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Periodic Review and Notice of Intended Regulatory Action Agency Background Document

Agency Name:	Board of Medicine
VAC Chapter Number:	18 VAC 85-50-10 et seq.
Regulation Title:	Regulations Governing the Practice of Physician Assistants
Action Title:	Periodic review
Date:	10/12/00

This information is required pursuant to the Administrative Process Act § 9-6.14:25, Executive Order Twenty-Five (98), and Executive Order Fifty-Eight (99) which outline procedures for periodic review of regulations of agencies within the executive branch. Each existing regulation is to be reviewed at least once every three years and measured against the specific public health, safety, and welfare goals assigned by agencies during the promulgation process.

This form should be used where the agency is planning to amend or repeal an existing regulation and is required to be submitted to the Registrar of Regulations as a Notice of Intended Regulatory Action (NOIRA) pursuant to the Administrative Process Act § 9-6.14:7.1 (B).

Summary

Please provide a brief summary of the regulation. There is no need to state each provision; instead give a general description of the regulation and alert the reader to its subject matter and intent.

Regulations are promulgated to provide educational, examination and practice requirements for the licensure of physician assistants. Provisions establish requirements for renewal or reinstatement of a license, supervisory responsibilities of physicians, requirements for a written, protocol, practice responsibilities for the assistant, standards for prescriptive authority, and fees to support the regulatory and disciplinary activities of the board.

Basis

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Please identify the state and/or federal source of legal authority for the regulation. The discussion of this authority should include a description of its scope and the extent to which the authority is mandatory or discretionary. Where applicable, explain where the regulation exceeds the minimum requirements of the state and/or federal mandate.

The statutory authority for this regulation is found in § 54.1-2400 and Chapter 29 of Title 54.1 of the Code of Virginia.

Section 54.1-2400 establishes the general powers and duties of health regulatory boards including the responsibility to establish qualifications for licensure, to set fees and schedules for renewal, to establish requirements for an inactive license and to promulgate regulations, in accordance with the Administrative Process Act, which are reasonable and necessary to effectively 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.
- 4. To establish schedules for renewals of registration, certification and licensure.
- 5. To levy and collect fees for application processing, examination, registration, certification or licensure and renewal that are sufficient to cover all expenses for the administration and operation of the Department of Health Professions, the Board of Health Professions and the health regulatory boards.
- 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 and Chapter 25 of this title.
- 7. To revoke, suspend, restrict, or refuse to issue or renew a registration, certificate or license which such board has authority to issue for causes enumerated in applicable law and regulations.
- 8. To appoint designees from their membership or immediate staff to coordinate with the Intervention Program Committee and to implement, as is necessary, the provisions of Chapter 25.1 (§ 54.1-2515 et seq.) of this title. Each health regulatory board shall appoint one such designee.
- 9. To take appropriate disciplinary action for violations of applicable law and regulations.

10. To appoint a special conference committee, composed of not less than two members of a health regulatory board, to act in accordance with § 9-6.14:11 upon receipt of information that a practitioner of the appropriate board may be subject to disciplinary action. The special conference committee may (i) exonerate the practitioner; (ii) reinstate the practitioner; (iii) place the practitioner on probation with such terms as it may deem appropriate; (iv) reprimand the practitioner; (v) modify a previous order; and (vi) impose a monetary penalty pursuant to § 54.1-2401. The order of the special conference committee shall become final thirty days after service of the order unless a written request to the board for a hearing is received within such time. If service of the decision to a party is accomplished by mail, three days shall be added to the thirty-day period. Upon receiving a timely written request for a hearing, the board or a panel of the board shall then proceed with a hearing as provided in § 9-6.14:12, and the action of the committee shall be vacated. This subdivision shall not be construed to affect the authority or procedures of the Boards of Medicine and Nursing pursuant to §§ 54.1-2919 and 54.1-3010.

