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## Fast-Track Regulation Agency Background Document

<b>Agency name</b>	Board of Medicine, Department of Health Professions
<b>Virginia Administrative Code (VAC) citation(s)</b>	18VAC85-50-10 et seq.
<b>Regulation title(s)</b>	Regulations Governing the Practice of Physician Assistants
<b>Action title</b>	Definition of supervision and pharmacology for weight loss
<b>Date this document prepared</b>	2/19/18

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*.

### Brief summary

*Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.*

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.

### Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

PA = physician assistant

**Statement of final agency action**

Please provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

On February 15, 2018, the Board of Medicine adopted amendments to 18VAC85-50-10 et seq., Regulations Governing the Practice of Physician Assistants.

**Legal basis**

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person'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 Code sections relating to licensure and practice of physician assistants are:

**§ 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.

**§ 54.1-2952.1. Prescription of certain controlled substances and devices by licensed physician assistant.**

A. In accordance with the provisions of this section and pursuant to the requirements of Chapter 33 (§ [54.1-3300](#) et seq.), a licensed physician assistant shall have the authority to prescribe controlled substances and devices as set forth in Chapter 34 (§ [54.1-3400](#) et seq.), provided that the physician assistant has entered into and is, at the time of writing a prescription, a party to a practice agreement with a licensed physician or podiatrist that provides for the direction and supervision by such licensee of the prescriptive practices of the physician assistant. Such practice agreements shall include the controlled substances the physician assistant is or is not authorized to prescribe and may restrict such prescriptive authority as deemed appropriate by the physician or podiatrist providing direction and supervision.

B. It shall be unlawful for the physician assistant to prescribe controlled substances or devices pursuant to this section unless such prescription is authorized by the practice agreement between the licensee and the assistant.

C. The Board of Medicine, in consultation with the Board of Pharmacy, shall promulgate such regulations governing the prescriptive authority of physician assistants as are deemed reasonable and necessary to ensure an appropriate standard of care for patients.

The regulations promulgated pursuant to this section shall include, at a minimum, (i) such requirements as may be necessary to ensure continued physician assistant competency that may include continuing education, testing, and/or any other requirement, and shall address the need to promote ethical practice, an appropriate standard of care, patient safety, the use of new pharmaceuticals, and appropriate communication with patients; and (ii) a requirement that the physician assistant disclose to his patients the name, address, and telephone number of the supervising licensee and that he is a physician assistant. A separate office for the physician assistant shall not be established.

D. This section shall not prohibit a licensed physician assistant from administering controlled substances in compliance with the definition of "administer" in § [54.1-3401](#) or from receiving and dispensing manufacturers' professional samples of controlled substances in compliance with the provisions of this section.

**§ 54.1-2952.2. When physician assistant signature accepted.**

Whenever any law or regulation requires a signature, certification, stamp, verification, affidavit, or endorsement by a physician, it shall be deemed to include a signature, certification, stamp, verification, affidavit, or endorsement by a physician assistant.

### Purpose

*Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.*

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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.

### Rationale for using fast-track process

*Please explain the rationale for using the fast-track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?*

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The Board initially issued a Notice of Intended Regulatory Action to begin the regulatory process; the proposed changes identified in the NOIRA were fully supported by the Virginia Academy of Physician Assistants and unanimously approved by members of the Advisory Board and the full Board of Medicine. Therefore, the Board determined to move forward with adoption of a fast-track action.

### Substance

*Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of changes" section below.*

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

- 1) Amended 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) Eliminated 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) Deleted in Section 101 the examples of various levels of supervision that may be spelled out in the practice agreement between the parties; and

- 4) Amended 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 added 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.*

### Issues

*Please identify the issues associated with the proposed regulatory action, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.*

- 1) There are no advantages or disadvantages to the public. The public continues to be protected by maintaining the requirement for physician oversight and certification of the PA’s competency to perform invasive procedures.
- 2) There are no advantages or disadvantages to the agency or the Commonwealth.
- 3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. The Board is authorized under § 54.1-2400 to “*To promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 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.*” There is no restraint on competition as a result of promulgating this regulation. To the contrary, it clarifies the levels of supervision and eliminates a current requirement for prescribing that may be burdensome for licensees.

