townhall.virginia.gov

Proposed Regulation
Agency Background Document

Agency name	Board of Medicine, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC85-20-10
Regulation title(s)	Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry and Chiropractic
Action title	Requirements for office-based anesthesia
Date this document prepared	8/20/15

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

Currently, regulations set out requirements for the administration of sedation or anesthesia in an office-based setting. Since the administration occurs away from a hospital setting, regulations specify appropriate patient assessment, informed consent, levels of anesthesia, protocols and procedures, and provision for emergencies. Amendments to the requirements for office-based anesthesia are adopted to: 1) include the administration of 300 or more milligrams of lidocaine under the applicability of the requirements; 2) ensure that the patient has adequate information in giving informed consent, including knowledge about whether the physician is board-certified or board-eligible; 3) require documentation of complications during surgery or recovery; 4) set a time-limit on procedures that may be performed in an office; 5) specify the availability of a

hospital to which a patient may be transferred; and 6) specify that the anesthesia provider or the doctor supervising the anesthesia must give the order for discharge.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

MSV = Medical Society of Virginia
ABMS = American Board of Medical Specialties

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.*

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation 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.

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.

The intent of the Board is to address the need for additional public protection in the administration of office-based anesthesia. 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 adopted regulatory changes as necessary to protect the health and safe of patients who undergo procedures in office-based settings.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of changes" section below.

Amendments to the requirements for office-based anesthesia are adopted to: 1) include the administration of 300 or more milligrams of lidocaine under the applicability of the requirements; 2) ensure that the patient has adequate information in giving informed consent, including knowledge about whether the physician is board-certified or board-eligible; 3) require documentation of complications during surgery or recovery; 4) set a time-limit on procedures that may be performed in an office; 5) specify the availability of a hospital to which a patient may be transferred; and 6) specify that the anesthesia provider or the doctor supervising the anesthesia must give the order for discharge.

Issues

Please identify the issues associated with the proposed regulatory action.

1) The primary advantage to the public is greater protection for office-based procedures requiring moderate sedation or anesthesia and more information about the physician, the plan for anesthesia and expectations for discharge. There are no disadvantages.
2) There are no advantages or disadvantages to the agency or the Commonwealth; and
3) This proposal was carefully negotiated with specialty groups of physicians to ensure that the central issue remained public protection but qualified providers were not excluded.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no localities particularly affected.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the [insert either: Board or agency] is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is 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 written comments for the public comment file may do so 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.. Comments may also be submitted through the Public Forum feature of the Virginia Regulatory Town Hall web site at: http://www.townhall.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will be held following the publication of this stage and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (**http://www.townhall.virginia.gov**) and on the Commonwealth Calendar website (https://www.virginia.gov/connect/commonwealth-calendar). Both oral and written comments may be submitted at that time.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

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**	There are no projected costs to the state to implement and enforce the proposed regulation. Any cost for an investigation and adjudication of a complaint would be borne by fees paid to the Board of Medicine by regulants.
Projected cost of the new regulations or changes to existing regulations on localities.	There are no costs to localities.
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	Doctors of medicine, osteopathy, and podiatry who perform office-based procedures utilizing sedation or anesthesia.
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: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	The Board has no estimate of the number who perform surgery in their offices with moderate sedation or deep/general anesthesia and who may be affected. It is likely that most doctors who do office-based surgery are already compliant with these requirements. Currently, there are 36,830 doctors of medicine, 2819 doctors of osteopathy, and 515 doctors of podiatry licensed in Virginia.
All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: **a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and** **b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.**	There are no projected costs for the new regulations which are directed towards better informed consent and physician responsibility.
Beneficial impact the regulation is designed to produce.	Patients who receive sedation or anesthesia in an office-based procedure will have more information and be better protected.

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. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

In the development of proposed regulations, the Board considered 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.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

There are no alternative regulatory methods consistent with public health and safety.

Public comment

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

Commenter	Comment	Agency response
Victoria Vastine, MD Va. Society of Plastic Surgeons	Practitioners are performing more complex procedures in the office. A workgroup, including representatives from plastic surgeons and family physicians, collaborated on the petition submitted by MSV. Strongly supports the draft language in the NOIRA to ensure patient safety.	The Board appreciates the work of the group and has adopted the proposal with minor changes.
Kenneth Wilhelm, DPM Va. Podiatric Medical Assn.	Opposes the limitation on board-certified or board-eligible to only practitioners certified by the ABMS. The proposal excludes podiatrists who are not certified under ABMS. Also, proposes changes to 54.1-2930 to include other specialty boards in podiatry.	The Board adopted an amendment to include the board certification for osteopaths and podiatrists. The request to amend 54.1-2930 cannot be addressed by the Board since it would require a change in the Code of Virginia.
Marc Jay Pinsky, DPM	Same comment as above	Same response as above

Family impact

Please assess the impact of this 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 and family stability.

