoring Program.

01/15/18 Senate: Referred to Committee on Education and Health

**SB 882 Prescription refill; protocol.**

*Chief patron:* DeSteph

*Summary as introduced:*
**Prescription refill; protocol.** Provides that a prescriber may authorize a registered nurse or licensed practical nurse to initiate a protocol for a prescription refill for Schedule VI controlled substances, provided that (i) the practitioner has established a bona-fide practitioner-patient relationship with the individual to receive the refill provided; (ii) there is a standing protocol written and maintained by the prescriber; (iii) there is a written order by the prescriber for the registered nurse or licensed practical nurse to initiate the protocol; (iv) the prescription refill is for a maintenance medication prescribed for chronic, long-term conditions and the medication is taken on a regular, recurring basis; (v) the prescription refill is for no more than 90 consecutive days; (vi) documentation sufficient to the Board of Pharmacy is maintained; and (vii) other requirements established by the Board of Pharmacy are met.

01/18/18 Senate: Referred to Committee on Education and Health

## Emergency Text

Action: Initial regulations
Stage: Emergency/NOIRA

CHAPTER 21

# REGULATIONS GOVERNING PRESCRIBING OF OPIOIDS AND BUPRENORPHINE

Part I
General Provisions

**18VAC85-21-10. Applicability.**

A. This chapter shall apply to doctors of medicine, osteopathic medicine, and podiatry and to physician assistants.

B. This chapter shall not apply to:

1. The treatment of acute or chronic pain related to (i) cancer, (ii) a patient in hospice care, or (iii) a patient in palliative care;

2. The treatment of acute or chronic pain during an inpatient hospital admission or in a nursing home or an assisted living facility that uses a sole source pharmacy; or

3. A patient enrolled in a clinical trial as authorized by state or federal law.

**18VAC85-21-20. Definitions.**

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Acute pain" means pain that occurs within the normal course of a disease or condition or as the result of surgery for which controlled substances may be prescribed for no more than three months.

"Board" means the Virginia Board of Medicine.

"Chronic pain" means nonmalignant pain that goes beyond the normal course of a disease or condition for which controlled substances may be prescribed for a period greater than three months.

"Controlled substance" means drugs listed in The Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia) in Schedules II through IV.

"FDA" means the U.S. Food and Drug Administration.

"MME" means morphine milligram equivalent.

"Prescription Monitoring Program" means the electronic system within the Department of Health Professions that monitors the dispensing of certain controlled substances.

"SAMHSA" means the federal Substance Abuse and Mental Health Services Administration.

Part II
Management of Acute Pain

**18VAC85-21-30. Evaluation of the acute pain patient.**

A. Nonpharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids. If an opioid is considered necessary for the treatment of acute pain, the practitioner shall give a short-acting opioid in the lowest effective dose for the fewest possible days.

B. Prior to initiating treatment with a controlled substance containing an opioid for a complaint of acute pain, the prescriber shall perform a history and physical examination appropriate to the complaint, query the Prescription Monitoring Program as set forth in § 54.1-2522.1of the Code of Virginia, and conduct an assessment of the patient's history and risk of substance [ ~~abuse~~ misuse ] .

**18VAC85-21-40. Treatment of acute pain with opioids.**

A. Initiation of opioid treatment for patients with acute pain shall be with short-acting opioids.

1. A prescriber providing treatment for acute pain shall not prescribe a controlled substance containing an opioid in a quantity that exceeds a seven-day supply as determined by the manufacturer's directions for use, unless extenuating circumstances are clearly documented in the medical record. This shall also apply to prescriptions of a controlled substance containing an opioid upon discharge from an emergency department.

2. An opioid prescribed as part of treatment for a surgical procedure shall be for no more than 14 consecutive days in accordance with manufacturer's direction and within the immediate perioperative period, unless extenuating circumstances are clearly documented in the medical record.

B. Initiation of opioid treatment for all patients shall include the following:

1. The practitioner shall carefully consider and document in the medical record the reasons to exceed 50 MME/day.

2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist.

3. Naloxone shall be prescribed for any patient when risk factors of prior overdose, substance [ ~~abuse~~ misuse ] , doses in excess of 120 MME/day, or concomitant benzodiazepine is present.

C. Due to a higher risk of fatal overdose when opioids are prescribed with benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses if these medications are prescribed.

