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:	Voluntary practice/change in supervision
Date:	4/4/03

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Please provide a brief summary of the new regulation, amendments to an existing regulation, or the regulation being repealed.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or changes contained in the proposed new regulation, amendments to an existing regulation, or the regulation being repealed.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.

Chapter 740 of the 2002 Acts of the Assembly mandates that the board promulgate regulations for an out-of-state practitioner to be exempt from licensure or certification to volunteer his services to a non-profit organization that has no paid employees and offers health care to underprivileged populations throughout the world. Regulations set forth the information and documentation that must provided prior to such service to ensure compliance with the statute.

Chapter 387 of the 2002 Acts of the Assembly mandates that the board promulgate regulations to implement provisions related to the supervision of a physician assistant and the protocol between the assistant and the physician. In accordance with the statute, regulations provide for continuous supervision but do not require the physical presence of the physician.

Enactment clauses in both chapters required the board to adopt emergency regulations, and the proposed regulations must replace those regulations prior to their expiration on July 18, 2003.

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 April 4, 2003, 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 changes in supervision and voluntary practice mandated by the 2002 General Assembly.

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 legal mandate to promulgate the regulation for the provision of voluntary health care services by out-of-state practitioners in clinics in underserved areas sponsored by nonprofit organizations is found in Chapter 740 of the 2002 Acts of the Assembly.

http://leg1.state.va.us/cgi-bin/legp504.exe?021+ful+CHAP0740

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Form: TH- 03

http://leg1.state.va.us/cgi-bin/legp504.exe?021+ful+CHAP0740

The specific legal authority to promulgate regulations for the supervision and evaluation of physician assistants is found in Chapter 387 of the 2002 Acts of the Assembly.

http://leg1.state.va.us/cgi-bin/legp504.exe?021+ful+CHAP0387

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 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 amended regulation for voluntary practice is to ensure that out-of-state practitioners who are registered and authorized to provide treatment to patients have provided sufficient information to determine their eligibility and their standing with the licensing board of their state. While the treatment is being provided free of charge to underserved populations in the state, the Board needs to carry out its statutory mandate to protect the public health, safety and welfare. Therefore, basic information on licensure must be verified by the board of the licensing state to ensure that a practitioner whose license has been previously suspended or revoked, who has been convicted of a felony or who is otherwise found to be in violation of applicable laws or regulations does not come into Virginia to practice, even on a voluntary basis.

The purpose of the amended regulation for continuous supervision is to ensure that provisions are in place for oversight of the physician assistant without a requirement that the physician be physically present at all times. Provisions for a written protocol setting out the assistant's scope of practice and a process for evaluation will ensure that the physician is aware of his responsibility for the health and safety of the patient.

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.

Voluntary Practice

Chapter 740 of the 2002 Acts of the Assembly provides specific conditions under which a health care practitioner who is licensed in another state can provide free care in underserved areas of Virginia. Statutory requirements include: 1) that they do not regularly practice in Virginia; 2) that they hold a current valid license or certificate in another U. S. jurisdiction; 3) that they volunteer to provide free care; 4) that they file copies of their licenses or certificates in advance with the Board; 5) that they notify the Board of the dates and location of services; and 6) that they acknowledge in writing that they will only provide services within the parameters stated in the application. The statute also provides specific requirements for the non-profit organization sponsoring provision of health care and allows the Board to charge a fee for each practitioner.

Form: TH-03

As provided in the law, the emergency regulations will insert requirements for a practitioner who wishes to volunteer under provisions of the act to file a complete application for registration on a form provided by the board at least 15 days prior to engaging in such practice; provide a complete list of professional licensure in each state in which he has held a license and a copy of any current license; provide the name of the nonprofit organization, the dates and location of the voluntary provision of services; pay a registration fee of \$10; and provide a notarized statement from a representative of the nonprofit organization attesting to its compliance with provisions of the applicable section of the Code of Virginia.

As also provided by the statute, the Board has the right to deny practice to any person whose license or certificate has been previously revoked or suspended, who has been convicted of a felony, or who is otherwise found to be in violation of applicable laws or regulations. In order to protect the health, safety and welfare of the consuming public and to ensure that the care provided by out-of-state practitioners will be minimally competent, the Board will use the information garnered from the application and verification from other states to determine whether the practitioner meets the criteria set forth in the law.

Supervision of physician assistants

Chapter 387 requires the "continuous supervision" of physician assistants by physicians but states that the supervision requirement should not be construed to require the physical presence of the physician during all times and places of service delivery by the assistant. With that change in the Code, several changes in current regulation were necessary. First, a definition of "continuous supervision" was added to provide for on-going, regular communication with the assistant on the care and treatment of patients. Second, the current definition of "general supervision" was amended to provide for accessibility of the physician without a requirement that he can be physically present to the assistant. The requirements in section 115 for notification to the board if the physician assistant is to perform duties away from the supervising physician is deleted as inconsistent with the new law. Likewise, an amendment will eliminate the requirement for the supervising physician to delegate his responsibility if he is unable to "personally" supervise the activities of the assistant.

