Virginia Regulatory Town Hall

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Proposed 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	9/19/05

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

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 physician qualified by experience and training in such a procedure.

Legal basis

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 number(s), if applicable, and (2) promulgating entity, i.e., the 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 (§ 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.

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 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 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

Please identify the anticipated economic impact of the proposed regulation.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	a) 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; b) The agency will incur some one-time costs (less than $1,000) for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities. Since most mailings to the PPG list are handled electronically, there is very little cost involved. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled. There are no on-going expenditures.
Projected cost of the regulation on localities	None
Description of the individuals, businesses or	The individuals who may be affected would be

other entities likely to be affected by the regulation	those practitioners of medicine, osteopathic medicine or podiatry who are qualified to perform major conductive blocks for diagnostic or therapeutic purposes.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	The actual number of entities that will be affected is unknown. The number of entities that could be potentially be affected are: Doctors of medicine & surgery 28,535 Doctors of osteopathy & surgery 1,103 Podiatrists 474 To the extent, a doctor in one of these categories conducts his practice in a small business, there may be some impact.
All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.	There is no cost of the regulation for affected individuals or businesses. Without the proposed clarification, they could be adversely affected by not being able to use conductive blocks for diagnostic or therapeutic purposes or by having to hire anesthesiologists or certified registered nurse anesthetists in their practices.

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.

Public comment

Please summarize all comments received during public comment period following the publication of the NOIRA, and provide the agency response.

An amendment was initially proposed as a fast-track regulation and was published in Volume 21, Issue 19, page 2597 of the Register of Regulations, dated May 30, 2005. A sixty-day comment period was provided with public comment to be received until July 29, 2005.

The fast-track regulation was intended to clarify that a major conductive block performed for diagnostic or therapeutic purposes could be administered by a doctor qualified by training and scope of practice or by a certified registered nurse anesthetist. The Board received more than the requisite number of ten objections to the inclusion of a certified registered nurse anesthetist.

Therefore, it terminated the fast-track process and promulgated a restated amendment under the Administrative Process Act, utilizing the fast-track notice as its notice of intended regulatory action.

The Board continued to receive public comment through July 29, 2005, most of which objected to the regulation allowing nurse anesthetists (CRNA) to perform major conductive blocks. At the Legislative Committee meeting of the Board on August 19, 2005, it was explained that this set of regulations cannot restrict the current scope of practice for a CRNA; these are regulations for the practice of doctors of medicine, osteopathic medicine, podiatry and chiropractic. The issue in this action is whether doctors who are not specialists in anesthesia can perform major conductive blocks if they are specifically trained to do so in the scope of their practice.

Therefore, the Legislative Committee recommended and the Board adopted an amendment that did not mention the practice of CRNA's, but only references doctors who perform major conductive blocks within their practice.

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. Detail all new provisions and/or all changes to existing sections.

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

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 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.