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Final Regulation Agency Background Document

Agency name	Board of Medicine, Department of Health Professions	
Virginia Administrative Code (VAC) citation	18 VAC 85-20	
Regulation title	Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry and Chiropractic	
Action title	Qualification for performance of major conductive block	
Document preparation date	6 6/22/06	

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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. If applicable, generally describe the existing regulation.

The proposed final action will 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 physician qualified by experience and training in such a procedure.

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 June 22, 2006, the Board of Medicine adopted a final regulation for 18VAC85-20-10 et seq., Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry and

Chiropractic to clarify the rule on performance of a major conductive block for diagnostic or therapeutic purposes in an office-based setting.

Legal basis

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Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter numbers, if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe 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, which 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:

...

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 (§ <u>54.1-100</u> et seq.) and Chapter 25 (§ <u>54.1-2500</u> et seq.) of this title. ...

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 it 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 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.

Substance

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Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

The final action amends 18VAC85-20-330 by differentiating between major conductive blocks performed for a surgical procedure, which 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.

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.

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 is no other pertinent matter of interest related to this action.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar's office, please put an asterisk next to any substantive changes.

There were no changes made to the proposed regulation since its publication.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

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Proposed regulations were published on January 23, 2006 with a 60-day comment period ending on March 24, 2006. A public hearing on proposed regulations was held on February 23, 2006. There were no public comments submitted.

All changes made in this regulatory action

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail new provisions and/or all changes to existing sections.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
330	n/a	Currently, the rules require that deep sedation, general anesthesia or a major conductive block shall only be administered by an anesthesiologist or by a certified registered nurse anesthetist.	The proposed rule would state that: Deep sedation, general anesthesia or a major conductive block shall be administered by an anesthesiologist or by a certified registered nurse anesthetist. But, a major conductive block performed for diagnostic or therapeutic purposes may be administered by a doctor qualified by training and scope of practice. A major conductive block includes procedures that many nonanesthesiologists 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.

Family impact

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

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