In addition, the law requires that the assistant and supervising physician(s) identify the assistant's scope of practice, including the delegation of medical tasks as appropriate to the assistant's level of competence, the relationship with and access to the physician, and an evaluation process for the assistant's performance. Therefore, amendments to requirements for the written protocol

between the assistant and supervisors are adopted to include a provision for an evaluation process. Current regulations require review of the record of services within 72 hours after care by the assistant; amended regulations delete that specific requirement and replace it with a requirement that the evaluation process specify the time period for review, proportionate to the acuity of care and practice setting. Though not required to review a patient chart within 72 hours or to be physically present while the assistant is rendering services, the supervising physician remains responsible for the care and treatment of patients.

Form: TH- 03

The final regulations are identical to the emergency regulation currently in effect with the exception of a technical change in section 115 B to delete the word "employing". Quite often in the medical practices, the staff, including physicians and physician assistants, are "employed" by a corporation or limited partnership. It is therefore inaccurate and misleading to refer to the supervising physician as the "employing" 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.

The primary advantages to the public of implementing the amended regulations on voluntary practice are as follows: a) additional practitioners may be available to staff voluntary clinics, especially in the Southwestern part of the state with proximity to several other states; b) a requirement for licensure in another state to be verified will ensure that the practitioner holds a current, unrestricted license; and c) the requirement for a notarized statement from a representative of the nonprofit organization will ensure compliance with provisions of law for voluntary practice.

The primary advantages to the public of implementing the amended regulations for continuous supervision are as follows: a) the PA may provide services for which he is trained without the supervising physician being present; b) physician oversight is still required, and the physician must be accessible for consultation within one hour and remains responsible for care and treatment of the patient. Therefore, the services of a physician assistant may be more available to certain populations of patients without sacrificing the regular, on-going communication with the supervising physician.

There are no disadvantages to the public as all amendments are intended to provide better access to licensed physician assistants or qualified practitioners who are duly licensed in another state.

There are no advantages or disadvantages to the agency; the amended regulation does not impose a new responsibility on the Board. Since the number of practitioners seeking registration for voluntary practice is expected to remain very small, it does not involve additional cost or staff time. The amendments for continuous supervision include some modification to the protocol

between the PA and the physician, but a protocol is already required, so no additional burden is imposed.

Form: TH- 03

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.

Proposed regulations were published on January 13, 2003, and the 60-day comment period concluded on March 13, 2003. A public hearing was held before the Legislative Committee of the Board of Medicine at the Department of Health Professions in Richmond on January 24, 2003. 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.

A new section (18 VAC 85-50-59. Registration for voluntary practice by out-of-state licensees) is added to specify the requirements for registration of out-of-state licensees to register for voluntary practice in Virginia:

The proposed regulations provide that a practitioner who does not hold a license to practice in Virginia and who seeks registration to practice on a voluntary basis under the auspices of a publicly supported, all volunteer, nonprofit organization with no paid employees that sponsors the provision of health care to populations of underserved people throughout the world shall:

- 1. File a complete application for registration on a form provided by the board at least 15 days prior to engaging in such practice;
- 2. Provide a complete list of professional licensure in each state in which he has held a license and a copy of any current license;
- 3. Provide the name of the nonprofit organization, the dates and location of the voluntary provision of services;
- 4. Pay a registration fee of \$10; and
- 5. Provide a notarized statement from a representative of the nonprofit organization attesting to its compliance with provisions of the applicable section of the Code of Virginia.

The following sections, related to the supervision and practice of physician assistants are being amended:

Form: TH-03

18 VAC 85-50-10. Definitions.

The definition of "general supervision" is amended to eliminate the requirement for the physician to be physically present during practice by a physician assistant. In exchange, general supervision is defined as having the physician available and either physically present or accessible for consultation within one hour.

The Board has also defined a supervisory relationship that does not involve the physical presence of the physician but does provide "continuous supervision," defined as an on-going, regular communication on the care and treatment of the patient. The term "continuous supervision" is used in the Code but had not been defined in regulation.

18 VAC 85-50-101. Requirements for a protocol.

Amendments are adopted to add statutory requirements (§ 54.1-2952) for identification of the PA's scope of practice, including but not limited to, delegation of tasks appropriate to the PA's level of competence, the PA's relationship with and access to the supervising physician, and an evaluation process for the performance of the PA. Those aspects of the supervisory relationship and practice of the PA were added to the requirement for a protocol.

18 VAC 85-50-110. Responsibilities of the supervisor.

The requirement for the physician to review the record of services rendered within 72 hours and sign the record is eliminated. The protocol, as stated in section 101, must provide for an evaluation process, which may include a review of the record within a certain time period.

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

Currently, subsection B provides that if the physician assistant is to regularly perform duties away from the supervising physician, he must notify the board. Since the physical presence of the physician is no longer required by law, that section has been eliminated. In the new subsection B, the word "personally" is deleted, since personal supervision requires the physical presence of the physician. The protocol may continue to require personal supervision, but it is not a requirement of regulation. Also, the word "employing" is struck, since many physician assistants are not "employed" by their supervising physician but by the corporate entity that owns the medical practice, surgi-center or hospital.

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.

Form: TH- 03

The regulatory action will not strengthen or erode the authority and rights of parents, encourage or discourage economic self-sufficiency, strengthen or erode the marital commitment or increase or decrease disposable family income. The ability of out-of-state practitioners to provide health care services at no charge to persons in underserved areas may benefit a small number of families who have limited access to such services. Likewise, the ability of physician assistants to provide care and treatment apart from the physical presence of the physician may allow an expansion of services to certain populations of consumers.