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- 11. To convene, at their discretion, a panel consisting of at least five board members or, if a quorum of the board is less than five members, consisting of a quorum of the members to conduct formal proceedings pursuant to § 9-6.14:12, decide the case, and issue a final agency case decision. Any decision rendered by majority vote of such panel shall have the same effect as if made by the full board and shall be subject to court review in accordance with the Administrative Process Act. No member who participates in an informal proceeding conducted in accordance with § 9-6.14:11 shall serve on a panel conducting formal proceedings pursuant to § 9-6.14:12 to consider the same matter.
- 12. To issue inactive licenses and certificates and promulgate regulations to carry out such purpose. Such regulations shall include, but not be limited to, the qualifications, renewal fees, and conditions for reactivation of such licenses or certificates.

In addition to general provisions in § 54.1-2400, the Board of Medicine is guided by provisions in the Medical Practice Act related to the licensure and regulation of physician assistants as follows:

§ 54.1-2949. License required.

It shall be unlawful for a person to practice or to hold himself out as practicing as a physician's or podiatrist's assistant unless he holds a license as such issued by the Board.

§ 54.1-2950. Requisite training and educational achievements of assistants.

The Board shall establish a testing program to determine the training and educational achievements of the assistant or the Board may accept other evidence, such as experience or completion of an approved training program, in lieu of testing and shall establish this as a prerequisite for approval of the licensee's application.

Pending the outcome of the next examination administered by the National Commission for Certification of Physician Assistants, the Board may grant provisional licensure to graduates of physician or podiatrists' assistants curricula which are approved by the Committee on Allied Health Education and Accreditation of the American Medical Association or the Committee on

Education of the American Podiatry Association. Such provisional licensure shall be granted at the discretion of the Board.

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§ 54.1-2950.1. Advisory Committee on Physician Assistants; membership; qualifications.

The Advisory Committee on Physician Assistants is hereby established. The Advisory Committee shall be appointed by the Governor and shall be composed of nine members: three shall be physician members of the Board of Medicine, one shall be a physician who supervises at least one physician assistant and who is not a member of the Board, four shall be licensed physician assistants who have practiced their professions for not less than three years prior to their appointments, and one shall be a citizen at-large. Members shall be appointed for terms of four years. Vacancies occurring other than by expiration of term shall be filled for the unexpired term. No person shall be eligible to serve on the Advisory Committee for more than two successive terms.

§ 54.1-2951.

Repealed by Acts 1998, c. 319.

§ 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.

§ 54.1-2951.2. Issuance of a license.

The Board shall issue the license to the physician assistant to practice under the supervision of a licensed doctor of medicine, osteopathy, or podiatry, in accordance with § 54.1-2951.1.

§ 54.1-2951.3. Restricted volunteer license for certain physician assistants.

- A. The Board may issue a restricted volunteer license to a physician assistant who meets the qualifications for licensure for physician assistants. The Board may refuse issuance of licensure pursuant to §§ 54.1-2915 and 54.1-2916.
- B. A person holding a restricted volunteer license under this section shall:
- 1. Only practice in public health or community free clinics approved by the Board;
- 2. Only treat patients who have no insurance or who are not eligible for financial assistance for medical care; and

- 3. Not receive remuneration directly or indirectly for practicing as a physician assistant.
- C. A physician assistant with a restricted volunteer license issued under this section shall only practice as a physician assistant and perform certain delegated acts which constitute the practice of medicine to the extent and in the manner authorized by the Board if:

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- 1. A physician who supervises physician assistants is available; or
- 2. The physician supervising any physician assistant periodically reviews the relevant patient records.
- D. A restricted volunteer license granted pursuant to this section shall be issued to the physician assistant without charge, shall expire twelve months from the date of issuance, and may be renewed annually in accordance with regulations promulgated by the Board.
- E. A physician assistant holding a restricted volunteer license issued pursuant to this section is subject to the provisions of this chapter and the regulations promulgated under this chapter unless otherwise provided for in this section.

§ 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.

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 services shall be limited to those which are educational, diagnostic, therapeutic or preventive in nature, but shall not include the establishment of a final diagnosis or treatment plan for the patient or the prescribing or dispensing of drugs, except 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 practicing in an emergency department shall be under the supervision of a physician present within the facility. 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.

