Advisory Board on Physician Assistants

Virginia Board of Medicine

June 8, 2017
1:00 p.m.

Advisory Board on Physician Assistants

Board of Medicine
June 8, 2017, 1:00 PM
9960 Mayland Drive, Suite 201
Henrico, Virginia

DRAFT UNAPPROVED

ADVISORY BOARD ON PHYSICIAN ASSISTANTS

Board of Medicine
June 9, 2016, 1:00 PM

The Advisory Board on Physician Assistants met Thursday, June 9, 2016, at 1:00 p.m. at the Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Richmond, Virginia.

MEMBERS PRESENT:	Thomas Parish PA-C, Chair Portia Tomlinson, PA-C, Vice-Chair Rachel Carlson, PA-C
MEMBERS ABSENT:	James Potter, MD Eileen F. Davis, R.N.
STAFF PRESENT:	William L. Harp, MD, Executive Director Alan Heaberlin, Deputy Executive Director Elaine Yeatts, Senior Regulatory Analyst ShaRon Clanton, Licensing Specialist
GUESTS PRESENT:	Robert Glasgow, PA-C, VAPA David Falkenstein, PA-C, VAPA

Call to Order

Mr. Parish called the meeting to order and announced the Emergency Evacuation Instructions.

Roll Call

Roll was called and a quorum was declared.

Approval of Minutes October 8, 2015

Ms. Carlson moved to approve the minutes dated October 8, 2015. The motion was seconded and carried.

Adoption of Agenda

Ms. Carlson moved to approve the adoption of the agenda. The motion was seconded and carried.

Public Comment on Agenda Items

None

NEW BUSINESS

1. **Review and vote to approve revised practice agreement regulations:**

The Advisory Board reviewed the revised practice agreement regulations provided by staff and discussed making further revisions. Ms. Carlson made a motion to request additional changes to 18VAC85-50-110.2(B) and to 18VAC85-50-115(A) and (B)(3). If these revisions are not exempt from the Administrative Process Act, a NOIRA will be issued. The motion was seconded and carried.

ANNOUNCEMENTS

Mr. Heaberlin announced there are currently 3,219 physician assistants with current active licenses and 26 with current inactive licenses.

Next Scheduled Meeting:

October 6, 2016 @ 1:00 p.m.

ADJOURNMENT

Mr. Parish moved to adjourn the meeting at 2:22 p.m. The motion was seconded and carried.

Thomas Parish, PA-C, Chair

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

ShaRon Clanton, Licensing Specialist

DRAFT UNAPPROVED

ADVISORY BOARD ON PHYSICIAN ASSISTANTS

Board of Medicine
February 2, 2017, 1:00 PM
9960 Mayland Drive, Suite 201
Richmond, VA
Training Room 2

The Advisory Board on Physician Assistants met Thursday, February 2, 2017 at 1:00 p.m. at the Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Richmond, Virginia.

MEMBERS PRESENT:	Thomas Parish PA-C, Chair Rachel Carlson, PA-C
MEMBERS ABSENT:	James Potter, MD Portia Tomlinson, PA-C, Vice Chair The Citizen Member Seat is vacant
STAFF PRESENT:	William L. Harp, MD, Executive Director Alan Heaberlin, Deputy Director for Licensure Elaine Yeatts, DHP Senior Policy Analyst ShaRon Clanton, Licensing Specialist
GUESTS PRESENT:	David Falkenstein, VAPA Lauren Bates-Rowe, MSV

Call to Order

Mr. Parish called the meeting to order and announced the Emergency Evacuation Instructions.

Roll Call

Roll was called. A quorum was not established.

Approval of Minutes June 9, 2016

The minutes were deferred until the next scheduled meeting due to the lack of a quorum.

Adoption of Agenda

The agenda could not be adopted due to the lack of a quorum.

Public Comment on Agenda Items

Mr. Falkenstein of the Virginia Academy of Physician Assistants discussed proposals for the elimination of certain regulatory language regarding supervision and to authorize physician assistants to perform the initial examination of patients who are treated with pharmacotherapy for weight loss.

1. **Legislative Report**

   Ms. Yeatts informed the Advisory Board about bills of interest from the 2017 session of the General Assembly. No action was required.

2. **Regulatory Panel on Opioid Regulations**

   Ms. Yeatts reviewed the draft regulations *Governing Prescribing for Pain and Prescribing of Buprenorphine* with the Advisory Board. She particularly noted Part II: Management of Acute Pain and Part III: Management of Chronic Pain.

3. **Draft Regulations for Invasive Procedures**

   Ms. Yeatts reviewed the draft regulation which would eliminate the submission of the document currently required for prior Board approval for the performance of invasive procedures without direct supervision.

