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Proposed Regulation
Agency Background Document

Agency name	Boards 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	Practice with a patient care team physician
Date this document prepared	12/6/19

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.

Amendments are adopted to 18VAC85-50 to comply with changes to the Code (Chapters 92 and 137 of the 2019 Acts of the Assembly) that eliminated practice by a physician assistant under the *supervision* of a physician or podiatrist and replaced the relationship between the two to one of practice in collaboration and consultation with a *patient care team physician or podiatrist.*

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

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the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

The Board of Medicine is complying with provisions of HB1952 and SB1209 of the 2019 General Assembly and is replacing emergency regulations adopted pursuant to the second enactment of the Acts.

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 specific statutory for this action is found in *§§ 54.1-2900, 54.1-2951.1 through 54.1-2952.1, 54.1-2953, and 54.1-2957 of the Code of Virginia*.

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.

The purpose of this regulatory action is compliance with statutory changes delineating the practice of a physician assistant. The amendments are consistent with the requirement for a

practice agreement between or among the parties and the responsibility of the patient care team physician or podiatrist for the health, safety, and welfare of patients who receive care.

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.

Amendments are adopted to 18VAC85-50 to comply with changes to the Code (Chapters 92 and 137 of the 2019 Acts of the Assembly) that eliminated practice by a physician assistant under the *supervision* of a physician or podiatrist and replaced the relationship between the two to one of practice in collaboration and consultation with a *patient care team physician or podiatrist.*

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 advantages or disadvantages to the public apart from those in the statutory language in Chapter 29 of Title 54.1. The changes do not substantially alter the practice model for physician assistants and physicians as they are currently employed.
2) There are no particular advantages or disadvantages to the agency.
3) Other matters. 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.*" Any restraint on competition as a result of promulgating this regulation is a foreseeable result of the statute, which sets out the definitions and practice requirements for practice with a patient care team physician or podiatrist.

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 are no applicable federal requirements.

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.

Impact on State Agencies

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	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 or entities for necessary functions of regulation. All notifications will be done electronically. There are no on-going expenditures.	
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.	There are no costs to other agencies.	
For all agencies: Benefits the regulatory change is designed to produce.	There are no specific benefits.	

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	There are no costs.
Benefits the regulatory change is designed to produce.	There are no benefits.

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.	Practitioners under the Board of Medicine – MDs, DOs, DPMs, and PAs
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.	Total licensure counts are: Doctors of Medicine & Surgery – 38,947 Doctors of Osteopathic Medicine – 3,834 Doctors of Podiatry – 553 Physician Assistants – 4,224 Since physician assistants are not required to submit practice agreements for Board approval, the Board has no information on how many such agreements are in place. All PAs are required to have a practice agreements with one or more doctors. All doctors who have agreements with PAs are affected by the change in the statute and these proposed regulations. It is not known how many are 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; d) purchases of equipment or services; and e) time required to comply with the requirements.	There are no associated costs.
Benefits the regulatory change is designed to produce.	The benefits are clarity and consistency with the statute. There are no significant differences in the way PAs and doctors currently practice.

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.

There are no viable alternatives to the proposed regulatory action, which is conforming to statutory provisions for physician assistants.

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 consistent with the mandate of the Code and public health and safety. Proposed regulations are consistent with the statutory changes made by the 2019 General Assembly.

Public Comment

Please summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency response. Ensure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency or board. If no comment was received, enter a specific statement to that effect.

There was a public comment period on the Notice of Intended Regulatory Action from 10/14/19 to 11/13/19; no comment was received.

Public Participation

Please include a statement that in addition to any other comments on the regulatory change, the agency is seeking comments on the costs and benefits of the regulatory change and the impacts of the regulated community. Also, indicate whether a public hearing will be held to receive comments.

In addition to any other comments, the Board of Medicine is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments for the public comment file may do so by mail, email or fax to Elaine Yeatts at elaine.yeatts@dhp.virginia.gov or at 9960 Mayland Drive, Henrico, VA 23233 or by fax at (804) 527-4434.. Comments may also be submitted through the Public Forum feature of the Virginia Regulatory Town Hall web site at: http://www.townhall.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

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

Detail of Changes

Please list all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation.

In every section of this chapter, there are amendments to change the terminology from "supervising physician" to "patient care team physician (or podiatrist)" and to change "supervision" to "collaboration and consultation" as the practice relationship.

In addition, the following amendments were necessary:

Current section number	Current requirement	Change, intent, rationale, and likely impact of new requirements
10	Sets out definitions used in the chapter	Words and terms defined in 54.1-2900 that are applicable to the chapter and this regulatory action are added. Amendments to terms defined in the chapter are necessary for consistency with their current usage. The term "supervision" is deleted because it is no longer applicable.
35	Sets out fees for licensure and renewal	The fee for submission of a new protocol is deleted as it is no longer required to submit a PA protocol.
110	Sets out responsibilities of the physician or podiatrist	Subdivision 4 is added for consistency with the Code (§ 54.1-2952) which specifically states: *A patient care team physician or patient care team podiatrist shall be available at all times to collaborate and consult with physician assistants.*
115	Sets out responsibilities of the physician assistant	Subsection A is amended to eliminate the language stating that the practice agreement "is approved and on file with the board." *It is no longer a requirement for practice agreements between a PA and physician or podiatrist to be submitted to the Board for approval, so that language is outdated.* Likewise, subsection B is amended to eliminate the phrase "who has registered with the board" because it is not required for a physician to register in order to have a practice agreement with a PA. Subdivision 3 of subsection D is eliminated because the requirement is specifically eliminated in the Code in subsection D of § 54.1-2952.
130	Sets out qualifications for approval of prescriptive authority	The requirement for the practice agreement to be approved by the Board is deleted, as it is no longer required. The requirement to "submit evidence of successfully passing of the NCCPA exam" is deleted because passage of that exam is necessary in order to be initially licensed; the language in this section is outdated and not necessary.

140	Sets out the approved drugs and devices	The requirement for the practice agreement to be submitted for authorization is deleted, as it is no longer required.