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- A. A licensed physician assistant shall have the authority to prescribe Schedule VI controlled substances and devices as set forth in Chapter 34 (§ 54.1-3400 et seq.) of this title pursuant to the requirements of Chapter 33 (§ 54.1-3300 et seq.) of this title 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.
- 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 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) a formulary of the specific Schedule VI drugs and devices that the assistant is eligible to prescribe pursuant to this section to the extent, and in the manner, authorized in a written protocol between the assistant and the supervising licensee; (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.

In order to maintain a current and appropriate list of specific Schedule VI drugs and devices, the Board of Medicine, in consultation with the Board of Pharmacy, may, from time to time, amend the formulary required by this subsection and, as provided in § 9-6.14:4.1, shall be exempted from the Administrative Process Act (§ 9-6.14:1 et seq.) when so doing. The Boards shall, however, jointly conduct public hearings prior to making such amendments to the formulary. Thirty days prior to conducting such hearing, the Boards shall give written notice by mail of the date, time, and place of the hearings to all currently licensed assistants and any other persons requesting to be notified of the hearings and publish notice of their intention to amend the formulary in the Virginia Register of Regulations. Interested parties shall be given reasonable opportunity to be heard and present information prior to final adoption of any amendments. Proposed and final amendments of the list shall also be published, pursuant to § 9-6.14:22, in the Virginia Register of Regulations. Final amendments to the formulary shall become effective upon filing with the Registrar of Regulations.

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

§ 54.1-2953. Renewal, revocation, suspension and refusal.

The approval of the Board for the employment of an assistant shall expire at the end of one year. A new application shall be submitted for approval, supplying such information as the Board may require, at the time and in the manner prescribed by the Board.

The Board may revoke, suspend or refuse to renew an approval for any of the following:

1. Any reason stated in this chapter for revocation or suspension of the license of a practitioner;

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- 2. Failure of the supervising licensee to supervise the assistant or failure of the employer to provide a licensee to supervise the assistant;
- 3. The assistant's engaging in acts beyond the scope of authority as approved by the Board;
- 4. Negligence or incompetence on the part of the assistant or the supervising licensee in his use of the assistant;
- 5. Violating or cooperating with others in violating any provision of this chapter or the regulations of the Board; or
- 6. A change in the Board's requirements for approval with which the assistant or the licensee does not comply.

Public Comment

Please summarize all public comment received as the result of the Notice of Periodic Review published in the Virginia Register and provide the agency response. Where applicable, describe critical issues or particular areas of concern in the regulation. Also please indicate if an informal advisory group was or will be formed for purposes of assisting in the periodic review or development of a proposal.

An announcement of the board's review of its regulations governing the licensure of physician assistants was posted on the Virginia Regulatory Townhall, sent to the Registrar of Regulations, and sent to persons on the Public Participation Guidelines mailing list for the board. Public comment was received until August 2, 2000. During the 30-day comment period, no comments were received from members of the public.

The Advisory Committee on Physician Assistants held a public meeting on September 15, 2000 to conduct a review of regulations and discuss related issues, such as the 72-hour requirement for chart review and signing by the supervising physician. The Advisory Committee voted to request amendments to the regulation, but the Board of Medicine determined that the current requirement was essential to public health and safety. Clarifying amendments are recommended for other sections of the regulations.

Effectiveness

Please provide a description of the specific and measurable goals of the regulation. Detail the effectiveness of the regulation in achieving such goals and the specific reasons the agency has determined that the regulation is essential to protect the health, safety or welfare of citizens. In addition, please indicate whether the regulation is clearly written and easily understandable by the individuals and entities affected.

The goals for this regulation are as follows:

1) Achieve a high level of satisfaction for application and renewal processes for all licensed practitioners.

The Board reviewed the responses of recent licensees on the Customer Service Satisfaction Surveys and determined that the application process and renewal of certification was effective in

that instructions for making application are clear and easy to understand and complete. Of those that responded, 95.5% agreed or strongly agreed that the instructions were easy to understand; 90% agreed or strongly agreed that the application was processed promptly; and 97.8% agreed or strongly agreed that the forms were easy to complete. Therefore, no changes in regulations are being considered in the application process.