D. Buprenorphine is not indicated for acute pain in the outpatient setting, except when a prescriber who has obtained a SAMHSA waiver is treating pain in a patient whose primary diagnosis is the disease of addiction.

**18VAC85-21-50. Medical records for acute pain.**

The medical record shall include a description of the pain, a presumptive diagnosis for the origin of the pain, an examination appropriate to the complaint, a treatment plan, and the medication prescribed or administered to include the date, type, dosage, and quantity prescribed or administered.

Part III
Management of Chronic Pain

**18VAC85-21-60. Evaluation of the chronic pain patient.**

A. Prior to initiating management of chronic pain with a controlled substance containing an opioid, a medical history and physical examination, to include a mental status examination, shall be performed and documented in the medical record, including:

1. The nature and intensity of the pain;

2. Current and past treatments for pain;

3. Underlying or coexisting diseases or conditions;

4. The effect of the pain on physical and psychological function, quality of life, and activities of daily living;

5. Psychiatric, addiction, and substance [ ~~abuse~~ misuse ] history of the patient and any family history of addiction or substance [ ~~abuse~~ misuse ] ;

6. A urine drug screen or serum medication level;

7. A query of the Prescription Monitoring Program as set forth in § 54.1-2522.1 of the Code of Virginia;

8. An assessment of the patient's history and risk of substance [ ~~abuse~~ misuse ] ; and

9. A request for prior applicable records.

B. Prior to initiating opioid treatment for chronic pain, the practitioner shall discuss with the patient the known risks and benefits of opioid therapy and the responsibilities of the patient during treatment to include securely storing the drug and properly disposing of any unwanted or unused drugs. The practitioner shall also discuss with the patient an exit strategy for the discontinuation of opioids in the event they are not effective.

**18VAC85-21-70. Treatment of chronic pain with opioids.**

A. Nonpharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids.

B. In initiating and treating with an opioid, the practitioner shall:

1. Carefully consider and document in the medical record the reasons to exceed 50 MME/day;

2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist.

3. Prescribe naloxone for any patient when risk factors of prior overdose, substance [ ~~abuse~~ misuse ] , doses in excess of 120 MME/day, or concomitant benzodiazepine is present; and

4. Document the rationale to continue opioid therapy every three months.

C. [ ~~Buprenorphine may be prescribed or administered for chronic pain in formulation and dosages that are FDA-approved for that purpose.~~ Buprenorphine mono-product in tablet form shall not be prescribed for chronic pain ] .

D. Due to a higher risk of fatal overdose when opioids, including buprenorphine, are given with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses of these medications if prescribed.

E. The practitioner shall regularly evaluate for opioid use disorder and shall initiate specific treatment for opioid use disorder, consult with an appropriate health care provider, or refer the patient for evaluation and treatment if indicated.

**18VAC85-21-80. Treatment plan for chronic pain.**

A. The medical record shall include a treatment plan that states measures to be used to determine progress in treatment, including pain relief and improved physical and psychosocial function, quality of life, and daily activities.

B. The treatment plan shall include further diagnostic evaluations and other treatment modalities or rehabilitation that may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

C. The prescriber shall document in the medical record the presence or absence of any indicators for medication [ ~~abuse~~ misuse ] , or diversion and shall take appropriate action.

**18VAC85-21-90. Informed consent and agreement for treatment for chronic pain.**

A. The practitioner shall document in the medical record informed consent, to include risks, benefits, and alternative approaches, prior to the initiation of opioids for chronic pain.

B. There shall be a written treatment agreement signed by the patient in the medical record that addresses the parameters of treatment, including those behaviors that will result in referral to a higher level of care, cessation of treatment, or dismissal from care.

C. The treatment agreement shall include notice that the practitioner will query and receive reports from the Prescription Monitoring Program and permission for the practitioner to:

1. Obtain urine drug screens or serum medication levels when requested; and

2. Consult with other prescribers or dispensing pharmacists for the patient.

D. Expected outcomes shall be documented in the medical record including improvement in pain relief and function or simply in pain relief. Limitations and side effects of chronic opioid therapy shall be documented in the medical record.

**18VAC85-21-100. Opioid therapy for chronic pain.**

A. The practitioner shall review the course of pain treatment and any new information about the etiology of the pain and the patient's state of health at least every three months.

B. Continuation of treatment with opioids shall be supported by documentation of continued benefit from such prescribing. If the patient's progress is unsatisfactory, the practitioner shall assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

C. The practitioner shall check the Prescription Monitoring Program at least every three months after the initiation of treatment.

