Form: TH- 03



Final Regulation Agency Background Document

Agency Name:	Board of Medicine, Department of Health Professions
VAC Chapter Number:	18 VAC 85-50-10 et seq.
Regulation Title:	Regulations Governing the Practice of Physician Assistants
Action Title:	Regulatory review – clarifications
Date:	6/7/02

Please refer to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99), and the *Virginia Register Form,Style and Procedure Manual* for more information and other materials required to be submitted in the final regulatory action package.

Summary

Please provide a brief summary of the new regulation, amendments to an existing regulation, or the regulation being repealed. There is no need to state each provision or amendment; instead give a summary of the regulatory action. If applicable, generally describe the existing regulation. Do not restate the regulation or the purpose and intent of the regulation in the summary. Rather, alert the reader to all substantive matters or changes contained in the proposed new regulation, amendments to an existing regulation, or the regulation being repealed. Please briefly and generally summarize any substantive changes made since the proposed action was published.

Regulations establish educational, examination and practice requirements for the licensure of physician assistants and provisions 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. The board is recommending amendments to address the need for clarification in sections 56, 115, and 170 of the regulation.

Changes Made Since the Proposed Stage

Form: TH-03

Please detail any changes, other than strictly editorial changes, made to the text of the proposed regulation since its publication. Please provide citations of the sections of the proposed regulation that have been altered since the proposed stage and a statement of the purpose of each change.

No changes to proposed regulations have been made in the adoption of final amendments.

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency: including the date the action was taken, the name of the agency taking the action, and the title of the regulation.

On June 6, 2002, the Board of Medicine adopted final amendments to 18 VAC 85-50-10 et seq., Regulations Governing the Practice of Physician Assistants, in order to implement clarifying changes recommended by a review of the regulation.

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority, shall be provided. If the final text differs from that of the proposed, please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the final regulation and that it comports with applicable state and/or federal law

Chapter 24 establishes the general powers and duties of health regulatory boards including the responsibility to promulgate regulations, levy fees, administer a licensure and renewal program, and discipline regulated professionals.

- § 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.

Form: TH-03

- 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.
- 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.

The specific authority for the Board to regulate physician assistants is found in the following sections:

§ 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. (1988, c. 765.)

§ 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.

Form: TH-03

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. (1973, c. 529, § 54-281.7; 1984, c. 46; 1988, c. 765; 1997, c. 806.)

§ 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.

(1998, c. 319.)

§ 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. (1998, c. 319.)

§ 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. (1998, c. 319.)

§ 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

Form: TH-03

- 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:
- 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.

(1998, c. 319.)

§ 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.

(1973, c. 529, §§ 54-281.4, 54-281.5; 1975, cc. 508, 565; 1985, c. 316; 1988, c. 765; 1992, c. 793; 1996, c. 779; 2000, cc. 467, 497.)

§ 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 and (ii) Schedules IV through VI controlled substances on and after January 1, 2003.

Form: TH- 03

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.

(1992, c. 793; 1997, c. 806; 1999, c. 745; 2001, c. 465.)

§ 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;
- 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.

The Assistant Attorney General who provides counsel to the Board of Medicine has provided a letter of assurance that the amended regulations are consistent with statutory law.

Purpose

Form: TH-03

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the final regulatory action and detail the specific reasons it is essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

The purpose of the amendments is to clarify and simplify the requirements by reorganizing the section on fees and eliminating language that is not consistent with actual practice and requirements of the Board. Amendments will assist in practitioner compliance with regulations which in turn provide the basis for licensure in order to protect the public health, safety and welfare.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement of the regulatory action's detail.

The section establishing fees is moved to Part I, General Provisions; no changes are proposed to the fees but language is added to specify that fees are not refundable. Renewal rules are amended to clarify that the Board requires a licensee to "verify" rather than provide documented evidence of compliance with continuing education requirements of the national credentialing body for the profession. An amendment to the responsibilities of the physician assistant will clarify that the Boards must be notified if the PA is to regularly perform duties away from his supervising physician.

Issues

Please provide a statement identifying the issues associated with the final regulatory action. The term "issues" means: 1) the advantages and disadvantages to the public of implementing the new provisions; 2) the 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, please include a sentence to that effect.

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 judgments 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.

Form: TH-03

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.

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.

Public Comment

Please summarize all public comment received during the public comment period and provide the agency response. If no public comment was received, please include a statement indicating that fact.

A public hearing was held before the Board of Medicine at the Department of Health Professions in Richmond on December 7, 2001. No comment was presented at that time nor was any written or electronically submitted comment received.

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or crosswalk - of changes implemented by the proposed regulatory action. Include citations to the specific sections of an existing regulation being amended and explain the consequences of the changes.

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.

Form: TH-03

18 VAC 85-50-170. Fees.

Amendments are recommended to place the fees under Part I, General Provisions for consistency 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

Please provide an analysis of the regulatory action that assesses the 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.

The Board has reviewed the adopted regulations and concluded that the amendments have no effect on strengthening the authority and rights of parents, on economic self-sufficiency, on the marital commitment or on disposable family income.