Virginia Regulatory Town Hall

Final 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, Chiropractic and Podiatry
Action Title:	Office-based anesthesia
Date:	February 11, 2003

Please refer to the Administrative Process Act (§ 9-6.14:9.1 *et seq.* of the *Code of Virginia*), Executive Order Twenty-Five (98), Executive Order Fifty-Eight (99) , and the *Virginia Register Form,Style and Procedure Manual* for more information and other materials required to be submitted in the final regulatory action package.

Summary

Please provide a brief summary of the new regulation, amendments to an existing regulation, or the regulation being repealed. There is no need to state each provision or amendment; instead give a summary of the regulatory action. If applicable, generally describe the existing regulation. Do not restate the regulation or the purpose and intent of the regulation in the summary. Rather, alert the reader to all substantive matters or changes contained in the proposed new regulation, amendments to an existing regulation, or the regulation being repealed. Please briefly and generally summarize any substantive changes made since the proposed action was published.

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 published a Notice of Intended Regulatory Action to amend its regulations. In addition, Chapter 324 of the 2002 Acts of the Assembly required the Board to "promulgate regulations governing the practice of medicine related to the administration of anesthesia in physicians' offices." Amendments to regulation are necessary 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.

Changes Made Since the Proposed Stage

Please detail any changes, other than strictly editorial changes, made to the text of the proposed regulation since its publication. Please provide citations of the sections of the proposed regulation that have been altered since the proposed stage and a statement of the purpose of each change.

In response to comment on the proposed regulations, the following changes have been made to the text of the proposed regulation since its publication:

18 VAC 85-20-320. General provisions.

Subsection A was amended to add a number 3 in order to clarify that the applicability of the regulation relates to the level of anesthesia or sedation intended by a practitioner in the anesthesia plan for each patient.

Subsection B 6 was amended to clarify that the doctor must be physically present or immediately available to manage complications or emergencies until the patient is discharged. A licensed anesthesia provider may be responsible for the diagnosis and treatment of anesthesia-related problems, but the doctor remains responsible for the patient until discharge.

18 VAC 85-20-330. Qualifications of providers.

Subsection C 1 was amended to give licensees six months from the effective date of the regulations to become certified in advanced resuscitation techniques.

Subsection C 2 was amended to specify that the four hours of continuing education must be in topics “related” to anesthesia, that the hours are a part of the 60 hours required for renewal, and that all hours are subject to a random audit by the Board.

18 VAC 85-20-360. Monitoring.

Subsection B 6 was amended to eliminate the requirement for a paper recorder with a continuous electrocardiograph.

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency: including the date the action was taken, the name of the agency taking the action, and the title of the regulation.

On February 6, 2003, the Board of Medicine adopted final amendments to 18 VAC 85-20-10 et seq., Regulations Governing the Practice of Medicine, Osteopathy, Podiatry & Chiropractic, in order to implement rules related to the administration of anesthesia in physicians' offices.

Basis

Please identify the state and/or federal source of legal authority to promulgate the regulation. The discussion of this statutory authority should: 1) describe its scope and the extent to which it is mandatory or discretionary; and 2) include a brief statement relating the content of the statutory authority to the specific regulation. In addition, where applicable, please describe the extent to which proposed changes exceed federal minimum requirements. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority, shall be provided. If the final text differs from that of the proposed, please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the final regulation and that it comports with applicable state and/or federal law

Chapter 24 establishes the general powers and duties of health regulatory boards including the responsibility to promulgate regulations, levy fees, administer a licensure and renewal program, and discipline regulated professionals.

§ 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.*
2. *To examine or cause to be examined applicants for certification or licensure. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.*
3. *To register, certify or license qualified applicants as practitioners of the particular profession or professions regulated by such board.*
4. *To establish schedules for renewals of registration, certification and licensure.*
5. *To levy and collect fees for application processing, examination, registration, certification or licensure and renewal that are sufficient to cover all expenses for the administration and operation of the Department of Health Professions, the Board of Health Professions and the health regulatory boards.*
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 and Chapter 25 of this title.*
7. *To revoke, suspend, restrict, or refuse to issue or renew a registration, certificate or license which such board has authority to issue for causes enumerated in applicable law and regulations.*
8. *To appoint designees from their membership or immediate staff to coordinate with the Intervention Program Committee and to implement, as is necessary, the provisions of Chapter 25.1 (§ 54.1-2515 et seq.) of this title. Each health regulatory board shall appoint one such designee.*
9. *To take appropriate disciplinary action for violations of applicable law and regulations.*
10. *To appoint a special conference committee, composed of not less than two members of a health regulatory board, to act in accordance with § 9-6.14:11 upon receipt of information that a practitioner of the appropriate board may be subject to disciplinary action. The special conference committee may (i) exonerate the practitioner; (ii) reinstate the practitioner; (iii) place the practitioner on probation with such terms as it may deem appropriate; (iv) reprimand the practitioner; (v) modify a previous order; and (vi) impose a monetary penalty*

pursuant to § 54.1-2401. The order of the special conference committee shall become final thirty days after service of the order unless a written request to the board for a hearing is received within such time. If service of the decision to a party is accomplished by mail, three days shall be added to the thirty-day period. Upon receiving a timely written request for a hearing, the board or a panel of the board shall then proceed with a hearing as provided in § 9-6.14:12, and the action of the committee shall be vacated. This subdivision shall not be construed to affect the authority or procedures of the Boards of Medicine and Nursing pursuant to §§ 54.1-2919 and 54.1-3010.