D. The practitioner shall order and review a urine drug screen or serum medication levels at the initiation of chronic pain management and at least every three months for the first year of treatment and at least every six months thereafter.

E. The practitioner shall regularly evaluate for opioid use disorder and shall initiate specific treatment for opioid use disorder, consult with an appropriate health care provider, or refer the patient for evaluation for treatment if indicated.

**18VAC85-21-110. Additional consultations.**

A. When necessary to achieve treatment goals, the prescriber shall refer the patient for additional evaluation and treatment.

B. When a prescriber makes the diagnosis of opioid use disorder, treatment for opioid use disorder shall be initiated or the patient shall be referred for evaluation and treatment.

**18VAC85-21-120. Medical records for chronic pain.**

The prescriber shall keep current, accurate, and complete records in an accessible manner readily available for review to include:

1. The medical history and physical examination;

2. Past medical history;

3. Applicable records from prior treatment providers or any documentation of attempts to obtain those records;

4. Diagnostic, therapeutic, and laboratory results;

5. Evaluations and consultations;

6. Treatment goals;

7. Discussion of risks and benefits;

8. Informed consent and agreement for treatment;

9. Treatments;

10. Medications (including date, type, dosage, and quantity prescribed and refills);

11. Patient instructions; and

12. Periodic reviews.

Part IV
Prescribing of Buprenorphine for Addiction Treatment

**18VAC85-21-130. General provisions pertaining to prescribing of buprenorphine for addiction treatment.**

A. Practitioners engaged in office-based opioid addiction treatment with buprenorphine shall have obtained a SAMHSA waiver and the appropriate U.S. Drug Enforcement Administration registration.

B. Practitioners shall abide by all federal and state laws and regulations governing the prescribing of buprenorphine for the treatment of opioid use disorder.

C. Physician assistants and nurse practitioners who have obtained a SAMHSA waiver shall only prescribe buprenorphine for opioid addiction pursuant to a practice agreement with a waivered doctor of medicine or doctor of osteopathic medicine.

D. Practitioners engaged in medication-assisted treatment shall either provide counseling in their practice or refer the patient to a mental health service provider, as defined in § 54.1-2400.1 of the Code of Virginia, who has the education and experience to provide substance [ ~~abuse~~ misuse ] counseling. The practitioner shall document provision of counseling or referral in the medical record.

**18VAC85-21-140. Patient assessment and treatment planning for addiction treatment.**

A. A practitioner shall perform and document an assessment that includes a comprehensive medical and psychiatric history, substance [ ~~abuse~~ misuse ] history, family history and psychosocial supports, appropriate physical examination, urine drug screen, pregnancy test for women of childbearing age and ability, a check of the Prescription Monitoring Program, and, when clinically indicated, infectious disease testing for human immunodeficiency virus, hepatitis B, hepatitis C, and tuberculosis.

B. The treatment plan shall include the practitioner's rationale for selecting medication-assisted treatment, patient education, written informed consent, how counseling will be accomplished, and a signed treatment agreement that outlines the responsibilities of the patient and the prescriber.

**18VAC85-21-150. Treatment with buprenorphine for addiction.**

A. Buprenorphine without naloxone (buprenorphine mono-product) shall not be prescribed except:

1. When a patient is pregnant;

2. When converting a patient from methadone or buprenorphine mono-product to buprenorphine containing naloxone for a period not to exceed seven days; [ ~~or~~ ]

3. In formulations other than tablet form for indications approved by the FDA [ ; or

4. 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 ] .

B. Buprenorphine mono-product tablets may be administered directly to patients in federally licensed opioid treatment programs. With the exception of those conditions listed in subsection A of this section, only the buprenorphine product containing naloxone shall be prescribed or dispensed for use off site from the program.

C. The evidence for the decision to use buprenorphine mono-product shall be fully documented in the medical record.

D. Due to a higher risk of fatal overdose when buprenorphine is prescribed with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses if these medications are prescribed.

E. Prior to starting medication-assisted treatment, the practitioner shall perform a check of the Prescription Monitoring Program.

F. During the induction phase, except for medically indicated circumstances as documented in the medical record, patients should be started on no more than eight milligrams of buprenorphine per day. The patient shall be seen by the prescriber at least once a week.

