Virginia Regulatory Town Hall

Emergency Regulation
Agency Background Document

Agency Name:	Board of Medicine, Department of Health Professions
VAC Chapter Number:	18 VAC 85-20-10 et seq.
Regulation Title:	**Regulations Governing the Practice of Medicine, Osteopathy, Podiatry and Chiropractic**
Action Title:	Office-based anesthesia
Date:	10/10/02

Section 9-6.14:4.1(C)(5) of the Administrative Process Act allows for the adoption of emergency regulations. Please refer to the APA, Executive Order Twenty-Four (98), and the *Virginia Register Form, Style and Procedure Manual* for more information and other materials required to be submitted in the emergency regulation submission package.

Emergency Preamble

Please provide a statement that the emergency regulation is necessary and provide detail of the nature of the emergency. Section 9-6.14:4.1(C)(5) of the Administrative Process Act states that an "emergency situation" means: (i) a situation involving an imminent threat to public health or safety; or (ii) a situation in which Virginia statutory law, the Virginia appropriation act, or federal law requires that a regulation shall be effective in 280 days or less from its enactment, or in which federal regulation requires a regulation to take effect no later than 280 days from its effective date. The statement should also identify that the regulation is not otherwise exempt under the provisions of § 9-6.14:4.1(C)(4).

Please include a brief summary of the emergency action. There is no need to state each provision or amendment.

Chapter 324 of the 2002 Acts of the Assembly requires the Board to "promulgate regulations governing the practice of medicine related to the administration of anesthesia in physicians' offices." Amendments to regulation are required to establish the applicability of the rules, qualifications of providers, protocols for anesthesia/procedure selection, requirements for informed consent, and procedures for monitoring, emergency transfers, and discharge. The enactment clause required the board to adopt regulations within 280 days or by January 7, 2003.

In response to a petition for rule-making concerning the use of anesthesia in physician offices, ambulatory surgery centers and other non-hospital settings, the Board of Medicine had already

published a Notice of Intended Regulatory Action and proposed regulations but will be unable to complete the regulatory process by the deadline set in the legislation. Therefore, emergency regulations are required in the interim until the adoption and approval of a final regulation.

Basis

Please identify the state and/or federal source of legal authority to promulgate the emergency regulation. The discussion of this emergency statutory authority should: 1) describe its scope; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. Full citations of legal authority and web site addresses, if available for locating the text of the cited authority, should be provided.

Please provide a statement that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the emergency regulation and that it comports with applicable state and/or federal law.

The legal authority to promulgate the emergency regulation is in second enactment clause of Chapter 324 of the 2002 Acts of the Assembly, which states: "That the Board of Medicine shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment. In doing so, the Board shall solicit and respond to public comment prior to the adoption of the emergency regulations." The statutory mandate is as follows:

§ 54.1-2912.1. Continued competency and office-based anesthesia requirements.

A. The Board shall prescribe by regulation such requirements as may be necessary to ensure continued practitioner competence which may include continuing education, testing, and/or any other requirement.

B. In promulgating such regulations, the Board shall consider (i) the need to promote ethical practice, (ii) an appropriate standard of care, (iii) patient safety, (iv) application of new medical technology, (v) appropriate communication with patients, and (vi) knowledge of the changing health care system.

C. The Board may approve persons who provide or accredit such programs in order to accomplish the purposes of this section.

D. Pursuant to § 54.1-2400 and its authority to establish the qualifications for registration, certification or licensure that are necessary to ensure competence and integrity to engage in the regulated practice, the Board of Medicine shall promulgate regulations governing the practice of medicine related to the administration of anesthesia in physicians' offices.

The Office of the Attorney General has certified that the "emergency situation" which exists is specified in § 2.2-4011 of the Code of Virginia as one in which the agency is required by statutory law to have a regulation in effect within 280 days from the enactment of the law.

http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+2.2-4011

Substance

Please detail any changes, other than strictly editorial changes, that would be implemented. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate. Please provide a cross-walk which includes citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed changes. The statement should set forth the specific reasons the agency has determined that the proposed regulatory action would be essential to protect the health, safety or welfare of Virginians. The statement should also delineate any potential issues that may need to be addressed as a permanent final regulation is developed.

