Virginia Regulatory Town Hall

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Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Board of Medicine, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC85-20-10
Regulation title	Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry and Chiropractic
Action title	Requirements for office-based anesthesia
Date this document prepared	10/20/14

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.*

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

A Notice of Intended Regulatory Action was approved by the Board of Medicine on October 16, 2014 in response to a petition for rule-making from the Medical Society of Virginia (MSV). The petition was published on September 8, 2014, posted on the Virginia Regulatory Townhall, and sent to the Board's public participation guidelines notification list to receive public comment ending October 8, 2014. Two comments were received.

The Virginia Society of Plastic Surgeons noted that the petition request resulted from a workgroup convened by MSV to explore issues related to the use of anesthesia during office-based surgical procedures. Along with the plastic surgeons, the Virginia Academy of Family Physicians and others collaborated with stakeholders to develop regulatory recommendations.

In its comment on the petition, the Virginia Podiatric Medical Association noted that the reference to board certification by the American Board of Medical Specialties (ABMS) was discriminatory to podiatrists since they are not part of the ABMS boards.

The intent of the Board is to address the need for additional public protection in the administration of office-based anesthesia. Specific amendments recommended by the petitioner will be considered, as well as comments received on the petition and on the NOIRA.

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.

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:*
>
> *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. ...*
>
> *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. ...*

Specific authority for regulation of office-based anesthesia is found in Chapter 29 of Title 54.1:

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

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

As more medical and surgical procedures are being performed in office-based settings, there is a greater need for standards in the administration of anesthesia to address possible consequences which could result in an emergency transport to a hospital and even in the death of a patient. Therefore, changes are recommended in the applicability of requirements for office-based anesthesia, documentation of complications, duration of such a procedure, informed consent by patient of the anesthesia plan, discharge planning and emergency transfer protocols. The Board will consider regulatory changes as necessary to ensure safe practice for patients who undergo procedures in office-based settings.

Substance

Please detail any changes that will be proposed. Be sure to define all acronyms. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.

The petition submitted by the Medical Society of Virginia (MSV) requested specific amendments to requirements for administration of office-based anesthesia. In approving the issuance of a Notice of Intended Regulatory Action, the Board is not proposing those amendments but is seeking comment on the provisions requested by the petitioner. The MSV petition recommended the following amendments:

18VAC85-20-320. General provisions.

A. Applicability of requirements for office-based anesthesia.

1. The administration of topical anesthesia, local anesthesia, minor conductive blocks, or minimal sedation/anxiolysis, not involving a drug-induced alteration of consciousness other than minimal preoperative tranquilization, is not subject to the requirements for office-based anesthesia. A health care practitioner administering such agents shall adhere to an accepted standard of care as appropriate to the level of anesthesia or sedation, including evaluation, drug selection, administration and management of complications.

2. The administration of moderate sedation/conscious sedation, deep sedation, general anesthesia, or regional anesthesia consisting of a major conductive block are subject to these requirements for office-based anesthesia. **The administration of 300 or more milligrams of lidocaine or equivalent doses of local anesthetics shall be deemed to be subject to these requirements for office-based anesthesia.**

3. Levels of anesthesia or sedation referred to in this chapter shall relate to the level of anesthesia or sedation intended **and documented** by the practitioner in the **pre-operative** anesthesia plan.

B. A doctor of medicine, osteopathic medicine, or podiatry administering office-based anesthesia or supervising such administration shall:

1. Perform a preanesthetic evaluation and examination or ensure that it has been performed;

2. Develop the anesthesia plan or ensure that it has been developed;

3. Ensure that the anesthesia plan has been discussed **with the patient or responsible party pre-operatively** and informed consent obtained;

4. Ensure patient assessment and monitoring through the pre-, peri-, and post-procedure phases, addressing not only physical and functional status, but also physiological and cognitive status;

5. Ensure provision of indicated post-anesthesia care; ~~and~~

6. Remain physically present or immediately available, as appropriate, to manage complications and emergencies until discharge criteria have been met, **and**

7. Document any complications occurring during surgery or during recovery in the medical record.

C. All written policies, procedures and protocols required for office-based anesthesia shall be maintained and available for inspection at the facility.

18VAC85-20-340. Procedure/anesthesia selection and patient evaluation.

A. A written protocol shall be developed and followed for procedure selection to include but not be limited to:

1. The doctor providing or supervising the anesthesia shall ensure that the procedure to be undertaken is within the scope of practice of the health care practitioners and the capabilities of the facility.

2. The procedure **or combined procedures** shall be of a duration and degree of complexity that **shall not exceed eight hours and that** will permit the patient to recover and be discharged from the facility in less than 24 hours.

