Virginia Regulatory Town Hall

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Proposed Regulation
Agency Background Document

Agency name	Board of Medicine, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC85-50
Regulation title	Regulations Governing the Practice of Physician Assistants
Action title	Practice protocol/responsibilities of a supervisor
Date this document prepared	3/7/11

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.

The Advisory Board on Physician Assistants and the Virginia Academy of Physician Assistants submitted a draft revision to the responsibilities for the supervising physician to eliminate the requirement for the physician to see a patient "not less frequently than every fourth visit for a continuing illness." The goal of the action is to allow the physician and his assistant to determine the evaluation process, as expressed in the written practice agreement submitted to the Board of Medicine.

As the Board considered changes to the "fourth visit rule," it also reviewed language in all of Part IV on Practice Requirements to review the use of and requirements for a "protocol." The Board reviewed the statutory requirements for a physician assistant/physician agreement and for an evaluation process and amended current regulations for consistency and clarity.

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

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

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:*
>
> *1. To establish the qualifications for registration, certification or licensure in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.*
>
> *2. To examine or cause to be examined applicants for certification or licensure. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.*
>
> *3. To register, certify or license qualified applicants as practitioners of the particular profession or professions regulated by such board.*
>
> …
> *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. …*

Specific authority for regulation of physician assistant practice is found in Chapter 29 of Title 54.1:

> ***§ 54.1-2951.1. Requirements for licensure as a physician assistant.***
> *A. The Board shall promulgate regulations establishing requirements for licensure as a physician assistant which shall include, but not be limited to, the following:*
> *1. Successful completion of a physician assistant program or surgeon assistant program accredited by the American Medical Association or a committee of the American Medical Association established to approve or accredit allied health education programs;*

2. Passage of the certifying examination administered by the National Commission on Certification of Physician Assistants; and
3. Documentation that the applicant for licensure has not had his license or certification as a physician assistant suspended or revoked and is not the subject of any disciplinary proceedings in another jurisdiction.
B. Prior to initiating practice with a supervising physician, the physician assistant shall notify the Board and provide information which shall include, but not be limited to, the following:
1. The name, address, telephone number and any changes thereto, of the physician or physicians who will supervise the assistant in the relevant practice setting; and
2. A description of the practice and the way in which the physician assistant will be utilized.

§ 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 apply to the Board to supervise 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 assistants shall not be construed as requiring the physical presence of the supervising physician during all times and places of service delivery by assistants. Each team of supervising physician and physician assistant shall identify the relevant physician assistant's scope of practice, including, but not limited to, 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.
No licensee shall be allowed to supervise more than two 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 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 written practice supervision agreement between the assistant and the supervising health care provider 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 written 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 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 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. The supervising physician shall review, prior to the patient's discharge, the services rendered to each patient by a physician assistant in a hospital's emergency department. An 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 assistant shall (i) retain exclusive supervisory control of and responsibility for the assistant and (ii) be available at all times for consultation with both the assistant and the emergency department physician. Prior to the patient's discharge from the emergency department, the 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 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 protocol, pursuant to regulations of the Board, to act as supervising physician for that assistant. Every licensee, professional corporation or partnership of licensees, hospital or commercial enterprise that employs an assistant shall be fully responsible for the acts of the assistant in the care and treatment of human beings.
§ 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.) 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.) of this title as follows: (i) Schedules V and VI controlled substances on and after July 1, 2001, (ii) Schedules IV through VI controlled substances on and after January 1, 2003, (iii) Schedule III through VI controlled substances on and after July 1, 2004, and (iv) Schedules II through VI controlled substances on and after July 1, 2007.

A licensed physician assistant shall have such prescriptive authority upon the provision to the Board of Medicine of such evidence as it may require that the assistant has entered into and is, at the time of writing a prescription, a party to a written agreement with a licensed physician or podiatrist which provides for the direction and supervision by such licensee of the prescriptive practices of the assistant. Such written 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 assistant to prescribe controlled substances or devices pursuant to this section unless such prescription is authorized by the written 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; (ii) 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; and (iii) a requirement that the 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 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 new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.