The Board has adopted a new section to set forth the rules for "Office-Based Anesthesia", including definitions that are applicable to these regulations. First, the rules establish applicability, excluding the delivery of anesthesia in hospital settings or federal facilities and excluding the administration of levels of anesthesia with little potential for complications, such as local, topical or minimal sedation. General provisions set out the responsibilities of the doctor of medicine, osteopathy or podiatry and require that all procedures and protocols be in writing and available for inspection.

Requirements for the providers of anesthesia include training in the level of anesthesia being given as well as in advanced resuscitative techniques. If the doctor administers anesthesia without a qualified anesthesia provider, he is required to devote four of his 60 hours of continuing education to anesthesia. Higher levels of anesthesia with greater risks to patients can only be delivered by qualified anesthesia providers, who are anesthesiologists or nurse anesthetists.

Regulations establish a requirement for a written protocol on procedure and anesthesia selection and on the evaluation of a patient to determine pre-existing conditions, physical classification, risks and benefits. Anesthesia in an office-based setting is not permitted for certain patients who are at very high risk. All patients must give informed consent after the anesthesia plan has been discussed.

Requirements for monitoring are established to include appropriate equipment that has been maintained up to industry standards. The equipment, drugs and supplies necessary for different levels of anesthesia are set out in the regulation. Procedures for monitoring patients during and after the procedure must be in writing and must include continuous clinical observation; and for deep sedation or general anesthesia, the practitioner is required to be present in the facility until discharge criteria have been met.

Finally, there are requirements for emergencies and transfer to a hospital, for discharge protocols and for reporting of serious incidents resulting from the delivery of office-based anesthesia.

Alternatives

Please describe the specific alternatives that were considered and the rationale used by the agency to select the least burdensome or intrusive method to meet the essential purpose of the action.

There were no alternatives to adoption of a regulation as it was mandated by Chapter 324 of the 2002 Acts of the Assembly, which required that regulations be promulgated within 280 days of

the enactment of the legislation or by January 7, 2003. Since the Board had already begun promulgation under the normal APA process and had completed the comment period on the NOIRA prior to introduction of legislation, the decision was made to proceed without the adoption of emergency regulation to allow for the maximum amount of input from the public, professional association and affected entities. It is now apparent that it is not possible to have a final regulation in effect by January 7th, so the Board has adopted the proposed regulation as an emergency regulation. In its adoption of an emergency regulation, the Board considered the following two issues raised during the public hearing on proposed regulations:

1) A representative of the UVA Medical Center requested a clarification of the exemption from regulatory requirements for a "licensed hospital" in the definition section, 18 VAC 85-20-310. She noted that UVA did not believe its clinics in other places, such as in Culpeper, should be included in the exemption, but did contend that the exemption should apply to clinics contiguous to the main hospital, where anesthesia services are immediately available. A spokesperson for the Virginia Hospital and Healthcare Association concurred that other hospitals would have similar situations. **In response, the Board amended the proposed definition of office-based to exclude hospitals "and their associated, contiguous clinics with immediate access to anesthesia services available within two minutes."** Since a patient who is not breathing can be dead within four minutes, the Board determined that a two-minute gap before anesthesia expertise and equipment could be available was minimal.

2) A representative of the Certified Nurse Anesthetists spoke in opposition to 18 VAC 85-20-320 B 6, requiring the physician administering anesthesia or supervising such administration to remain physically present or immediately available, as appropriate, for diagnosis, treatment and management of anesthesia-related complications or emergencies. The concern expressed was that, in situations where there is a nurse anesthetist providing the anesthesia, it should not be necessary for the doctor to remain responsible for complications or emergencies after the procedure related to the anesthesia. Staff suggested alternative language, but after much discussion, the Board voted to adopt the language of the proposed regulation to ensure that the doctor remains responsible for the patient and the activities of those who practice under his supervision. The Board felt that it was a reasonable requirement and necessary for public protection.