3. The level of anesthesia used shall be appropriate for the patient, the surgical procedure, the clinical setting, the education and training of the personnel, and the equipment available. The choice of specific anesthesia agents and techniques shall focus on providing an anesthetic that will be effective, appropriate and will address the specific needs of patients while also ensuring rapid recovery to normal function with maximum efforts to control post-operative pain, nausea or other side effects.

B. A written protocol shall be developed for patient evaluation to include but not be limited to:

1. The preoperative anesthesia evaluation of a patient shall be performed by the health care practitioner administering the anesthesia or supervising the administration of anesthesia. It shall consist of performing an appropriate history and physical examination, determining the patient's physical status classification, developing a plan of anesthesia care, acquainting the patient or the responsible individual with the proposed plan and discussing the risks and benefits.

2. The condition of the patient, specific morbidities that complicate anesthetic management, the specific intrinsic risks involved, and the nature of the planned procedure shall be considered in evaluating a patient for office-based anesthesia.

3. Patients who have pre-existing medical or other conditions that may be of particular risk for complications shall be referred to a facility appropriate for the procedure and administration of anesthesia. Nothing relieves the licensed health care practitioner of the responsibility to make a medical determination of the appropriate surgical facility or setting.

C. Office-based anesthesia shall only be provided for patients in physical status classifications for Classes I, II and III. Patients in Classes IV and V shall not be provided anesthesia in an office-based setting.

18VAC85-20-350. Informed consent.

A. Prior to administration, the anesthesia plan shall be discussed with the patient or responsible party by the health care practitioner administering the anesthesia or supervising the administration of anesthesia. Informed consent for the nature and objectives of the anesthesia planned shall be in writing and obtained from the patient or responsible party before the procedure is performed. **Such consent shall include a discussion of discharge planning and what care or assistance the patient is expected to require after discharge.** Informed consent shall only be obtained after a discussion of the risks, benefits, and alternatives, contain the name of the anesthesia provider and be documented in the medical record.

B. The surgical consent forms shall be executed by the patient or the responsible party and shall contain a statement that the doctor performing the surgery is board certified or board eligible by one of the ABMS boards and list which board or contain a statement that doctor performing the surgery is not board certified or board eligible.

C. The surgical consent forms shall indicate whether the surgery is elective, medically necessary, or if a consent is obtained in an emergency, the nature of the emergency.

18VAC85-20-370. Emergency and transfer protocols.

A. There shall be written protocols for handling emergency situations, including medical emergencies and internal and external disasters. All personnel shall be appropriately trained in and regularly review the protocols and the equipment and procedures for handling emergencies.

B. There shall be written protocols for the timely and safe transfer of patients to a prespecified hospital or hospitals within a reasonable proximity. **For purposes of this section "reasonable proximity" shall mean a licensed general hospital capable of providing necessary services within 30 minutes notice to the hospital.** There shall be a **written or electronic** transfer agreement with such hospital or hospitals.

18VAC85-20-380. Discharge policies and procedures.

A. There shall be written policies and procedures outlining discharge criteria. Such criteria shall include stable vital signs, responsiveness and orientation, ability to move voluntarily, controlled pain, and minimal nausea and vomiting.

B. Discharge from anesthesia care is the responsibility of the health care practitioner providing **or the doctor supervising** the anesthesia care and shall only occur when**: (i)** patients have met specific physician-defined criteria**; and (ii) ordered by the health care practitioner providing or the doctor supervising the anesthetic care**.

C. Written instructions and an emergency phone number shall be provided to the patient. Patients shall be discharged with a responsible individual who has been instructed with regard to the patient's care.

D. At least one person trained in advanced resuscitative techniques shall be immediately available until all patients are discharged.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

In the development of proposed regulations, the Board will consider alternatives suggested by commenters to the petition and to the NOIRA. There are no non-regulatory actions that can meet the essential purpose of public protection for patients receiving office-based anesthesia during a medical procedure or surgery.

Public participation

Please indicate whether the agency is seeking comments on the intended regulatory action, including ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments on this notice.

The agency is seeking comments on the intended regulatory action, including but not limited to 1) ideas to assist in the development of a proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail, email, or fax to Elaine Yeatts at **elaine.yeatts@dhp.virginia.gov** or at 9960 Mayland Drive, Henrico, VA 23233 or by fax at (804) 527-4434. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by the last day of the public comment period.

A public hearing will be held after publication of proposed regulations and notice of the hearing may be found on the Virginia Regulatory Town Hall website (**www.townhall.virginia.gov**) and can be found in the Calendar of Events section of the Virginia Register of Regulations. Both oral and written comments may be submitted at that time.

The Board will use the Legislative Committee as its regulatory panel to consider comments on the NOIRA and make develop recommendations for consideration by the full Board. The Legislative Committee consists of members who represent a variety of specialties and practices, as well as a citizen member of the Board.

Family impact

Assess the potential 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.