### Requirements more restrictive than federal

*Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.*

There are no applicable federal requirements.

### Localities particularly affected

*Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.*

There are no localities particularly affected.

### Regulatory flexibility analysis

*Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.*

There are no alternative regulatory methods; the proposed regulation clarifies current requirements.

### Economic impact

*Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.*

<p><b>Projected cost to the state to implement and enforce the proposed regulation, including:</b>  <b>a) fund source / fund detail; and</b>  <b>b) a delineation of one-time versus on-going expenditures</b></p>	<p>There is no cost for implementation or enforcement. The amendment will eliminate a requirement that is burdensome in some physician practices.</p>
<p><b>Projected cost of the new regulations or changes to existing regulations on localities.</b></p>	<p>There are no costs to localities.</p>
<p><b>Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.</b></p>	<p>The individuals affected will be physician assistants and supervising physicians.</p>
<p><b>Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected.</b> Small business means a business entity, including its affiliates, that:  a) is independently owned and operated and;  b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>There are 3,612 persons who hold a current Virginia license as a physician assistant. Each of those may have multiple supervising physicians. There is no estimate of the number of small businesses because physician assistants do not practice independently and work in many types of practices and employment settings.</p>
<p><b>All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including:</b>  <b>a) the projected reporting, recordkeeping, and</b></p>	<p>There are no costs; the current regulation will increase efficiency and therefore, reduce costs.</p>

<p><b>other administrative costs required for compliance by small businesses; and b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.</b></p>	
<p><b>Beneficial impact the regulation is designed to produce.</b></p>	<p>Greater efficiency and facilitation of practice by PAs.</p>

### 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.*

Since this is a less intrusive and costly regulation, there are no alternatives that meet the essential purpose of the action.

### Public participation notice

*If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register; and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.*

### Family impact

*Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.*

There is no impact on the family and family stability.

### Detail of changes

*Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being*



proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below.

Current section number	Proposed new section number, if applicable	Proposed change, intent, rationale, and likely impact of proposed requirements
10	Sets out definitions for words and terms used in the chapter	The proposed change will simply the various definitions of supervision and consolidate into one definition for “supervision.” That definition is a combination of the current definitions for “general supervision” and “continuous supervision.” There is no substantive change.
101	Sets out the requirements for a practice agreement.	In section 10, there is a definition for a supervising physician; that has been moved into section 101. Additionally, the reference to various levels of supervision has been deleted. There are no substantive changes.
110	Establishes the responsibilities for the supervisor	In subdivision 2, the physician is responsible for attesting that the PA is competent to perform an invasive procedure; the current rule requires the physician to directly “supervise” the performance, but the physician is actually observing the PA in the performance. The word “supervising” is changed to “observing.” The words “general” and “direct” are being deleted as used to describe “supervision.” The revised definition of “supervision” is the same as the current definition of “general” supervision. In #2, the word “direct” is deleted because the definition of direct supervision was deleted; the key requirement of direct supervision (having the physician in the room) was added to the invasive procedures regulation.
115	Establishes the responsibilities of the PA	Currently, the definition of an alternate supervising physician is found in section 10; the language is being moved to section 115, which is the section that sets out the requirements for a practice agreement with a supervising or alternate supervising physician.
181	Sets out the requirements for pharmacotherapy for weight loss treatment	<p>In subsection C of 18VAC85-20-90C (Regulations for physicians), it is stated that: <i>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.</i></p> <p>However, there is no such authorization specifically stated in Chapter 50. Therefore, the proposed amendment to section 181 will specify state what the PA is allowed to do for a practice receiving pharmacotherapy for weight loss treatment, if so authorized by a practice agreement.</p>