G. During the stabilization phase, the prescriber shall increase the daily dosage of buprenorphine in safe and effective increments to achieve the lowest dose that avoids intoxication, withdrawal, or significant drug craving.

H. Practitioners shall take steps to reduce the chances of buprenorphine diversion by using the lowest effective dose, appropriate frequency of office visits, pill counts, and checks of the Prescription Monitoring Program. The practitioner shall also require urine drug screens or serum medication levels at least every three months for the first year of treatment and at least every six months thereafter.

I. Documentation of the rationale for prescribed doses exceeding 16 milligrams of buprenorphine per day shall be placed in the medical record. Dosages exceeding 24 milligrams of buprenorphine per day shall not be prescribed.

J. The practitioner shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a mental health service provider, as defined in § 54.1-2400.1 of the Code of Virginia, who has the education and experience to provide substance ~~abuse~~ misuse counseling.

**18VAC85-21-160. Special populations in addiction treatment.**

A. Pregnant women [ ~~shall~~ may ] be treated with the buprenorphine mono-product, usually 16 milligrams per day or less.

B. Patients younger than the age of 16 years shall not be prescribed buprenorphine for addiction treatment unless such treatment is approved by the FDA.

C. The progress of patients with chronic pain shall be assessed by reduction of pain and functional objectives that can be identified, quantified, and independently verified.

D. Practitioners shall (i) evaluate patients with medical comorbidities by history, physical exam, appropriate laboratory studies and (ii) be aware of interactions of buprenorphine with other prescribed medications.

E. Practitioners shall not undertake buprenorphine treatment with a patient who has psychiatric comorbidities and is not stable. A patient who is determined by the prescriber to be psychiatrically unstable shall be referred for psychiatric evaluation and treatment prior to initiating medication-assisted treatment.

**18VAC85-21-170. Medical records for opioid addiction treatment.**

A. Records shall be timely, accurate, legible, complete, and readily accessible for review.

B. The treatment agreement and informed consent shall be maintained in the medical record.

C. Confidentiality requirements of 42 CFR, Part 2 shall be followed.

D. Compliance with 18VAC85-20-27, which prohibits willful or negligent breach of confidentiality or unauthorized disclosure of confidential Prescription Monitoring Program information, shall be maintained.

## TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING
## BOARD OF MEDICINE
### Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the Board of Medicine intends to consider amending **18VAC85-20, Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry, and Chiropractic**, and **18VAC85-50, Regulations Governing the Practice of Physician Assistants**. Consistent with provisions of Chapter 390 of the 2017 Acts of Assembly, laser hair removal must be performed by a "properly trained person" who is a licensee or a "properly trained person under the direction and supervision" of a doctor, physician assistant, or nurse practitioner. The purpose of the proposed action is to provide a regulatory framework for "direction and supervision" so that the laser hair technician, the supervising practitioner, and the public will understand the scope of responsibility for such direction and supervision.

The agency intends to hold a public hearing on the proposed action after publication in the Virginia Register.

Statutory Authority: § 54.1-2400 of the Code of Virginia.

Public Comment Deadline: November 1, 2017.

Agency Contact: William L. Harp, M.D., Executive Director, Board of Medicine, 9960 Mayland Drive, Suite 300, Richmond, VA 23233-1463, telephone (804) 367-4621, FAX (804) 527-4429, or email william.harp@dhp.virginia.gov.

VA.R. Doc. No. R18-5269; Filed September 8, 2017, 2:53 p.m.

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# Notice of Intended Regulatory Action (NOIRA)
# Agency Background Document

| | |
|---|---|
| **Agency name** | Board of Medicine, Department of Health Professions |
| **Virginia Administrative Code (VAC) citation(s)** | 18VAC85-20<br>18VAC85-50 |
| **Regulation title(s)** | Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry, and Chiropractic<br>Regulations Governing the Practice of Physician Assistants |
| **Action title** | Direction and supervision of laser hair removal |
| **Date this document prepared** | 7/14/17 |

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

## Subject matter and intent

*Please describe briefly the subject matter, intent, and goals of the planned regulatory action.*

Consistent with provisions of HB2119 of the 2017 General Assembly, laser hair removal must be performed by a "properly trained person" who is a licensee or by a "properly trained person under the direction and supervision" of a doctor, physician assistant, or nurse practitioner. The intent of this action is to provide a regulatory framework for "direction and supervision" so the laser hair technician, the supervising practitioner and the public will understand the scope of responsibility for such direction and supervision.