4. **Procurement of Botox by Physician Assistants**

   Ms. Carlson sought guidance in determining whether physician assistants could procure Botox. Dr. Harp said that Botox is a schedule VI drug, and if the ability to purchase Botox was included in the practice agreement, then a physician assistant was authorized to do so.

Announcements

Mr. Heaberlin stated there were currently 3524 physician assistants with active licenses and 26 with inactive licenses.

Next Scheduled Meeting: June 8, 2017 @ 1:00 p.m.

Adjournment

Meeting was adjourned at 2:15 p.m.

_____
Thomas Parish, PA-C, Chair

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

_____
ShaRon Clanton, Licensing Specialist

Commonwealth of Virginia

REGULATIONS

GOVERNING THE PRACTICE OF PHYSICIAN ASSISTANTS

VIRGINIA BOARD OF MEDICINE

Title of Regulations: 18 VAC 85-50-10 et seq.

Statutory Authority: § 54.1-2400 and Chapter 29 of Title 54.1 of the *Code of Virginia*

Revised Date: October 5, 2016

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Part I. General Provisions.

18VAC85-50-10. Definitions.

A. The following words and terms shall have the meanings ascribed to them in §54.1-2900 of the Code of Virginia:

"Board."

"Physician assistant."

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

"Group practice" means the practice of a group of two or more doctors of medicine, osteopathy, or podiatry licensed by the board who practice as a partnership or professional corporation.

"Institution" means a hospital, nursing home or other health care facility, community health center, public health center, industrial medicine or corporation clinic, a medical service facility, student health center, or other setting approved by the board.

"NCCPA" means the National Commission on Certification of Physician Assistants.

"Practice agreement" means a written agreement developed by the supervising physician and the physician assistant that defines the supervisory relationship between the physician assistant and the physician, the prescriptive authority of the physician assistant, and the circumstances under which the physician will see and evaluate the patient.

"Supervision" means:

1. "Alternate supervising physician" means a member of the same group or professional corporation or partnership of any licensee, any hospital or any commercial enterprise with the supervising physician. Such alternating supervising physician shall be a physician licensed in the Commonwealth who has registered with the board and who has accepted responsibility for the supervision of the service that a physician assistant renders.

2. "Direct supervision" means the physician is in the room in which a procedure is being performed.

3. "General supervision" means the supervising physician is easily available and can be physically present or accessible for consultation with the physician assistant within one hour.

4. "Personal supervision" means the supervising physician is within the facility in which the physician's assistant is functioning.

5. "Supervising physician" means the doctor of medicine, osteopathy, or podiatry licensed in the Commonwealth who has accepted responsibility for the supervision of the service that a physician assistant renders.

6. "Continuous supervision" means the supervising physician has on-going, regular communication with the physician assistant on the care and treatment of patients.

18VAC85-50-20. (Repealed.)

18VAC85-50-21. Current name and address.

Each licensee shall furnish the board his current name and address of record. All notices required by law or by this chapter given by the board to any such licensee shall be validly given when mailed to the latest address of record provided or served to the licensee. Any change of name or address of record or the public address, if different from the address of record, shall be furnished to the board within 30 days of such change.

18VAC85-50-30. Public participation guidelines.

A separate board regulation, 18VAC85-10-10 et seq., provides for involvement of the public in the development of all regulations of the Virginia Board of Medicine.

18VAC85-50-35. Fees.

Unless otherwise provided, the following fees shall not be refundable:

1. The initial application fee for a license, payable at the time application is filed, shall be $130.

2. The biennial fee for renewal of an active license shall be $135 and for renewal of an inactive license shall be $70, payable in each odd-numbered year in the birth month of the licensee. For 2017, the fee for renewal of an active license shall be $108 and the fee for renewal of an inactive license shall be $54.

3. The additional fee for late renewal of licensure within one renewal cycle shall be $50.

4. A restricted volunteer license shall expire 12 months from the date of issuance and may be renewed without charge by receipt of a renewal application that verifies that the physician assistant continues to comply with provisions of §54.1-2951.3 of the Code of Virginia.

5. The fee for review and approval of a new protocol submitted following initial licensure shall be $15.

6. The fee for reinstatement of a license pursuant to §54.1-2408.2 of the Code of Virginia shall be $2,000.

7. The fee for a duplicate license shall be $5, and the fee for a duplicate wall certificate shall be $15.

8. The fee for a returned check shall be $35.

9. The fee for a letter of good standing/verification to another jurisdiction shall be $10.

10. The fee for an application or for the biennial renewal of a restricted volunteer license shall be $35, due in the licensee's birth month. An additional fee for late renewal of licensure shall be $15 for each renewal cycle.