In its request for amendments, the Virginia Academy of Physician Assistants (VAPA) noted that the regulation currently restricts the practice of a physician with his/her physician assistant (PA) by mandating the exact number of successive visits each patient may receive from the PA. The rule may negatively impact scheduling of patients and the care and treatment of chronic illnesses. According to the VAPA, it would be preferable for the supervising physician to determine the frequency of review of PA services and the frequency of seeing patients with continuing illnesses, depending on his medical judgment and knowledge of the patient. Since the physician is ultimately responsible for coordinating and managing the care of the patient, amendments to the supervisory responsibilities of a physician will provide appropriate oversight and evaluation to protect the health and safety of patients being jointly treated by PA's and supervising physicians.

Substance

Please briefly identify and explain new substantive provisions (for new regulations), substantive changes to existing sections or both where appropriate. (More detail about all provisions or changes is requested in the "Detail of changes" section.)

The amendment to 18VAC85-50-110. Responsibilities of the supervisor, which was recommended by the Advisory Board on Physician Assistants is:

> The supervising physician shall:
>
> 1. ~~See and evaluate any patient who presents the same complaint twice in a single episode of care and has failed to improve significantly. Such physician involvement shall occur not less frequently than every fourth visit for a continuing illness.~~ 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 PA/Physician Protocol for the evaluation process.

In the process of considering amendments to the "fourth visit," the Board also amended its current regulations for prescriptive authority for PA's to ensure compliance with § 54.1-2952 and with § 54.1-2952.1, which requires a written agreement setting out the controlled substances (by schedule or class of drugs) the PA is allowed to prescribe and requirements for site visits if the PA practices in a location other than where the supervising physician regularly practices.

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 the regulatory action poses no disadvantages to the public or the Commonwealth, please indicate.

1) The advantage of the amended regulation is more flexibility in the scheduling of patients with the supervising physician or the PA, while specifying that the physician must be involved with a patient for a continuous illness or see the patient who presents for the same complaint twice in a single episode and has not improved. Greater specificity in the content of a practice agreement with delineation of roles and responsibilities is beneficial to practitioners and patients. There are no disadvantages.
2) There are no advantages or disadvantages to the Commonwealth.
3) There are no other pertinent matters of interest.

Requirements more restrictive than federal

Please identify and describe any requirements of the proposal, which are more restrictive than applicable federal requirements. Include a rationale 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.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the board/agency 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 may do so via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail to Elaine Yeatts at Department of Health Professions, 9960 Mayland Drive, Suite 300, Richmond, VA 23233 or **elaine.yeatts@dhp.virginia.gov** or by fax to (804) 527-4434**.** Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last date of the public comment period.

[A public hearing will be held and notice of the public hearing may appear on the Virginia Regulatory Town Hall website (www.townhall.virginia.gov) and the Commonwealth Calendar. Both oral and written comments may be submitted at that time.

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 requirements create the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source, and (b) a delineation of one-time versus on-going expenditures.	a) 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; b) The agency will incur minimal costs (less than $500) for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities. Since most mailings to the PPG list are handled electronically, there is very little cost involved. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled. There are no on-going expenditures relating amendments to regulations for physician assistants.
Projected cost of the *new regulations or changes to existing regulations* on localities.	None
Description of the individuals, businesses or other entities likely to be affected by the *new regulations or changes to existing regulations*.	The entities that are likely to be affected by these regulations would be PA's and the physicians who supervise their practice.
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 (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	There are 1,781 PA's with a current/active license in Virginia. Approximately 90% of those have a practice agreement with a primary supervising physician and probably 75% of those have multiple alternate supervising physicians of approximately 3 to 20. Since PA's do not practice independently, none would be considered small businesses. It is unknown how many supervising physicians are considered small businesses, so the agency does not

	categorize employment (hospital-based, office-based, etc.)
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. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. 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.	There are no costs to small businesses or other entities.
Beneficial impact the regulation is designed to produce.	Physician practices may have greater flexibility in scheduling patients.