## Legal basis

*Please identify the (1) the agency (includes any type of promulgating entity) and(2) the state and/or federal legal authority for the proposed regulatory action, including the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable. Your citation should include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.*

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Medicine the authority to promulgate regulations to administer the regulatory system:

***§ 54.1-2400 -General powers and duties of health regulatory boards***
*The general powers and duties of health regulatory boards shall be:*
...
*6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title. ...*

The specific authority to promulgate this regulation is found in Chapter 390 of the 2017 Acts of the Assembly, which added:

*§ 54.1-2973.1. Practice of laser hair removal.*

*The practice of laser hair removal shall be performed by a properly trained person licensed to practice medicine or osteopathic medicine or a physician assistant as authorized pursuant to § 54.1-2952 or a nurse practitioner as authorized pursuant to § 54.1-2957 or by a properly trained person under the direction and supervision of a licensed doctor of medicine or osteopathic medicine or a physician assistant as authorized pursuant to § 54.1-2952 or a nurse practitioner as authorized pursuant to § 54.1-2957 who may delegate such practice in accordance with subdivision A 6 of § 54.1-2901.*

## Purpose

*Please describe the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, please explain any potential issues that may need to be addressed as the regulation is developed.*

A review of the practice of laser hair removal in 2016 concluded that the lack of comprehensive regulation over the use of laser technology for hair removal poses a risk of harm to the public's health, safety and welfare. While the Code has been amended as of July 1, 2017, the level and extent of "direction and supervision" has not been defined. The purpose of this action is to develop regulations for some mechanism for determining whether someone has been "properly trained" and for the required direction and supervision.

## Substance

*Please briefly identify and explain the new substantive provisions that are being considered, the substantive changes to existing sections that are being considered, or both.*

Regulations will specify the responsibility of the licensed doctor or physician assistant for ensuring that someone is "properly trained" and for the required level of direction and supervision.

## Alternatives

*Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.*

In the 2016 Session of the General Assembly, HB957 was introduced which would have required individuals who practice laser hair removal to be licensed by the Board of Medicine. The bill defined "laser hair removal" and established the Advisory Board on Laser Hair Removal to advise the Board of Medicine on this discipline. The Department of Health Professions did not support licensure for these practitioners, and the bill was carried over to 2017.

At the request of the patron of HB957 (the same patron of HB2119 in 2017), the Department of Professional and Occupational Regulation and the Department of Health Professions reviewed the issue of laser hair removal. Among its findings was information that the Food and Drug Administration Center for Drug Evaluation and Research warning consumers about serious and life-threatening side effects from laser hair removal treatments including blistering, discoloration, swelling, redness, and scarring. It recommended that both the procedure itself and the topical anesthetics often used should be performed only under the direction of a medical professional. Improper use of skin numbing products to lessen pain before or after laser hair removal has resulted in death.

According to a recent study published in the journal *JAMA Dermatology,* which reviewed nearly 200 cosmetic laser surgery lawsuits, data suggest an "increased inherent risk of injury" exists with non-physician operators. Laser hair removal was the most common procedure resulting in injury and litigation, followed by skin rejuvenation treatments. The authors found that 86% of laser hair removal litigation between 2008 and 2012 involved non-physician operators; in 2011, only one out 10 lawsuits was filed against a physician operator (90.9% of cases involved non-physicians).

In May 2016, the American Academy of Dermatology revised its official position statement on the practice of dermatology to include the use of all lasers and light sources capable of altering or causing biologic change or damage to skin and subcutaneous tissue. As such, procedures using lasers should be performed only by health professionals under physician supervision.

The American Society for Dermatologic Surgery Association (ASDSA) also strongly opposes the use of laser technology by anyone other than properly trained medical professionals.

The Board will have to determine the level of direction of supervision necessary to protect the public without be overly restrictive and burdensome.

## Public participation

*Please indicate whether the agency is seeking comments on the intended regulatory action, including ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments. Please include one of the following choices: 1) a panel will be appointed and the agency's contact if you're interested in serving on the panel is _____; 2) a panel will not be used; or 3) public comment is invited as to whether to use a panel to assist in the development of this regulatory proposal.*

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The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation.

The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Townhall website , www.townhall.virginia.gov, or by mail, email or fax to Elaine Yeatts, Agency Regulatory Coordinator, 9960 Mayland Drive, Richmond, VA 23233 or **elaine.yeatts@dhp.virginia.gov** or by fax to (804) 527-4434. Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (**http://www.townhall.virginia.gov**) and on the Commonwealth Calendar website (https://www.virginia.gov/connect/commonwealth-calendar). Both oral and written comments may be submitted at that time.

