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Fast-Track Regulation
Agency Background Document

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	Periodic review
Date this document prepared	10/24/18

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations.*

Brief Summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

Chapter 450 of the 2016 made substantive changes to the statutory requirements for the practice and licensure of physician assistants. An exempt regulatory action was promulgated with an effective date of October 5, 2016. However, during its periodic review of regulations, the Advisory Board identified several sections that are currently inconsistent with the 2016 deletion of the requirement for a practice agreement with prescriptive authority to be submitted and approved by the Board. (Chapter 450: A. In accordance with the provisions of this section and pursuant to the requirements of Chapter 33 (§ 54.1-3300 et seq.) ~~of this title~~, 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…~~A licensed physician assistant shall have such prescriptive authority upon the provision to the Board of Medicine of such evidence as it may require~~, *provided* that the *physician* assistant has entered into and is, at the time of writing a prescription, a party to a ~~written~~ *practice* agreement with a licensed physician or podiatrist ~~which~~ *that* provides for the direction and supervision by such licensee of the prescriptive practices of the *physician* assistant.)

Accordingly, amendments are adopted to update and clarify the regulations.

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 October 18, 2018, the Board of Medicine amended 18VAC85-50-10 et seq., Regulations Governing the Practice of Physician Assistants.

Mandate and Impetus

Please identify the mandate for this regulatory change, and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, board decision, etc.). For purposes of executive branch review, "mandate" has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

As required by Virginia Code § 2.2-4012.1, please also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track process.

As required by Executive Order 14 (2018), the Board of Medicine conducted a periodic review of this chapter. The amendments are clarifying or intended for consistency with statutory provisions. There are no substantive changes, so the amendments are not expected to be controversial.

Legal Basis

Please identify (1) the agency or other promulgating entity, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must 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 or promulgating entity'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 statutory provisions for practice of a physician assistant and prescriptive authority are found in :

§ 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.

Purpose

Please explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it's intended to solve.

It is necessary to retain the current chapter because licensure and regulation of physician assistants under the Board of Medicine is a requirement of statute. The provisions of this chapter will delete references to an outdated requirement for a practice agreement to be submitted and approved by the Board and will clrify the practice of physician assistants to further protect the health and safety of persons who receive treatment and care from such practitioners. The regulatory change is consistent with the principle that regulations should be clearly written and easily understandable.

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.

Pursuant to its periodic review of Chapter 120, the Board has adopted amendments to delete outdated or unnecessary language. Chapter 450 of the 2016 made substantive changes to the statutory requirements for the practice and licensure of physician assistants. An exempt regulatory action was promulgated with an effective date of October 5, 2016. However, during its periodic review of regulations, the Advisory Board identified several sections that are currently inconsistent with the 2016 deletion of the requirement for a practice agreement with prescriptive authority to be submitted and approved by the Board.

Issues

Please identify the issues associated with the regulatory change, 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, include a specific statement to that effect.

1) There are no real advantages or disadvantages to the public. The amendments are clarifying and consistent with current practice and with the Code of Virginia.
2) There are no advantages or disadvantages to the agency or the Commonwealth.
3) There are no other pertinent matters of interest. 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 "*promulgate regulations in accordance with the Administrative Process Act which are reasonable and necessary to administer effectively the regulatory system.*"
   The proposed amendments are a foreseeable result of the statute requiring the Board to protect the health and safety of citizens of the Commonwealth.

Requirements More Restrictive than Federal

Please identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and 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 specific statement to that effect.

There is no applicable federal requirement.

Agencies, Localities, and Other Entities Particularly Affected

Please identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected - None

Localities Particularly Affected - None

Other Entities Particularly Affected - None

Economic Impact

Pursuant to § 2.2-4007.04 of the Code of Virginia, please identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic

impact, specify which new requirement or change in requirement creates the anticipated economic impact. Please keep in mind that this is change versus the status quo.

For your agency: projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	There are no projected costs or savings resulting from the change. As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners for necessary functions of regulation; The agency will incur no additional costs for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities.
For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	None
For all agencies: Benefits the regulatory change is designed to produce.	None

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	No costs
Benefits the regulatory change is designed to produce.	None

Impact on Other Entities

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	Licensed physician assistants
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. 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.	There are 3,841 persons who hold a license as a physician assistant in Virginia. Physician assistants are employed by physician practices or health care systems; they do not typically operate small businesses.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Please be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees;	None

d) purchases of equipment or services; and e) time required to comply with the requirements.	
Benefits the regulatory change is designed to produce.	The amended regulations are clarifying or correcting outdated regulation.

Alternatives

Please describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. 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 regulatory change.

The amendments do not change the substance of the chapter; there are no alternatives. The amendments make the regulations less burdensome and intrusive.

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) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing 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 regulatory change.

There are no alternative regulatory methods for clarifying the language of a regulation and statute other than promulgating a regulatory action.

Public Participation

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.

Detail of Changes

Current section number	Current requirement	Change, intent, rationale, and likely impact of new requirements
115	Sets out the responsibilities of a physician assistant	Subsection A 1 is amended to delete reference to board approval of practice agreement and

		include the execution of a practice agreement for an alternate supervising physician outside of the area of practice for the supervising physician. Subsection D is amended to delete outdated language about board forms for practice agreements. Such forms are not provided by the Board and are not required to be submitted to the Board.
130	Sets out the qualifications for approval of prescriptive authority	The 2016 changes to the statute eliminated the requirement for board approval of a practice agreement for prescriptive authority, so that provision in #2 is deletion. Likewise, the provision in #3 is redundant and unnecessary; in order to be licensed as a PA, one must submit evidence of successful passage of the NCCPA examination. It does not need to be listed as a qualification for prescriptive authority.
140	Sets out the requirements for approved drugs and devices	Subsection B is amended to delete the phrase “as submitted for authorization” because the Code no longer requires submission of a practice agreement for prescriptive authority.