Alternatives

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

In order to revise the current requirement for physician involvement with physician assistant care of patients, it is necessary to amend section 110 on responsibilities of the supervising physician. There is a specific requirement for the physician to see a patient not less frequently than every fourth visit for a continuing illness. The intent of the regulatory change would be to allow more flexibility with each practice team; and to accomplish that, there is no alternative other than promulgation of regulations.

Regulatory flexibility analysis

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; regulations for licensure of PA's are mandated by the Code of Virginia.

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

A Notice of Intended Regulatory Action was published on December 6, 2010 with comment until January 5, 2011.

Commenter	Comment	Agency response
Virginia Academy of Physician Assistants	Supports the intent for changes to the "fourth visit rule"	The Board appreciated the comment.
Medical Society of Virginia	Supports the changes in the regulations; worked with VAPA on suggested language	The Board appreciated the comment.

Family impact

Please assess the impact of the proposed 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 institution of the family and family stability.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact if implemented in each section. Please describe the difference between the requirements of the new provisions and the current practice or if applicable, the requirements of other existing regulations in place.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all provisions of the new regulation or changes to existing regulations between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

Current section number	Current requirement	Proposed change, rationale, and consequences
10	Sets out the definition of a "protocol"	The term "protocol" is amended to "practice agreement" in the definition section and throughout the regulation for consistency with terminology and requirements of the Code of Virginia. § 54.1-2952 requires a physician assistant and his supervising physician(s) to have a written practice

		agreement. A written practice agreement is more descriptive than a protocol of the document that sets out the relationship and circumstances under which the physician will see and evaluate the patient.
110	Sets out the requirements for a practice agreement	In addition to the change in terminology, the Board has amended subsection C to specify that the practice agreements must 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. *Subsection C of § 54.1-2952.1 specifically mandates such requirements in an agreement, but it is currently not included in section 101 in regulation.* Subsection D is added to specify that if the initial practice agreement did not include prescriptive authority, an addendum to the practice agreement for prescriptive authority must be submitted. *§ 54.1-2952.1 specifies that the practice agreement must include the schedules of drugs and circumstances in which the PA is allowed to prescribe. If the original practice agreement did not include prescriptive authority for the PA, it is necessary to submit an amended agreement to be in compliance with the law. Section 150 of the regulations currently requires submission of a new protocol with an initial application for prescriptive authority; subsection D is a clearer statement of the requirement.* Subsection E is added to require that if there are any changes in supervision, authorization or scope of practice, a revised practice agreement must be submitted at the time of the change. *Section 150 of the regulations currently requires submission of a new protocol with each biennial renewal and if there have been any changes. The Board does not require a new protocol with the biennial renewal, but does require notification of changes. Subsection E is a more accurate statement of the requirement.*
110	Sets out the responsibilities of the supervisor	The requirements are eliminated for the supervisor to 1) see and evaluate any patient who presents the same complaint twice in a single episode of care and has failed to improve significantly; and 2) have involvement with the patient not less frequently than every fourth visit for a continuing illness. The language is amended to require the physician to 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; and 2) be involved with any patient with a continuing illness as noted in the PA/Physician Protocol for the evaluation process. *The amendment to the "fourth visit rule" was requested by the Virginia Academy of Physician Assistants (VAPA), which noted that the regulation currently restricts the*

		practice of a physician with his/her physician assistant (PA) by mandating the exact number of successive visits each patient may receive from the PA. According to the VAPA, it would be preferable for the supervising physician to determine the frequency of review of PA services and the frequency of seeing patients with continuing illnesses, depending on his medical judgment and knowledge of the patient. The PA Advisory Board and the full Board of Medicine concurred in the recommendation.
150	Sets out the requirements for a protocol for prescriptive authority	The regulations in section 150 are clearly stated in the Code and/or have been restated in section 101. Therefore, section 150 is being repealed.