The Board may convene a Regulatory Advisory Panel to develop proposed regulations based on comments it receives from the NOIRA.

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# Notice of Intended Regulatory Action (NOIRA)
# Agency Background Document

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|---|---|
| **Agency name** | Board of Medicine, Department of Health Professions |
| **Virginia Administrative Code (VAC) citation(s)** | 18VAC85-50 |
| **Regulation title(s)** | Regulations Governing the Practice of Physician Assistants |
| **Action title** | Definition of supervision and pharmacology for weight loss |
| **Date this document prepared** | 10/26/17 |

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

## Subject matter and intent

*Please describe briefly the subject matter, intent, and goals of the planned regulatory action.*

The purpose of the proposed regulatory action is to simplify and clarify the definitions and usage of various terms for supervision for more consistency with the Code and with actual practice of physician assistants and supervising physicians. Further the action will add a provision in the regulation on pharmacotherapy for weight loss to clarify that a physician assistant can conduct the physical examination, review tests, and prescribe drugs, if so authorized in a practice agreement with a supervising physician.

## Legal basis

*Please identify the (1) the agency (includes any type of promulgating entity) and (2) the state and/or federal legal authority for the proposed regulatory action, including the most relevant citations to the Code*

*of Virginia or General Assembly chapter number(s), if applicable. Your citation should include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.*

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Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Medicine the authority to promulgate regulations to administer the regulatory system:

***§ 54.1-2400 -General powers and duties of health regulatory boards***
*The general powers and duties of health regulatory boards shall be:*
...
*6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title. ...*

Regulations on supervision of physician assistants are promulgated in accordance with:

***§ 54.1-2952. Supervision of assistants by licensed physician, or podiatrist; services that may be performed by assistants; responsibility of licensee; employment of assistants.***
*A. A physician or a podiatrist licensed under this chapter may supervise physician assistants and delegate certain acts which constitute the practice of medicine to the extent and in the manner authorized by the Board. The physician shall provide continuous supervision as required by this section; however, the requirement for physician supervision of physician assistants shall not be construed as requiring the physical presence of the supervising physician during all times and places of service delivery by physician assistants. Each team of supervising physician and physician assistant shall identify the relevant physician assistant's scope of practice, including the delegation of medical tasks as appropriate to the physician assistant's level of competence, the physician assistant's relationship with and access to the supervising physician, and an evaluation process for the physician assistant's performance.*

*Physician assistants appointed as medical examiners pursuant to § 32.1-282 shall be under the continuous supervision of a licensed doctor of medicine or osteopathic medicine who has been appointed to serve as a medical examiner pursuant to § 32.1-282.*

*No licensee shall be allowed to supervise more than six physician assistants at any one time.*

*Any professional corporation or partnership of any licensee, any hospital and any commercial enterprise having medical facilities for its employees which are supervised by one or more physicians or podiatrists may employ one or more physician assistants in accordance with the provisions of this section.*

*Activities shall be delegated in a manner consistent with sound medical practice and the protection of the health and safety of the patient. Such activities shall be set forth in a practice supervision agreement between the physician assistant and the supervising physician or podiatrist and may include health care services which are educational, diagnostic, therapeutic,*

*preventive, or include treatment, but shall not include the establishment of a final diagnosis or treatment plan for the patient unless set forth in the practice supervision agreement. Prescribing or dispensing of drugs may be permitted as provided in § 54.1-2952.1. In addition, a licensee is authorized to delegate and supervise initial and ongoing evaluation and treatment of any patient in a hospital, including its emergency department, when performed under the direction, supervision and control of the supervising licensee. When practicing in a hospital, the physician assistant shall report any acute or significant finding or change in a patient's clinical status to the supervising physician as soon as circumstances require and shall record such finding in appropriate institutional records. The physician assistant shall transfer to a supervising physician the direction of care of a patient in an emergency department who has a life-threatening injury or illness. Prior to the patient's discharge, the services rendered to each patient by a physician assistant in a hospital's emergency department shall be reviewed in accordance with the practice agreement and the policies and procedures of the health care institution. A physician assistant who is employed to practice in an emergency department shall be under the supervision of a physician present within the facility.*