11. *To convene, at their discretion, a panel consisting of at least five board members or, if a quorum of the board is less than five members, consisting of a quorum of the members to conduct formal proceedings pursuant to § 9-6.14:12, decide the case, and issue a final agency case decision. Any decision rendered by majority vote of such panel shall have the same effect as if made by the full board and shall be subject to court review in accordance with the Administrative Process Act. No member who participates in an informal proceeding conducted in accordance with § 9-6.14:11 shall serve on a panel conducting formal proceedings pursuant to § 9-6.14:12 to consider the same matter.*
12. *To issue inactive licenses and certificates and promulgate regulations to carry out such purpose. Such regulations shall include, but not be limited to, the qualifications, renewal fees, and conditions for reactivation of such licenses or certificates.*

The specific mandate to promulgate regulation for office-based anesthesia is found in:

§ 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 by letter that the Board has the statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

Purpose

Please provide a statement explaining the need for the new or amended regulation. This statement must include the rationale or justification of the final regulatory action and detail the specific reasons it is

essential to protect the health, safety or welfare of citizens. A statement of a general nature is not acceptable, particular rationales must be explicitly discussed. Please include a discussion of the goals of the proposal and the problems the proposal is intended to solve.

In 1999, a letter to the Board of Medicine from the Medical Society of Virginia stated that there is a growing concern for patients and that the Board is the appropriate agency to ensure that anesthetic services delivered in non-hospital settings are delivered in the safest environment possible. It was their position that such regulations would provide the necessary oversight without the burdensome requirement of licensure under a state agency. In response, the Board has adopted regulations to provide some assurance that moderate or general anesthesia is being delivered and monitored by qualified practitioners, who have appropriately selected the level of anesthesia, informed the patient about anesthesia, and are adequately equipped and prepared to handle any emergency that might arise.

The Board did not choose to regulate the surgical practice or the office in which the anesthesia is being performed, nor does the Board intend to license or inspect the premises where office-based anesthesia is being performed. It was careful to address regulations to the narrow intent of the law and its own notice of intended regulatory action. Likewise, the Board did not address the practice of anesthesia by certified registered nurse anesthetists, since that profession is jointly regulated with the Board of Nursing under a different set of regulations. The purpose of this regulation was to clearly establish the responsibility of the doctor providing anesthesia or supervising the delivery of anesthesia for the safety and well-being of the patient. Thus it is the doctor's responsibility to ensure that patient health and safety is adequately protected when anesthesia is being delivered in an office-based setting.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. Please note that a more detailed discussion is required under the statement of the regulatory action's detail.

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.

Issues

Please provide a statement identifying the issues associated with the final regulatory action. The term "issues" means: 1) the advantages and disadvantages to the public of implementing the new provisions; 2) the 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 include a sentence to that effect.

Advantages and disadvantages to the public:

With the proliferation of out-patient surgery and procedures requiring anesthesia, there has been a growing concern about the safety of patients in an unregulated environment. Most doctors practice with an accepted standard of care, including utilizing licensed anesthesia providers, equipping their offices with essential rescue and monitoring equipment, and carefully selecting the appropriate anesthesia and inform the patient in advance. But the medical community is well aware of serious complications resulting from lesser standards of care in out-patient settings. Therefore, these regulations will provide a clearer standard by which doctors are expected to practice and give patients a higher degree of safety when receiving office-based anesthesia. As insurers and physicians encourage more procedures to be performed in an office-based practice or surgi-center rather than a hospital, these regulations will provide a definite advantage to patients, who typically do not have sufficient knowledge to judge whether the doctor and the facility are appropriately equipped and trained and whether adequate care is being taken to prepare and monitor their recovery. Since the regulations do not apply to the more common and less risky forms of anesthesia or sedation, there should be no disadvantages to the public in terms of limiting access or increasing cost.

Advantages and disadvantages to the agency:

There are no specific advantages or disadvantages to the agency. Regulations that set standards for practice may create an opportunity for complaints for non-compliance, but under current laws and regulations, failure to appropriately provide and monitor anesthesia could be considered substandard care and subject the licensee to disciplinary action. The advantage of these regulations is derived from having a more objective standard on which to base such a decision or

make findings in a disciplinary case involving anesthesia. However, with more objective rules to follow, practitioners who are conscientious about their practice and protecting their patients should be able to avoid incidents of unprofessional conduct related to delivery of anesthesia.

Public Comment

Please summarize all public comment received during the public comment period and provide the agency response. If no public comment was received, please include a statement indicating that fact.