Part II. Requirements for Practice as a physician assistant.

18VAC85-50-40. General requirements.

A. No person shall practice as a physician assistant in the Commonwealth of Virginia except as provided in this chapter.

B. All services rendered by a physician assistant shall be performed only under the continuous supervision of a doctor of medicine, osteopathy, or podiatry licensed by this board to practice in the Commonwealth.

18VAC85-50-50. Licensure: entry requirements and application.

The applicant seeking licensure as a physician assistant shall submit:

1. A completed application and fee as prescribed by the board.

2. Documentation of successful completion of an educational program as prescribed in §54.1-2951.1 of the Code of Virginia.

3. Documentation of passage of the certifying examination administered by the National Commission on Certification of Physician Assistants.

4. Documentation that the applicant has not had a license or certification as a physician assistant suspended or revoked and is not the subject of any disciplinary proceedings in another jurisdiction.

18VAC85-50-55. Provisional licensure.

Pending the outcome of the next examination administered by the NCCPA, an applicant who has met all other requirements of 18VAC85-50-50 at the time his initial application is submitted may be granted provisional licensure by the board. The provisional licensure shall be valid until the applicant takes the next subsequent NCCPA examination and its results are reported, but this period of validity shall not exceed 30 days following the reporting of the examination scores, after which the provisional license shall be invalid.

18VAC85-50-56. Renewal of license.

A. Every licensed physician assistant intending to continue to practice shall biennially renew the license in each odd numbered year in the licensee's birth month by:

1. Returning the renewal form and fee as prescribed by the board; and

2. Verifying compliance with continuing medical education standards established by the NCCPA.

B. Any physician assistant who allows his NCCPA certification to lapse shall be considered not licensed by the board. Any such assistant who proposes to resume his practice shall make a new application for licensure.

18VAC85-50-57. Discontinuation of employment.

If for any reason the assistant discontinues working in the employment and under the supervision of a licensed practitioner, a new practice agreement shall be entered into in order for the assistant either to be reemployed by the same practitioner or to accept new employment with another supervising physician.

18VAC85-50-58. Inactive licensure.

A. A physician assistant who holds a current, unrestricted license in Virginia shall, upon a request on the renewal application and submission of the required fee, be issued an inactive license.

1. The holder of an inactive license shall not be required to maintain certification by the NCCPA.

2. An inactive licensee shall not be entitled to practice as a physician assistant in Virginia.

B. An inactive licensee may reactivate his license upon submission of:

1. The required application;

2. Payment of the difference between the current renewal fee for inactive licensure and the renewal fee for active licensure for the biennium in which the license is being reactivated; and

3. Documentation of having maintained certification or having been recertified by the NCCPA.

C. The board reserves the right to deny a request for reactivation to any licensee who has been determined to have committed an act in violation of §54.1-2915 of the Code of Virginia or any provisions of this chapter.

18VAC85-50-59. Registration for voluntary practice by out-of-state licensees.

Any physician assistant who does not hold a license to practice in Virginia and who seeks registration to practice under subdivision 27 of §54.1-2901 of the Code of Virginia on a voluntary basis under the auspices of a publicly supported, all volunteer, nonprofit organization that sponsors the provision of health care to populations of underserved people shall:

1. File a complete application for registration on a form provided by the board at least five business days prior to engaging in such practice. An incomplete application will not be considered;

2. Provide a complete record of professional licensure in each state in which he has held a license and a copy of any current license;

3. Provide the name of the nonprofit organization, the dates and location of the voluntary provision of services;

4. Pay a registration fee of $10; and

5. Provide a notarized statement from a representative of the nonprofit organization attesting to its compliance with provisions of subdivision 27 of §54.1-2901 of the Code of Virginia.

18VAC85-50-60. (Repealed.)

18VAC85-50-61. Restricted volunteer license.

A. A physician assistant who held an unrestricted license issued by the Virginia Board of Medicine or by a board in another state as a licensee in good standing at the time the license expired or became inactive may be issued a restricted volunteer license to practice without compensation in a clinic that is organized in whole or in part for the delivery of health care services without charge in accordance with §54.1-106 of the Code of Virginia.

B. To be issued a restricted volunteer license, a physician assistant shall submit an application to the board that documents compliance with requirements of §54.1-2928.1 of the Code of Virginia and the application fee prescribed in 18VAC85-50-35.