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2) Review regulations to ensure consistency and application to the current practices of physician assistants.

In recent years, changes to the physician assistant regulations have been made to conform them to changes in practice and to legislative actions amending the Code of Virginia. Those include the elimination of the secondary license for multiple practice settings, the elimination of reporting on invasive procedures, the establishment of a volunteer restricted license, and most recently, less restrictive requirements for practice in an emergency department of a hospital. During this review of regulations, the Board identified a few requirements that require clarification.

Alternatives

Please describe the specific alternatives for achieving the purpose of the existing regulation that have been considered as a part of the periodic review process. This description should include an explanation of why such alternatives were rejected and this regulation reflects the least burdensome alternative available for achieving the purpose of the regulation.

Regulations for the licensure of physician assistants are mandated by law, so the Board did not consider the alternative of repealing 18 VAC 85-50-10 et seq. The amendments that are recommended are relatively minor, but will serve to clarify and simplify the requirements.

During its review of regulations, the Advisory Committee on Physician Assistants discussed the fact that compliance with the requirement for a chart review and signature of the supervising physician within 72 hours of services being rendered by a physician assistant is difficult to achieve. Dictation of the physician assistant assessment and orders is often not completed within 72 hours; such a short time frame causes managerial problems in settings where assistants are employed. Physicians who are overwhelmed with patient care tend to rubber stamp the chart without taking the time to actually review the care given by the assistant. Although the Board of Medicine understood the dilemma faced by busy physicians, it also believes that a longer time frame might possibly affect the health and safety of the public. While cases of an emergency or acute nature may require the immediate involvement of the physician, many patients receive their direct care from a physician assistant whose judgements and treatments should be reviewed by a supervising physician in a timely manner. Therefore, the Board considered the various options for an appropriate requirement and determined that the current requirement of 72 hours for a chart review was adequate but not unnecessarily burdensome.

The current regulation states that the assistant must get board approval to perform duties away from the supervising physician. It was not the intent of the Board that every single action performed by the assistant must have prior approval. The intent of the regulation is to ensure

that the assistant is not practicing medicine independently of a supervising physician. Therefore, the Board recommends amending the requirement to clarify that the board must know the details of the practice and must approve duties which the assistant <u>regularly</u> performs away from the supervising physician.

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Finally, the Board recommends amending the renewal regulations to clarify that the licensee must attest on the renewal form to compliance with continuing education requirements of the national credentialing body for physician assistants (NCCPA). Renewal forms and fees are sent to a lock box and automated. It is impractical and unnecessary for every assistant to actually submit the documentation. If questions arise about compliance, the Board may request that documentation be provided.

Recommendation

Please state whether the agency is recommending the regulation be amended or terminated and the reasons such a recommendation is being made.

The board is recommending amendments to its regulations for the licensure of physician assistants in order to address the need for clarification in sections 56, 115, and 170 of the regulation.

Substance

Please detail any changes that would be implemented.

18 VAC 85-50-56. Renewal of license.

Current regulations state that the licensee intending to renew his license must present documented evidence of continuing medical education standards established by the national credentialing body for the profession. In fact, the licensee does not actually submit the documentation but is required to attest to compliance.

18 VAC 85-50-115. Responsibilities of the physician assistant.

Subsection B requires the assistant who is to perform duties away from the supervising physician to first obtain board approval for any such arrangement. The Board recommends amending the regulation to clarify that board approval is necessary if the assistant is to regularly perform duties away from the supervisor.

18 VAC 85-50-170. Fees.

Amendments are recommended to place the fees under Part I, General Provisions for consistently with other regulations under the Board of Medicine and to state the current policy of the board, which is that all fees are nonrefundable unless otherwise specified.

Family Impact Statement

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Please provide a preliminary analysis of the proposed regulatory action that assesses the potential impact on the institution of the family and family stability including the extent to which 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.

In its preliminary analysis of the proposed regulatory action, the agency has determined that there is no potential impact on the institution of the family and family stability and no effect on family income.