



Fast Track Proposed Regulation Agency Background Document

Agency name	Board of Medicine, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC85-50-10 et seq.
Regulation title	Regulations Governing the Practice of Physician Assistants
Action title	Qualifications for performance of fluoroscopy
Date this document prepared	2/20/14

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes.

Chapter 81 of the 2012 Acts of the Assembly required the Board of Medicine to promulgate regulations to implement provisions of the act with 280 days of its enactment. Therefore, the Board adopted emergency regulations establishing the criteria for use of fluoroscopy by physician assistants, and this action will make those regulations permanent.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

None

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

On February 20, 2014, the Board of Medicine adopted amendments to 18VAC85-50-10 et seq., Regulations Governing the Practice of Physician Assistants.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person’s overall regulatory authority.

Chapter 24 of Title 54.1 establishes the general powers and duties of health regulatory boards including the responsibility to promulgate regulations.

§ 54.1-2400. General powers and duties of health regulatory boards.--The general powers and duties of health regulatory boards shall be:

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.

The specific mandate to promulgate regulations is found in § 54.1-2952 of the Code of Virginia:

§ 54.1-2952. Supervision of assistants by licensed physician, or podiatrist; services that may be performed by assistants; responsibility of licensee; employment of assistants.

C. Notwithstanding the provisions of § 54.1-2956.8:1, a licensed physician assistant who (i) is working under the supervision of a licensed doctor of medicine or osteopathy specializing in the field of radiology, (ii) has been trained in the proper use of equipment for the purpose of performing radiologic technology procedures consistent with Board regulations, and (iii) has successfully completed the exam administered by the American Registry of Radiologic Technologists for physician assistants for the purpose of performing radiologic technology procedures may use fluoroscopy for guidance of diagnostic and therapeutic procedures.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The purpose of the regulation is to establish the qualifications of a physician assistant who may use fluoroscopy for guidance of diagnostic and therapeutic procedures under the supervision of a physician specializing in the field of radiology. Fluoroscopy is a radiological procedure which is not within the usual scope of practice of a physician assistant. Therefore, additional education, training and testing is required to ensure minimal competency to perform the procedure. The goal of the amended regulation is to set qualifications that are consistent with those recommended by the national professional bodies for both radiologic technologists and physician assistants.

Fluoroscopy is a radiologic procedure that emits high levels of ionizing radiation and is used for diagnostic and therapeutic purposes. Performed improperly, it can do harm to a patient or cause a misdiagnosis that can harm a patient. Since it is typically outside the scope of practice for physician assistants and not covered in their pre-licensure educational programs and examinations, additional qualifications must be established to ensure minimal competency to perform the procedure with safety and effectiveness.

Rationale for using fast track process

Please explain the rationale for using the fast track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

An emergency regulation became effective on November 12, 2013, and a Notice of Intended Regulatory Action was published for the replacement of the emergency. During the 30-day comment period, there was no comment and there have been no issues reported by providers.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the "Detail of changes" section.) Please be sure to define any acronyms.

Amendments to section 117 set out qualifications by which a physician assistant working under the supervision of a licensed doctor of medicine or osteopathy specializing in the field of radiology is authorized to use fluoroscopy for guidance of diagnostic and therapeutic procedures provided such activity is specified in his protocol. Those qualifications are:

1. Completion of at least 40 hours of structured didactic educational instruction and at least 40 hours of supervised clinical experience as set forth in the Fluoroscopy Educational Framework for the Physician Assistant created by the American Academy of Physician Assistants (AAPA) and the American Registry of Radiologic Technologists (ARRT); and
3. Successful passage of the ARRT Fluoroscopy Examination.

Issues

Please identify the issues associated with the proposed regulatory action, including:

- 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 indicate.

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- 1) The primary advantage of the amendment is a very modest expansion of practice by mid-level providers, specifically physician assistants working under the supervision of radiologists. There are no disadvantages; there is adequate education and training to assure minimal competency for safe and effective practice.
 - 2) There are no advantages or disadvantages to the Commonwealth.
 - 3) There are no other pertinent issues.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There is no requirement more restrictive than federal requirements

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no localities particularly affected.

Regulatory flexibility analysis

Pursuant to §2.2-4007.1B of the Code of Virginia, please describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

There is no regulatory flexibility consistent with health and safety of patients receiving fluoroscopy from physician assistants.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact. Please keep in mind that we are looking at the impact of the proposed changes to the status quo.

Description of the individuals, businesses or other entities likely to be affected (positively or negatively) by this regulatory proposal. Think broadly, e.g., these entities may or may not be regulated by this board	Entities affected would be physician assistants working under a physician with a specialty in radiology.
Agency’s best estimate of the number of (1) entities that will be affected, including (2) small businesses affected. Small business means a business, including affiliates, that is independently owned and operated, employs fewer than 500 full-time employees, or has gross annual sales of less than \$6 million.	There is no estimate of the number of physician assistants and supervising radiologists who are or will be affected.
Benefits expected as a result of this regulatory proposal.	Expanded utilization of mid-level providers in provision of radiology services.
Projected cost to the state to implement and enforce this regulatory proposal.	There are no costs to implement.
Projected cost to localities to implement and enforce this regulatory proposal.	None
All projected costs of this regulatory proposal for affected individuals, businesses, or other entities. Please be specific and include all costs, including projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses, and costs related to real estate development.	Practitioners seeking to comply with the qualifications for provision of fluoroscopy would incur costs for completion of the educational and clinical hours and passage of the ARRT fluoroscopy exam for physician assistants.

Alternatives

Please describe any viable 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. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

There are no alternatives that will achieve the essential purpose of the action. The specific content of the regulation was recommended by both the American Registry of Radiologic Technologists (ARRT) and the American Academy of Physician Assistants (AAPA). The ARRT and AAPA collaborated on a consensus curriculum of didactic instruction (40 hours) and a clinical component (40 hours) in preparation for the ARRT Fluoroscopy Examination. Both organizations have written to the Board in support of the regulations specified in section 117, and the Advisory Board on Physician Assistants has unanimously endorsed the recommended regulation.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent 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.

There is no impact on the family.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all differences between the pre-emergency regulation and this proposed regulation, and (2) only changes made since the publication of the emergency regulation.

The proposed amendment to section 117 is identical to the emergency regulation currently in effect.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, and likely impact of proposed requirements
N/A	117	N/A	<p>18VAC85-50-117. Authorization to use fluoroscopy. A physician assistant working under the supervision of a licensed doctor of medicine or osteopathy specializing in the field of radiology is authorized to use fluoroscopy for guidance of diagnostic and therapeutic procedures provided such activity is specified in his protocol and he has met the following qualifications:</p> <ol style="list-style-type: none"> 1. Completion of at least 40 hours of structured didactic educational instruction and at least 40 hours of supervised clinical experience as set forth in the Fluoroscopy Educational Framework for the Physician Assistant created by the American Academy of Physician Assistants (AAPA) and the American Registry of Radiologic Technologists (ARRT); and 3. Successful passage of the ARRT Fluoroscopy Examination. <p><i>The intent of the regulation is to establish minimal qualifications for physician assistants to perform</i></p>

			<p><i>fluoroscopy, using a nationally-recognized training regime and examination approved for that purpose. The impact of the regulation will be limited to radiology practices in which physician assistants are employed and may be utilized to assist in performance of diagnostic and therapeutic use of fluoroscopy.</i></p>
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