C. The licensee who intends to continue practicing with a restricted volunteer license shall renew biennially during his birth month, meet the continued competency requirements prescribed in subsection D of this section, and pay to the board the renewal fee prescribed in 18VAC85-50-35.

D. The holder of a restricted volunteer license shall not be required to attest to hours of continuing education for the first renewal of such a license. For each renewal thereafter, the licensee shall attest to obtaining 50 hours of continuing education during the biennial renewal period with at least 25 hours in Type 1 and no more than 25 hours in Type 2 as acceptable to the NCCPA.

18VAC85-50-70 to 18VAC85-50-100. (Repealed.)

Part IV. Practice Requirements

18VAC85-50-101. Requirements for a practice agreement.

A. Prior to initiation of practice, a physician assistant and his supervising physician shall enter into a written or electronic practice agreement that spells out the roles and functions of the assistant. Any such practice agreement shall take into account such factors as the physician assistant's level of competence, the number of patients, the types of illness treated by the physician, the nature of the treatment, special procedures, and the nature of the physician availability in ensuring direct physician involvement at an early stage and regularly thereafter. The practice agreement shall also provide an evaluation process for the physician assistant's performance, including a requirement specifying the time period, proportionate to the acuity of care and practice setting, within which the supervising physician shall review the record of services rendered by the physician assistant. The practice agreement may include requirements for periodic site visits by supervising licensees who

supervise and direct assistants who provide services at a location other than where the licensee regularly practices.

B. The board may require information regarding the level of supervision, (i.e., "direct," "personal," or "general") with which the supervising physician plans to supervise the physician assistant for selected tasks. The board may also require the supervising physician to document the assistant's competence in performing such tasks.

C. If the role of the assistant includes prescribing for drugs and devices, the written practice agreement shall include those schedules and categories of drugs and devices that are within the scope of practice and proficiency of the supervising physician.

D. If the initial practice agreement did not include prescriptive authority, there shall be an addendum to the practice agreement for prescriptive authority.

E. If there are any changes in supervision, authorization, or scope of practice, a revised practice agreement shall be entered into at the time of the change.

18VAC85-50-110. Responsibilities of the supervisor.

The supervising physician shall:

1. Review the clinical course and treatment plan for any patient who presents for the same acute complaint twice in a single episode of care and has failed to improve as expected. The supervising physician shall be involved with any patient with a continuing illness as noted in the written or electronic practice agreement for the evaluation process.

2. Be responsible for all invasive procedures.

a. Under general supervision, a physician assistant may insert a nasogastric tube, bladder catheter, needle, or peripheral intravenous catheter, but not a flow-directed catheter, and may perform minor suturing, venipuncture, and subcutaneous intramuscular or intravenous injection.

b. All other invasive procedures not listed in subdivision 2 a of this section must be performed under direct supervision unless, after directly supervising the performance of a specific invasive procedure three times or more, the supervising physician attests to the competence of the physician assistant to perform the specific procedure without direct supervision by certifying to the board in writing the number of times the specific procedure has been performed and that the physician assistant is competent to perform the specific procedure. After such certification has been accepted and approved by the board, the physician assistant may perform the procedure under general supervision.

3. Be responsible for all prescriptions issued by the assistant and attest to the competence of the assistant to prescribe drugs and devices.

18VAC85-50-115. Responsibilities of the physician assistant.

A. The physician assistant shall not render independent health care and shall:

1. Perform only those medical care services that are within the scope of the practice and proficiency of the supervising physician as prescribed in the physician assistant's practice agreement. When a physician assistant is to be supervised by an alternate supervising physician outside the scope of specialty of the supervising physician, then the physician assistant's functions shall be limited to those areas not requiring specialized clinical judgment, unless a separate practice agreement for that alternate supervising physician is approved and on file with the board.

2. Prescribe only those drugs and devices as allowed in Part V (18VAC85-50-130 et seq.) of this chapter.
3. Wear during the course of performing his duties identification showing clearly that he is a physician assistant.

B. If, due to illness, vacation, or unexpected absence, the supervising physician or alternate supervising physician is unable to supervise the activities of his assistant, such supervising physician may temporarily delegate the responsibility to another doctor of medicine, osteopathic medicine, or podiatry. Temporary coverage may not exceed four weeks unless special permission is granted by the board.

C. With respect to assistants employed by institutions, the following additional regulations shall apply:

1. No assistant may render care to a patient unless the physician responsible for that patient has signed the practice agreement to act as supervising physician for that assistant. The board shall make available appropriate forms for physicians to join the practice agreement for an assistant employed by an institution.

2. Any such practice agreement as described in subdivision 1 of this subsection shall delineate the duties which said physician authorizes the assistant to perform.