In the adoption of the proposed regulation for outpatient (office-based) anesthesia, the initial approach was to first identify an existing professional standard for delivery of anesthesia. It was contemplated that the Board could incorporate that standard by reference in regulation and simply add a section to the regulations on Unprofessional Conduct requiring adherence to those guidelines. Through comments received on the NOIRA and materials provided to members of the advisory committee on office-based anesthesia, it became apparent that a single professional standard did not exist that would provide for minimal competency and safe delivery of anesthesia without a potential adverse effect on access and cost of care. For example, the committee considered the Guidelines for Office-Based Anesthesia approved by the House of Delegates of the American Society of Anesthesiologists (ASA) in October 13, 1999, but those standards were strongly opposed by the certified registered nurse anesthetists who are the only anesthesia provider available in many patient settings.

The committee also considered standards of accreditation bodies such as the Joint Commission (JCHO) accreditation of office-based surgery, the American Association for the Accreditation of Ambulatory Surgical Facilities (AAAASF) or the Accreditation Association for Ambulatory Health Care (AAAHC). Equipment and facility standards required for any of these accreditations are more extensive than those set forth in these regulations and are regarded as the optimum in out-patient surgery. Therefore, the Board chose to adopt rules that provide sufficient patient protection without excessive requirements that may limit availability and increase cost of care.

Simultaneously with the development of these regulations, a Special Committee on Outpatient Surgery of the Federation of State Medical Boards (FSMB) was in the process of drafting recommendations to assist state medical boards in the oversight of outpatient surgery in currently unregulated settings. That committee reviewed nationally recognized accreditation standards, standards of various professional groups, and statutes/rules already adopted by a number of states. They also looked at current literature on outpatient surgery in developing recommended rules for such practice. Their recommendation to state boards was adoption of one of the following: 1) the FSMB Model Guidelines; 2) accreditation by a recognized national organization; or 3) development of individual state standards or rules. While the committee advising the Board of Medicine borrowed heavily from the Model Guidelines of the FSMB, they found them to be insufficient in some areas and over-reaching in others. Therefore, the most reasonable approach was to develop guidelines appropriate to Virginia that would provide a minimal standard for patient safety.

To determine which requirements were essential, the Board relied on the expertise of the advisory committee members, additional comment and input from other practitioners who reviewed drafts, FSMB guidelines, standards from professional associations and rules adopted by other states. For example, the advisory committee looked at rules or guidelines for office-based surgery in Rhode Island, Oklahoma, Florida, North Carolina, Texas, California, New Jersey, Ohio, New York, Georgia, Connecticut and the District of Columbia. As with the FSMB guidelines, the Board utilized language from other states that was appropriate to the goals and needs of this regulatory action.

Throughout the development of regulations, the advisory committee was cognizant of its responsibility to recommend requirements that were essential for patient protection but not excessive. On a number of issues, there were compromises to lessen the potential impact of regulation. So, for example, when it was agreed to exclude minimal levels of sedation, local or topical anesthesia, or minor conductive blocks, the concerns many practitioners had about a possible impact of these requirements were immediately negated.

Theorizing that there needed to be one person in the surgery suite administering anesthesia and another person performing the surgery, there was support for requiring all providers of anesthesia to be someone other than the operating doctor. The compromise recommendation was to require the use of an anesthesiologist or CRNA for deeper levels of anesthesia, but permit the operating doctor accompanied by a licensed nurse or resident or intern to utilize conscious sedation/moderate anesthesia. Originally, there was a proposal to require all doctors who administer or supervise the administration of anesthesia to obtain some number of hours of

continuing education in the subject of anesthesia. That proposal was opposed by doctors who employ CRNA's and was amended to require that those who provide anesthesia without a licensed anesthesia provider obtain four hours in anesthesia (out of the 60 required for renewal).

Other issues arose related to such things as whether the pre-anesthesia plan/history and physical needs to be signed by the doctor; it was agreed that that was the responsibility of the anesthesia provider under a written protocol for the practice. It is the responsibility of the doctor administering anesthesia or supervision administration to ensure that it has been done. There were also comments about the necessity of some monitoring equipment, and accordingly, the Board amended the draft language to eliminate or modify several requirements. Some members advocated for a requirement that the operating doctor have privileges in a nearby hospital, but it was decided to require a transfer agreement instead. On a number of other issues, the committee and/or the Board adjusted and compromised to adopt less burdensome requirements, so long as the essential purpose of patient safety was not sacrificed.

Family Impact Statement

Please provide a preliminary analysis of the potential impact of the emergency action on the institution of the family and family stability including to what extent the 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.