



Notice of Intended Regulatory Action (NOIRA) 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	9/28/10

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*.

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

The Advisory Board on Physician Assistants and the Virginia Academy of Physician Assistants have 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 would be to allow the physician and his assistant to determine the evaluation process, as expressed in the practice protocol submitted to the Board of Medicine.

As the Board considers changes to the “fourth visit rule,” it will also review language in all of Part IV on Practice Requirements to review the use of and requirements for a “protocol.” The Board will review the statutory requirements for a physician assistant/physician agreement and for an evaluation process to determine whether current regulations are consistent and clear.

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., 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.

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

In its request for amendments, the Virginia Academy of Physician Assistants (VAPA) notes 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 detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.

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.~~ 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 will also review the statutory requirements for a written practice agreement and for an evaluation process for the PA's performance. Additionally, the Board will consider its current regulations for prescriptive authority for PA's to ensure compliance 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.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

In order to eliminate or 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.

Public participation

Please indicate whether the agency is seeking comments on the intended regulatory action, including ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments on this notice.

The agency is seeking comments on the intended regulatory action, including but not limited to 1) ideas to assist in the development of a proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency is also 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 comments may do so via the Regulatory Townhall website, www.townhall.virginia.gov, or 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. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by the last day of the public comment period.

A public hearing will be held after publication of proposed regulations and notice of the hearing may be found on the Virginia Regulatory Town Hall website (www.townhall.virginia.gov) and can be found in the Calendar of Events section of the Virginia Register of Regulations. Both oral and written comments may be submitted at that time.

Participatory approach

Please indicate, to the extent known, if advisers (e.g., ad hoc advisory committees, regulatory advisory panels) will be involved in the development of the proposed regulation. Indicate that 1) the agency is not using the participatory approach in the development of the proposal because the agency has authorized proceeding without using the participatory approach; 2) the agency is using the participatory approach in the development of the proposal; or 3) the agency is inviting comment on whether to use the participatory approach to assist the agency in the development of a proposal.

The Board of Medicine will use the Advisory Board on Physician Assistants in the development of the proposed regulations. The Advisory Board is composed of three physician assistants, a physician who supervises physician assistants and a member of the public. Additionally, the Advisory Board will be assisted by representatives of the Virginia Academy of Physician Assistants.

Family impact

Assess the potential 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.