3. The assistant shall, as soon as circumstances may dictate, report an acute or significant finding or change in clinical status to the supervising physician concerning the examination of the patient. The assistant shall also record his findings in appropriate institutional records.

D. Practice by a physician assistant in a hospital, including an emergency department, shall be in accordance with §54.1-2952 of the Code of Virginia.

18VAC85-50-116. Volunteer restricted license for certain physician assistants.

The issuance of a volunteer restricted license and the practice of a physician assistant under such a license shall be in accordance with the provisions of §54.1-2951.3 of the Code of Virginia.

18VAC85-50-117. Authorization to use fluoroscopy.

A physician assistant working under the supervision of a licensed doctor of medicine or osteopathy specializing in the field of radiology is authorized to use fluoroscopy for guidance of diagnostic and therapeutic procedures provided such activity is specified in his protocol and he has met the following qualifications:

1. Completion of at least 40 hours of structured didactic educational instruction and at least 40 hours of supervised clinical experience as set forth in the Fluoroscopy Educational Framework for the Physician Assistant created by the American Academy of Physician Assistants (AAPA) and the American Society of Radiologic Technologists (ASRT); and

2. Successful passage of the American Registry of Radiologic Technologists (ARRT) Fluoroscopy Examination.

Part V. Prescriptive Authority.

18VAC85-50-120. [Repealed]

18VAC85-50-130. Qualifications for approval of prescriptive authority.

An applicant for prescriptive authority shall meet the following requirements:

1. Hold a current, unrestricted license as a physician assistant in the Commonwealth;

2. Submit a practice agreement acceptable to the board prescribed in 18VAC85-50-101. This practice agreement must be approved by the board prior to issuance of prescriptive authority;

3. Submit evidence of successful passing of the NCCPA exam; and

4. Submit evidence of successful completion of a minimum of 35 hours of acceptable training to the board in pharmacology.

18VAC85-50-140. Approved drugs and devices.

A. The approved drugs and devices which the physician assistant with prescriptive authority may prescribe, administer, or dispense manufacturer's professional samples shall be in accordance with provisions of §54.1-2952.1 of the Code of Virginia:

B. The physician assistant may prescribe only those categories of drugs and devices included in the practice agreement as submitted for authorization. The supervising physician retains the authority to restrict certain drugs within these approved categories.

C. The physician assistant, pursuant to §54.1-2952.1 of the Code of Virginia, shall only dispense manufacturer's professional samples or administer controlled substances in good faith for medical or therapeutic purposes within the course of his professional practice.

18VAC85-50-150. (Repealed.)

18VAC85-50-160. Disclosure.

A. Each prescription for a Schedule II through V drug shall bear the name of the supervising physician and of the physician assistant.

B. The physician assistant shall disclose to the patient that he is a licensed physician assistant, and also the name, address and telephone number of the supervising physician. Such disclosure shall either be included on the prescription or be given in writing to the patient.

18VAC85-50-170. (Repealed.)

Part V. Standards of Professional Conduct.

18VAC85-50-175. Confidentiality.

A. A practitioner shall not willfully or negligently breach the confidentiality between a practitioner and a patient. A breach of confidentiality that is required or permitted by applicable law or beyond the control of the practitioner shall not be considered negligent or willful.

B. Unauthorized use or disclosure of confidential information received from the Prescription Monitoring Program shall be grounds for disciplinary action

18VAC85-50-176. Treating and prescribing for self or family.

A. Treating or prescribing shall be based on a bona fide practitioner-patient relationship, and prescribing shall meet the criteria set forth in § 54.1-3303 of the Code of Virginia.

B. A practitioner shall not prescribe a controlled substance to himself or a family member, other than Schedule VI as defined in § 54.1-3455 of the Code of Virginia, unless the prescribing occurs in an emergency situation or in isolated settings where there is no other qualified practitioner available to the patient, or it is for a single episode of an acute illness through one prescribed course of medication.

C. When treating or prescribing for self or family, the practitioner shall maintain a patient record documenting compliance with statutory criteria for a bona fide practitioner-patient relationship.

18VAC85-50-177. Patient records.

A. Practitioners shall comply with provisions of § 32.1-127.1:03 related to the confidentiality and disclosure of patient records.

B. Practitioners shall properly manage patient records and shall maintain timely, accurate, legible and complete records.

C. Practitioners shall provide patient records to another practitioner or to the patient or his personal representative in a timely manner and in accordance with provisions of § 32.1-127.1:03 of the Code of Virginia.

18VAC85-50-178. Practitioner-patient communication.