Detail of changes

*Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please list separately: (1) all differences between the **pre**-emergency regulation and this proposed regulation; and 2) only changes made since the publication of the emergency regulation.*

For changes to existing regulation(s), use this chart:

Current section number	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
320	Sets out the general provisions for the applicability of regulations for office-based anesthesia	An amendment to subsection A (2) would add "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." *Currently the administration of large doses of lidocaine would not fall under the types of sedation or anesthesia that are subject to the requirements of this Part. The recommendation for inclusion was made to protect patients who may be at risk for anesthesia complications with high doses of lidocaine or equivalent doses of local anesthetics.* An amendment to subsection A (3) would specify that the levels of anesthesia or sedation referred to in this chapter shall relate to the level of anesthesia or sedation intended but also documented by the practitioner in the pre-operative anesthesia plan. *It is necessary for the practitioner to document the level of anesthesia intended in the plan developed prior to administration. Otherwise, there is no record of the intent*

		should there be complications or should the level of sedation exceed the intent of the administration. Subsection B (3) is amended to clarify that the discussion concerning the anesthesia plan has occurred with the patient or responsible party pre-operatively. *The intent of the requirement for a discussion of the anesthesia plan has always been that it take place before the procedure and with the patient or responsible party. However, the amendment will make the regulation more definitive.* Subsection B (7) is added to require documentation in the patient record of any complications occurring during surgery or during recovery. *Without documentation, there is no record upon which to rely for patient care and for a possible investigation of a complaint.*
340	Sets out the procedures for the selection of anesthesia or sedation and the evaluation of a patient	The amendment to subsection A (2) specifies that the procedure or combined procedures shall be of a duration and degree of complexity that shall not exceed four hours and that will permit the patient to recover and be discharged from the facility in less than 24 hours. The procedure or combined procedures may be extended for up to eight hours if the anesthesia is provided by an anesthesiologist or a certified registered nurse anesthetist. *Currently, the only limitation on office-based anesthesia or sedation is that the patient is able to recover and be discharged in less than 24 hours. There is no specificity about how long the procedure or combination of procedures should last with the patient sedated or anesthetized. The petition from MSV recommended a limitation of eight hours for the procedure or procedures, but members of the Board felt that length of time presented risk to patients unless the anesthesia was being provided by a specialized professional, namely an anesthesiologist or certified registered nurse anesthetist. Such a professional is solely focused on the anesthesia and better trained to recognize and deal with any possible complications, leaving the physician to focus on the procedure.*
350	Sets out provisions for informed consent in the delivery of office-based anesthesia	An amendment to subsection A adds a requirement for the informed consent with a patient or responsible party must include a discussion of discharge planning and what care or assistance the patient is expected to require after discharge. *MSV and board members agree that the patient is not fully informed unless there has been a discussion of what to expect when the patient is discharged. Such a discussion is part of the continuum of care expected of a responsible*

		physician in performing office-based surgery and anesthesia. Subsection B is added to require that 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 American Board of Medical Specialties boards, the Bureau of Osteopathic Specialists of the American Osteopathic Association, or the American Board of foot and Ankle Surgery. The forms shall either list which board or contain a statement that doctor performing the surgery is not board certified or board eligible. *There is concern that some patients believe they are receiving a surgical procedure from a specialist. The requirement to include information about whether the physician is board-eligible or board-certified is not intended to disqualify general practitioners or family physicians from performing office-based surgery but is intended to ensure that patients are fully informed about the procedure, the anesthesia, and the qualification of the physician.* *In the petition from MSV, only the American Board of Medical Specialties was listed. In response to comment, the Board added specialty boards referenced in the Code for podiatrists and osteopaths.* Subsection C is added a requirement for 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. *The intent of the additional requirement is assurance that the patient is fully informed about the procedure for his protection. The consent form already required a discussion of the risks, benefits, and alternatives in the anesthesia plan, so this additional provision ensures that the patient understands the nature of the procedure.*
370	Sets out the requirements for emergency and transfer protocols	Currently, there is a requirement for written protocols for the timely and safe transfer of patients to a prespecified hospital or hospitals within a reasonable proximity. The amendment will add: 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. The amendment will allow the transfer agreement to be kept in writing or electronically. *The term "reasonable proximity" provided no clear standard for practitioners or for the Board. If complications arise during an office-based procedure, the hospital to which the patient must be transferred should be*

		within 30 minutes or less.
380	Sets out the discharge policies and procedures	An amendment to subsection B will provide that 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. *The amendments will clarify that the responsibility for patient discharge falls to the anesthesia provider or the doctor supervising the anesthetic care.*