*Further, unless otherwise prohibited by federal law or by hospital bylaws, rules, or policies, nothing in this section shall prohibit any physician assistant who is not employed by the emergency physician or his professional entity from practicing in a hospital emergency department, within the scope of his practice, while under continuous physician supervision as required by this section, whether or not the supervising physician is physically present in the facility. The supervising physician who authorizes such practice by his physician assistant shall (i) retain exclusive supervisory control of and responsibility for the physician assistant and (ii) be available at all times for consultation with both the physician assistant and the emergency department physician. Prior to the patient's discharge from the emergency department, the physician assistant shall communicate the proposed disposition plan for any patient under his care to both his supervising physician and the emergency department physician. No person shall have control of or supervisory responsibility for any physician assistant who is not employed by the person or the person's business entity.*

*B. No physician assistant shall perform any delegated acts except at the direction of the licensee and under his supervision and control. No physician assistant practicing in a hospital shall render care to a patient unless the physician responsible for that patient has signed the practice agreement, pursuant to regulations of the Board, to act as supervising physician for that physician assistant. Every licensee, professional corporation or partnership of licensees, hospital or commercial enterprise that employs a physician assistant shall be fully responsible for the acts of the physician assistant in the care and treatment of human beings.*

*C. Notwithstanding the provisions of § 54.1-2956.8:1, a licensed physician assistant who (i) is working under the supervision of a licensed doctor of medicine or osteopathy specializing in the field of radiology, (ii) has been trained in the proper use of equipment for the purpose of performing radiologic technology procedures consistent with Board regulations, and (iii) has successfully completed the exam administered by the American Registry of Radiologic Technologists for physician assistants for the purpose of performing radiologic technology procedures may use fluoroscopy for guidance of diagnostic and therapeutic procedures.*

## Purpose

*Please describe the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, please explain any potential issues that may need to be addressed as the regulation is developed.*

The purpose of the regulatory action is clarity and consistency in rules relating to supervision of physician assistants and removal of any unnecessary rules that may impede the ability of assistants to practice to the full extent of their training and competency as permitted by law. There are no substantive changes that affect the supervisory role of a physician, and proposed regulations will continue to protect public health and safety.

## Substance

*Please briefly identify and explain the new substantive provisions that are being considered, the substantive changes to existing sections that are being considered, or both.*

Relating to the use of supervision in regulation, the Board intends to:

1) Amend the definition of "supervision" by combining the meanings of general and continuous supervision, so the new definition would be: Supervision means the supervising physician has on-going, regular communication with the physician assistant on the care and treatment of patients (current definition of "continuous supervision") and is easily available and can be physically present or accessible for consultation with the physician assistant within one hour (current definition of "general supervision");
2) Eliminate definitions of "direct supervision" and "personal supervision" The definitions of "alternative supervising physician" and "supervising physician" will be moved to the appropriate places in the listing of words and terms being defined;
3) Delete in Section 101 the examples of various levels of supervision that may be spelled out in the practice agreement between the parties; and
4) Amend Section 110 to change the word "supervising" to "observing" in order to clarify the responsibility of the physician in attesting to the competency of a physician assistant to perform invasive procedures.

Relating to regulations in Section 181 on pharmacotherapy for weight loss, the Board intends to add a subsection C, which is similar to language in subsection C of Section 90 in regulations for physicians. *The new subsection C would read: If specifically authorized in his practice agreement with a supervising physician, a physician assistant may perform the physical examination, review tests, and prescribe Schedules III through VI controlled substances for treatment of obesity, as specified in subsection B of this section.*

## Alternatives

*Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.*

*Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.*

The proposal is a less burdensome and intrusive alternative that meets the essential purpose of the action, so no alternatives were considered.

## Public participation

*Please indicate whether the agency is seeking comments on the intended regulatory action, including ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments. Please include one of the following choices: 1) a panel will be appointed and the agency's contact if you're interested in serving on the panel is _____; 2) a panel will not be used; or 3) public comment is invited as to whether to use a panel to assist in the development of this regulatory proposal.*

The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation.

The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

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A public hearing will be held following the publication of the proposed stage of this regulatory action and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (**http://www.townhall.virginia.gov**) and on the Commonwealth Calendar website (https://www.virginia.gov/connect/commonwealth-calendar). Both oral and written comments may be submitted at that time.

The Board will utilize the Advisory Board on Physician Assistants to develop proposed amendments to regulation.