A. Except as provided in § 32.1-127.1:03 F of the Code of Virginia, a practitioner shall accurately inform a patient or his legally authorized representative of his medical diagnoses, prognosis and prescribed treatment or plan of care. A practitioner shall not deliberately make a false or misleading

statement regarding the practitioner's skill or the efficacy or value of a medication, treatment, or procedure prescribed or directed by the practitioner in the treatment of any disease or condition.
B. A practitioner shall present information relating to the patient's care to a patient or his legally authorized representative in understandable terms and encourage participation in the decisions regarding the patient's care.

C. Before surgery or any invasive procedure is performed, informed consent shall be obtained from the patient in accordance with the policies of the health care entity. Practitioners shall inform patients of the risks, benefits, and alternatives of the recommended surgery or invasive procedure that a reasonably prudent practitioner in similar practice in Virginia would tell a patient.

1. In the instance of a minor or a patient who is incapable of making an informed decision on his own behalf or is incapable of communicating such a decision due to a physical or mental disorder, the legally authorized person available to give consent shall be informed and the consent documented.

2. An exception to the requirement for consent prior to performance of surgery or an invasive procedure may be made in an emergency situation when a delay in obtaining consent would likely result in imminent harm to the patient.

3. For the purposes of this provision, "invasive procedure" shall mean any diagnostic or therapeutic procedure performed on a patient that is not part of routine, general care and for which the usual practice within the health care entity is to document specific informed consent from the patient or surrogate decision-maker prior to proceeding.

18VAC85-50-179. Practitioner responsibility.

A. A practitioner shall not:

1. Perform procedures or techniques that are outside the scope of his practice or for which he is not trained and individually competent;

2. Knowingly allow subordinates to jeopardize patient safety or provide patient care outside of the subordinate's scope of practice or area of responsibility. Practitioners shall delegate patient care only to subordinates who are properly trained and supervised;

3. Engage in an egregious pattern of disruptive behavior or interaction in a health care setting that interferes with patient care or could reasonably be expected to adversely impact the quality of care rendered to a patient; or

4. Exploit the practitioner/patient relationship for personal gain.

B. Advocating for patient safety or improvement in patient care within a health care entity shall not constitute disruptive behavior provided the practitioner does not engage in behavior prohibited in A 3 of this section.

18VAC85-50-180. Vitamins, minerals and food supplements.

A. The recommendation or direction for the use of vitamins, minerals or food supplements and the rationale for that recommendation shall be documented by the practitioner. The recommendation or direction shall be based upon a reasonable expectation that such use will result in a favorable patient outcome, including preventive practices, and that a greater benefit will be achieved than that which can be expected without such use.

B. Vitamins, minerals, or food supplements, or a combination of the three, shall not be sold, dispensed, recommended, prescribed, or suggested in doses that would be contraindicated based on the individual patient's overall medical condition and medications.

C. The practitioner shall conform to the standards of his particular branch of the healing arts in the therapeutic application of vitamins, minerals or food supplement therapy.

18VAC85-50-181. Pharmacotherapy for weight loss.

A.A practitioner shall not prescribe amphetamine, Schedule II, for the purpose of weight reduction or control.

B. A practitioner shall not prescribe controlled substances, Schedules III through VI, for the purpose of weight reduction or control in the treatment of obesity, unless the following conditions are met:

1. An appropriate history and physical examination, are performed and recorded at the time of initiation of pharmacotherapy for obesity by the prescribing physician, and the physician reviews the results of laboratory work, as indicated, including testing for thyroid function;

2. If the drug to be prescribed could adversely affect cardiac function, the physician shall review the results of an electrocardiogram performed and interpreted within 90 days of initial prescribing for treatment of obesity;

3. A diet and exercise program for weight loss is prescribed and recorded;

4. The patient is seen within the first 30 days following initiation of pharmacotherapy for weight loss, by the prescribing physician or a licensed practitioner with prescriptive authority working under the supervision of the prescribing physician, at which time a recording shall be made of blood pressure, pulse, and any other tests as may be necessary for monitoring potential adverse effects of drug therapy;

5. The treating physician shall direct the follow-up care, including the intervals for patient visits and the continuation of or any subsequent changes in pharmacotherapy. Continuation of prescribing for treatment of obesity shall occur only if the patient has continued progress toward achieving or maintaining a target weight and has no significant adverse effects from the prescribed program.

18VAC85-50-182. Anabolic steroids.

A physician assistant shall not prescribe or administer anabolic steroids to any patient for other than accepted therapeutic purposes.

18VAC85-50-183. Sexual contact.

