Form: TH- 02

Virginia Regulatory Town Hall

Proposed 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:	Periodic review
Date:	4/6/01

This information is required pursuant 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*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

Summary

Please provide a brief summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed. There is no need to state each provision or amendment or restate the purpose and intent of the regulation; instead give a summary of the regulatory action and alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

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.

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 must be provided. Please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed 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.*

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 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

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the proposed 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 proposed 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 providing detail of the regulatory action's changes.

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 proposed regulatory action. The term "issues" means: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, 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.

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 regularly 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.

Fiscal Impact

Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; and e) the projected cost of the regulation for affected individuals, businesses, or other entities.

Projected cost to the state to implement and enforce:

(i) Fund source: 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.

(ii) Budget activity by program or subprogram: There is no change required in the budget of the Commonwealth as a result of this program.

(iii) One-time versus ongoing expenditures: The agency will incur some one-time costs (less than $1,000) for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending copies of final regulations to regulated entities. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled.

Projected cost on localities:

There are no projected costs to localities.

Description of entities that are likely to be affected by regulation:

The entities that are likely to be affected by these regulations would be licensed physician assistants.

Estimate of number of entities to be affected:

Currently, there are approximately 700 licensed as physician assistants in the Commonwealth.

Projected costs to the affected entities:

There is no projected cost for compliance with the amendments.

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 cross-walk - of changes implemented by the proposed regulatory action. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed 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.

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.

Alternatives

Please describe the specific 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.

Regulations for the licensure of physician assistants are mandated by law, so during the periodic review 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. Regulations are amended 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, a few requirements were identified that require clarification in order for there to be consistency with the current policies and practices of the Board.

Public Comment

Please summarize all public comment received during the NOIRA comment period and provide the agency response.

An announcement of the board's intent to amend 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 February 14, 2001. 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 the periodic 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 on chart review, 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.

Clarity of the Regulation

Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

The Advisory Board on Physician Assistants, comprised of licensed physician who supervise physician assistants, licensed physician assistants and members of the Board reviewed all existing regulations for clarity and ease of compliance. The Assistant Attorney General who provides counsel to the Board has been involved during the development and adoption of proposed regulations to ensure clarity and compliance with law and regulation.

Periodic Review

Please supply a schedule setting forth when the agency will initiate a review and re-evaluation to determine if the regulation should be continued, amended, or terminated. The specific and measurable regulatory goals should be outlined with this schedule. The review shall take place no later than three years after the proposed regulation is expected to be effective.

Public participation guidelines require the Board to review regulations each biennium or as required by Executive Order. Regulations will be reviewed again during the 2003-04 fiscal year.

Family Impact Statement

Please provide an 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 nor will the amendments serve to increase or decrease disposable family income.