



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:	Volunteer practice; Change in supervision requirements
Date:	10/10/2002

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summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed.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.

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 be 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.

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.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400 (6) provides the Board the authority to promulgate regulations to administer the regulatory system:

§ 54.1-2400 -General powers and duties of health regulatory boards

The general powers and duties of health regulatory boards shall be:

...

6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ [54.1-100](#) et seq.) and Chapter 25 (§ [54.1-2500](#) et seq.) of this title. ...

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>

The specific legal authority to promulgate regulations for the supervision and evaluation of physician assistants is in second enactment clause of Chapter 387 of the 2002 Acts of the Assembly, which states: "That the Board of Medicine shall promulgate regulations to implement the provisions of this act within 280 days of its enactment."

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

The Office of the Attorney General has certified by letter that the Board has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal 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 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 providing detail of the regulatory action's changes.

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.

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.

The proposed 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 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.

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.

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 \$2,000) 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 in Virginia and their supervising physicians. Physician assistants licensed in other states would be affected by the voluntary practice amendments.

Estimate of number of entities to be affected:

There are 882 physician assistants licensed in Virginia; each has one or more supervising physicians. It is not known how many will be affected by the revised rules, since the level of supervision may be determined by the licensees and set forth in the protocol. It is also unknown the number of out-of-state practitioners who may be affected by the voluntary practice regulations, but, given the limited scope of the law, the number is expected to be very small. To date, no out-of-state PA's have been authorized to practice under the emergency regulations.

Projected costs to the affected entities:

There is no cost for compliance for changes in rules on supervision. There is a charge of \$10 to apply for authorization to practice on a voluntary basis at a specific location for a limited period of time.

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.

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:

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.

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.

There were no alternatives to adoption of an emergency regulation as it was mandated by Chapters 387 and 740 of the 2002 Acts of the Assembly.

Voluntary practice

The most burdensome aspect of the regulation on voluntary practice is specifically mandated by the Code, and that is that the group sponsoring the practice of the health care provider must be 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.” Meeting such stringent criteria may be difficult for many nonprofits who would like to set up one-time or temporary clinics in underserved areas of Virginia and utilize the services of out-of-state practitioners who are willing to provide services at no charge. Since the qualifying language for the organization is taken from the provisions of law, the Board had no option about those criteria.

The law is also very specific in providing an exemption from the requirement for licensure in Virginia, so the regulations simply set forth the process for filing an application and submitting the documentation necessary to determine whether the applicant and the organization meet the statutory qualifications. The law provides that the applicant notify the Board at least 15 days before provision of services, but the Board will not be able to process an application until it is complete and the qualifications and licensure have been verified. There is also a provision in the legislation for a fee to be paid prior to providing services in Virginia, so the Board has adopted a very minimal fee of \$10 to cover some of the costs of processing the application.

Since there is already an exemption in § 54.1-2901 (16) for: *“Any practitioner of the healing arts licensed or certified and in good standing with the applicable regulatory agency in another state or Canada when that practitioner of the healing arts is in Virginia temporarily and such practitioner has been issued a temporary license or certification by the Board from practicing medicine or the duties of the profession for which he is licensed or certified (i) in a summer camp or in conjunction with patients who are participating in recreational activities, (ii) while participating in continuing educational programs prescribed by the Board, or (iii) by rendering at any site any health care services within the limits of his license, voluntarily and without compensation, to any patient of any clinic which is organized in whole or in part for the delivery of health care services without charge as provided in § 54.1-106.”* A temporary license for

limited practice in a free clinic is currently issued by the Board under the current exemption. Therefore, it was necessary for proposed regulations to stipulate that the requirements do not apply to a person applying under that provision in the Code.

Supervision of assistants

Since the change in § 54.1-2952 does not require the physical presence of the supervising physician at all times and in all settings in which the assistant is providing care and treatment, several rules in Chapter 50 had to be revised accordingly. Current definitions provide several levels of supervision with “general” requiring only the availability of the physician and an ability to be physically present within one hour. Since the law now allows PA’s to practice without the physician being physically present, general supervision was amended to provide for the physician to be easily available or accessible for consultation within one hour. In general supervision, his physical presence is not required. Depending on the level of acuity and practice setting, the written protocol between the assistant and physician may require personal or direct supervision for certain procedures or circumstances. Likewise, a rule for notifying the board if the assistant is going to perform duties away from the supervisor was unnecessary.

Current regulations require a review of the record of services rendered within 72 hours of care. Some physician assistants and supervising physicians have found that requirement to be burdensome and unworkable. The Board determined that the amended law requiring an evaluation process for the PA’s performance could replace the specific requirement for chart review within 72 hours. With amended regulations, the schedule for review would be determined in the written protocol, which must be on file with the board. The protocol must specify the appropriate time period for evaluation, based on the acuity of care and practice setting. Depending on the nature of the practice, it may be necessary for the supervising physician to review the care and treatment provided more frequently than 72 hours or it may be possible to evaluate performance on a less frequent basis.

With the passage of House Bill 1318 (Chapter 740 of the 2002 Acts) and House Bill 687 (Chapter 387 of the 2002 Acts), the Board is mandated to promulgate regulations implementing provisions of the law within 280 days. It has also adopted a Notice of Intended Regulatory Action to receive comment on its intent to replace the emergency regulations with permanent regulations.

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 was posted on the Virginia Regulatory Townhall, sent to the Registrar of Regulations, and sent to persons on the PPG mailing list for the board. Public comment was received August 12, 2002 until September 11, 2002. During the 30-day comment period, no comments were received from members of the public.

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.

Members of the Board met in open session to work on the emergency regulations and the proposed regulations. The public has been invited to comment during the course of those meetings. No comments have been received regarding the need for clarity in the proposed amendments. 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. These regulations will be reviewed again during the 2004-05 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.

The proposed regulatory action would 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.