A. For purposes of § 54.1-2915 A 12 and A 19 of the Code of Virginia and this section, sexual contact includes, but is not limited to, sexual behavior or verbal or physical behavior which:

1. May reasonably be interpreted as intended for the sexual arousal or gratification of the practitioner, the patient, or both; or

2. May reasonably be interpreted as romantic involvement with a patient regardless of whether such involvement occurs in the professional setting or outside of it.

B. Sexual contact with a patient.

1. The determination of when a person is a patient for purposes of § 54.1-2915 A 19 of the Code of Virginia is made on a case-by-case basis with consideration given to the nature, extent, and context of the professional relationship between the practitioner and the person. The fact that a person is not actively receiving treatment or professional services from a practitioner is not determinative of this issue. A person is presumed to remain a patient until the patient-practitioner relationship is terminated.

2. The consent to, initiation of, or participation in sexual behavior or involvement with a practitioner by a patient does not change the nature of the conduct nor negate the statutory prohibition.

C. Sexual contact between a practitioner and a former patient.

Sexual contact between a practitioner and a former patient after termination of the practitioner-patient relationship may still constitute unprofessional conduct if the sexual contact is a result of the exploitation of trust, knowledge, or influence of emotions derived from the professional relationship.

D. Sexual contact between a practitioner and a key third party shall constitute unprofessional conduct if the sexual contact is a result of the exploitation of trust, knowledge or influence derived from the professional relationship or if the contact has had or is likely to have an adverse effect on patient care. For purposes of this section, key third party of a patient shall mean: spouse or partner, parent or child, guardian, or legal representative of the patient.

E. Sexual contact between a supervisor and a trainee shall constitute unprofessional conduct if the sexual contact is a result of the exploitation of trust, knowledge or influence derived from the professional relationship or if the contact has had or is likely to have an adverse effect on patient care.

18VAC85-50-184. Refusal to provide information.

A practitioner shall not willfully refuse to provide information or records as requested or required by the board or its representative pursuant to an investigation or to the enforcement of a statute or regulation.

DOCUMENTS INCORPORATED BY REFERENCE

Fluoroscopy Educational Framework for the Physician Assistant, December 2009, American Academy of Physician Assistants, 950 North Washington Street, Alexandria, VA 22314 and the American Society of Radiologic Technologists, 15000 Central Avenue, SE, Albuquerque, NM 87123

Amendment to Physician Assistant Regulation

Effective: June 29, 2017

18VAC85-50-110. Responsibilities of the supervisor.

The supervising physician shall:

1. Review the clinical course and treatment plan for any patient who presents for the same acute complaint twice in a single episode of care and has failed to improve as expected. The supervising physician shall be involved with any patient with a continuing illness as noted in the written or electronic practice agreement for the evaluation process.

2. Be responsible for all invasive procedures.

a. Under general supervision, a physician assistant may insert a nasogastric tube, bladder catheter, needle, or peripheral intravenous catheter, but not a flow-directed catheter, and may perform minor suturing, venipuncture, and subcutaneous intramuscular or intravenous injection.

b. All other invasive procedures not listed in subdivision 2 a of this section must be performed under direct supervision unless, after directly supervising the performance of a specific invasive procedure three times or more, the supervising physician attests on the practice agreement to the competence of the physician assistant to perform the specific procedure without direct supervision ~~by certifying to the board in writing the number of times the specific procedure has been performed and that the physician assistant is competent to perform the specific procedure. After such certification has been accepted and approved by the board, the physician assistant may perform the procedure under general supervision~~.

3. Be responsible for all prescriptions issued by the assistant and attest to the competence of the assistant to prescribe drugs and devices.

From: Virginia Board of Medicine
Sent: Tuesday, March 14, 2017 7:01 PM
Subject: Board of Medicine Regulations on Opioid Prescribing and Buprenorphine

Virginia Department of Health Professions

Virginia Board of Medicine

Virginia Board of Medicine

Dear Prescriber,

In response to the escalating opioid crisis in Virginia – and recently passed legislation – the Board of Medicine has promulgated regulations on the prescribing of opioids for pain. These regulations, which take effect March 15th, will:

- Provide clear, evidence-based guidance on the proper prescribing for acute and chronic pain.
- Decrease the number of patients who abuse or develop an addiction to opioids.
- Rein in intentional and indiscriminate overprescribing by practitioners who treat pain.

The Board worked diligently with pain experts, addiction experts and stakeholders to develop regulations that will not hinder the good practice of medicine but will prevent the diversion of opioids for non-medicinal use.

As you consider these regulations, make sure that the needs of patients currently receiving opioids for chronic pain are taken into account. It is critically important that no patients in Virginia find themselves looking for narcotics outside of the medical system – ie, on the street.

