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Fast Track Regulation Agency Background Document

Agency name	Agency name Board of Medicine, Department of Health Professions	
Virginia Administrative Code (VAC) citation		
Regulation title	Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry and Chiropractic	
Action title	Clarification of qualification for performance of major conductive block	
Document preparation date	11/24/04	

This information is required for executive review (<u>www.townhall.state.va.us/dpbpages/apaintro.htm#execreview</u>) and the Virginia Registrar of Regulations (<u>legis.state.va.us/codecomm/register/regindex.htm</u>), pursuant to the Virginia Administrative Process Act (<u>www.townhall.state.va.us/dpbpages/dpb_apa.htm</u>), Executive Orders 21 (2002) and 58 (1999) (<u>www.governor.state.va.us/Press_Policy/Executive_Orders/EOHome.html</u>), and the *Virginia Register Form, Style and Procedure Manual* (<u>http://legis.state.va.us/codecomm/register/download/styl8_95.rtf</u>).</u>

Brief summary

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

The proposed action would clarify that the intent of regulations for performance of office-based anesthesia was to address the administration of anesthesia in an office-based setting by an amendment stating that performance of a major conductive block for diagnostic or therapeutic purposes does not require the services of an anesthesiologist or a certified registered nurse anesthetist, but could be administered by a qualified physician.

Statement of agency final 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 November 19, 2004, the Board of Medicine took action to amend 18 VAC 85-20-10 et seq., Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry and Chiropractic through the fast-track regulatory process to amend section 330, establishing qualification for providers of office-based anesthesia.

Legal basis

Please identify the state and/or federal source of legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including General Assembly bill and chapter numbers, if applicable, and (2) promulgating entity, i.e., the agency, board, or person. Describe the scope of the legal authority and the extent to which the authority is mandatory or discretionary.

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 of Medicine 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:

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.

...

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. ...

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal and the problems the proposal is intended to solve.

The purpose of the action is to ensure that section 330 is clarified and does not prohibit the delivery of medical services that can and have been performed safely in Virginia by qualified physicians. A major conductive block includes procedures that many non-anesthesiologists perform for therapeutic and diagnostic purposes; such procedures are currently performed by

interventional physiatrists and other specialties in medicine. In order for patients in Virginia to continue receiving such procedures without a concern that the doctor performing the block may be in violation of regulations of the Board, the provisions for qualification of anesthesia providers must be clarified.

The intent of the current requirement for office-based anesthesia was to ensure that anesthesia was being administered by an anesthesiologist or certified registered nurse anesthetists while the operating doctor was focused on the surgical procedure. When a major conductive block is performed for diagnostic or therapeutic purposes, the administering physician, if appropriately qualified in such a procedure, is focused on the procedure and on patient response to the delivery of the anesthesia.

Rationale for using fast track process

Please explain why the fast track process is being used to promulgate this regulation.

Please note: If an objection to the use of the fast-track process is received within the 60-day public comment period from (1) 10 or more persons, (2) any member of the applicable standing committee of either house of the General Assembly or (3) any member of the Joint Commission on Administrative Rules, the agency shall (i) file notice of the objection with the Registrar of Regulations for publication in the Virginia Register, and (ii) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

The fast-track process is being used to promulgate the amendment because it is a clarification of the intent of the Board in promulgating regulations for office-based anesthesia. It was not the Board's intent to limit or restrict the practice of physicians who use a major conductive block in their office practices for diagnostic or therapeutic purposes. Therefore, the Board believes the change is mostly clarifying and reflective of current practice.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" section.)

The proposed fast-track action amends 18VAC85-20-330 by differentiating between major conductive blocks performed for a surgical procedure shall only be administered by an anesthesiologist or by a certified registered nurse anesthetist. A major conductive block performed for diagnostic or therapeutic purposes may be administered for a non-surgical procedure by a doctor qualified by training and scope of practice or by a certified registered nurse anesthetist.

Issues

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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 the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.

There are no disadvantages to the public of this amendment. Without a clarification of the rules, physicians who currently perform major conductive blocks for diagnostic or therapeutic purposes would be concerned about a violation of Board rules or would need to hire an anesthesia provider to perform a procedure for which he is already qualified. Either alternative would be detrimental to the affordability of and access to necessary medical treatments and procedures. Failure to amend this regulation would create a disadvantage to the public.

There are no disadvantages to the agency or the Commonwealth; the proposed regulation will clarify office-based anesthesia regulations for consistency with the Board's intent for the rules.

There are no other pertinent matters of interest.

Economic impact

Projected cost to the state to implement and enforce the proposed regulation, including	The agency will incur some one-time costs (less than $\$1000$) for mailings to the Public Participation
(a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	\$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 or distribute notices by email. There are no ongoing expenditures related to this amendment. 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.
Projected cost of the regulation on localities	None
Description of the individuals, businesses or other entities likely to be affected by the regulation	The individuals who may be affected would be those practitioners of medicine, osteopathic medicine or podiatry who are qualified to perform major conductive blocks.
Agency's best estimate of the number of such entities that will be affected	The actual number of entities that will be affectedis unknown. The number of entities that could bepotentially be affected are:Doctors of medicine & surgery28,535Doctors of osteopathy & surgery1,103Podiatrists474

Projected cost of the regulation for affected	There is no projected cost to affected entities.
individuals, businesses, or other entities	

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.

The Board considered issuance of a guidance document that would provide an interpretation of the intent of the rule but determined that the only appropriate alternative was clarification of the regulation by amending to be consistent with its interpretation. Amending the regulation to allow current delivery of major conductive blocks for diagnostic or therapeutic purposes by doctors trained and qualified to do so will alleviate concern by those doctors that they may be in violation of state regulations.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability.

There is no impact on the institution of the family and family stability.

Detail of changes

Please detail all changes that are being proposed and the consequences of the proposed changes.

Current section number	Current requirement	Proposed change and rationale
330	Currently, the rules require that deep sedation, general anesthesia <i>or a major</i> <i>conductive block</i> shall only be administered by an anesthesiologist or by a certified registered nurse anesthetist.	The proposed rule would eliminate "a major conductive block" in the requirement for administration by an anesthesiologist or by a certified registered nurse anesthetist and add a new section stating that: "A major conductive block performed for a surgical procedure shall only be administered by an anesthesiologist or by a certified registered nurse anesthetist. A major conductive block performed for diagnostic or therapeutic purposes may be administered for a non-surgical procedure by a doctor qualified by training and scope of practice or by a certified

registered nurse anesthetist."
If a doctor has been appropriately trained, meets the other qualifications stated in section 330, and adheres to the requirements for monitoring patients, the amended regulation would clarify that he could perform a major conductive block for a non- surgical procedure. Doctors (such as chiropractors)
who do not have the administration of anesthesia in
their scope of practice who not be permitted by this
regulation, nor would doctors of medicine,
osteopathic medicine or podiatry would have not
been specifically and appropriately trained.