Here is a link to the new regulations. Please take the time to review them. Some of the key provisions are listed below.

Acute Pain

- Treatment with opioids for acute pain must be with short-acting opioids, and for a seven-day supply or less (unless extenuating circumstances are clearly documented in the medical record).
- Treatment with opioids as part of treatment for a surgical procedure must be for a fourteen-day supply or less (unless extenuating circumstances are clearly documented in the medical record).
- An appropriate history and examination must be performed, including a check of the PMP in accordance with state law.
- Morphine Milligram Equivalent (MME) should be considered, and naloxone must be

co-prescribed if the MME exceeds 120 MME/day. Here is a link to the CDC calculator for MME.

Chronic Pain

- An appropriate history and examination must be performed, as detailed in the regulations.
- The practitioner must discuss risks, benefits, proper storage and disposal with the patient.
- Naloxone must be prescribed for any patient when one or more of the following risk factors is present: prior overdose, substance abuse, doses in excess of 120 MME/day, or concomitant benzodiazepine.
- Urine drug screen or serum medication levels shall be conducted 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.

In addition, Part IV of these regulations covers the treatment of addiction with buprenorphine. Medication Assisted Treatment (MAT) is an essential part of recovery for many individuals but unfortunately the mono-product form (Subutex) is increasingly being diverted and abused. Key provisions of the buprenorphine regulations include:

- Practitioners engaged in office-based opioid addiction treatment with buprenorphine shall have obtained a SAMHSA waiver and the appropriate Drug Enforcement Administration registration.
- Buprenorphine without naloxone (ie, the mono-product) shall only be prescribed when a patient is pregnant, when converting a patient from methadone, and in formulations other than tablet form for indications approved by the FDA.

Although the final numbers are not yet in, in 2016 approximately 1100 Virginians died of an opioid overdose – a 30% increase over 2015. Even for those who died of a heroin overdose, their addiction often began with a legitimate prescription for pain.

Thank you for your help as we work together to end the opioid crisis in Virginia.

William L. Harp, MD
Executive Director
Virginia Board of Medicine

Commonwealth of Virginia

REGULATIONS

GOVERNING PRESCRIBING OPIOIDS AND BUPRENORPHINE

VIRGINIA BOARD OF MEDICINE

Title of Regulations: 18 VAC 85-21-10 et seq.

Statutory Authority: § 54.1-2400 and Chapter 29 of Title 54.1 of the *Code of Virginia*

Effective Date: March 15, 2017

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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 cancer, a patient in hospice care, or a patient in palliative care;

2. The treatment of acute or chronic pain during an inpatient hospital admission, 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" shall mean 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" shall mean the Virginia Board of Medicine.

"Chronic pain" shall mean non-malignant 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" shall mean drugs listed in The Drug Control Act of the Code of Virginia in Schedules II through IV.

"FDA" shall mean the U.S. Food and Drug Administration.

"MME" shall mean morphine milligram equivalent.

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

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

Part II. Management of Acute Pain.

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

A. Non-pharmacologic 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.

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, 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 history of the patient and any family history of addiction or substance abuse;

6. A urine drug screen or serum medication level;

7. A query 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; 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. Non-pharmacologic 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, 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.

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 healthcare 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 but not limited to 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 records the presence or absence of any indicators for medication misuse, abuse 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 which will result in referral to a higher level of care, cessation of treatment, or dismissal from care.

C. The treatment agreement shall include, but not be limited to, 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. Practitioners shall check the Prescription Monitoring Program at least every three months after the initiation of treatment.

D. 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 healthcare 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 and/or any documentation of attempts to obtain;

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 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 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 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 HIV, Hepatitis B, Hepatitis C and TB.

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.

B. Buprenorphine mono-product tablets may be administered directly to patients in federally licensed opioid treatment programs (OTPs). With the exception of those conditions listed in subsection A, only the buprenorphine product containing naloxone shall be prescribed or dispensed for use offsite 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 8 mg. 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 mg. of buprenorphine per day shall be placed in the medical record. Dosages exceeding 24 mg. 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 counseling.

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

A. Pregnant women shall be treated with the buprenorphine mono-product, usually 16 mg. per day or less.

B. Patients under 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 which can be identified, quantified and independently verified.

D. Practitioners shall evaluate patients with medical comorbidities by history, physical exam, appropriate laboratory studies, and 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 that 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 Board of Medicine Regulation 18VAC85-20-27, which prohibits willful or negligent breach of confidentiality or unauthorized disclosure of confidential Prescription Monitoring Program information, shall be maintained.