Proposed regulations were published in the Virginia Register of Regulations on September 23, 2002. Public comment was requested for a 60-day period ending November 22, 2002. The following written comment was received:

From five individuals or gastroenterology practice groups and the Virginia Gastroenterology Society:

1) Noted that conscious sedation is the intent in performance of endoscopic procedures with the armamentarium of agents used, but occasionally a patient can slip into deep sedation, requiring reversal agents. Under the proposed regulations, there is concern that a physician can unintentionally violate the rules for administration of deep sedation. Suggests that endoscopic procedures be exempt from rules on conscious sedation or that rule be modified to indicate the intent of the sedation. Noted use of propofol and growing database suggesting that non-anesthesiologists can administer drug safely.

> ***Board response:*** *As recommended by the Ad Hoc Committee on Office-Based Anesthesia ("Committee"), the Board has amended the proposed regulation to clarify that for purposes of compliance with requirements, the level of anesthesia or sedation is whatever was intended for the patient in the anesthesia plan. The Board does not recommend exemption of any specific procedures since the regulations are intended for the delivery of anesthesia in an office-based setting.*

2) Agreed that ACLS should be the standard for training for all physicians administering office-based anesthesia, but requested some period of time in which to comply, suggesting 6 months as sufficient time to have people trained.

> ***Board response****: The Board has amended subsection C of section 330 to specify that practitioners have six months to comply with the requirement for certification in advanced resuscitation techniques.*

3) Requested more specificity about the 4 hours required for continuing education in administration of anesthesia. Suggested that the Board develop an educational module for doctors that would include pharmacology, administration, potential complications, monitoring and other related topics. Also requested an effective date by which the 4 hours would be required.

> ***Board response:*** *The Committee and the Board did not recommend additional specificity about the continuing education requirement, other than to clarify that the hours must pertain to topics related to anesthesia. It also added language to make it clear that the 4 hours are a part of the 60 hours required for licensure renewal and not over and above and that all hours are subject to random audit.*

4) Suggested that the regulation specifically include Endoscopy with specific examples to prevent misinterpretation.

Board response: *The Board does not recommend reference to any specific procedures since the regulations are intended for the delivery of anesthesia in an office-based setting.*

From a nurse anesthetist, two physicians and the Virginia Association of Nurse Anesthetists:

Objected to regulation requiring doctor to remain physically present or immediately available to diagnose and treat anesthesia-related problems or complications (320 B 6). The implication is that all physicians (even though with a nurse anesthetists in charge of the anesthesia) would have to have training in diagnosing and treating anesthesia related problems. Provision appears contradictory with requirements in section 360. Suggested amendment to require that the physician ensure that appropriate anesthesia trained personnel remain available to diagnose and treat complications.

Board response: ***The Committee and the Board recommended an amendment to section 320 B 6 to clarify that the doctor is responsible for managing complications and emergencies until discharge criteria have been met. That responsibility is more clearly spelled out in sections 360 and 380.***

From a family practice in White Stone:

1) Regulation requires a paper record of the EKG and that is not current practice; doctors get a continuous reading from the EKG.

Board response: *An amendment to section 360 eliminating the requirement of a paper recorder has been adopted in response to the comment.*

2) Regulations should allow medical assistants to administer conscious sedation under supervision.

Board response: *The Committee and the Board did not agree with the comment that medical assistants, who are unregulated and unlicensed, should be allowed to administer conscious sedation. Regulations require that to be done by a licensed doctor, with a registered nurse assisting and monitoring the patient, or the sedation could be provided by a nurse anesthetist.*

3) Questioned what is considered a reasonable distance for transfer to a hospital (could be across the Bay from Tangier Island.

Board response: *Regulations require a written protocol for handling emergency situations and for the transfer of patients to a pre-specified hospital within reasonable proximity. For patients on Tangier Island, reasonable proximity would be across the Chesapeake Bay.*

4) Questioned whether CME has to be face-to-face.

Board response: *There is no requirement that the required CME for anesthesia be face-to-face or even that it be category 1.*

From the President of Mid-Atlantic Permanente Medical Group:

1) Noted that monitoring techniques may have to be updated from time to time & suggested incorporation of ASA "Guidelines for Non-operating Room Anesthetizing Locations."

Board response: *The Committee reviewed the guidelines and requirements of several related organizations or credentials bodies but recommended that the Board not tie its regulations to any of those.*

2) Suggested that physicians who administer anesthesia obtain CME specifically in airway management and in monitoring.

Board response: *The Board considered several requests for more specificity about continuing education requirements but chose to permit the practitioner to select those courses or activities that are directly related to his use of anesthesia or sedation. Current certification in ACLS is required, so airway management and monitoring should be topics covered.*

From a group of nephrologists:
Suggested that ESRD patients (those receiving de-clotting shunts under conscious sedation) be exempt.

Board response: *ESRD patients generally have health problems that necessitate additional caution with the administration of any anesthesia or sedation. In addition, the regulations are not procedure-specific, so the Board does not recommend an exemption from these requirements for any particular procedure.*

From the Joint Commission of Accreditation of Healthcare Organizations:
Requested that the Board recognize their office-based surgery accreditation program in lieu of compliance with regulations.

Board response: *The Committee reviewed the guidelines and requirements of several related organizations or credentialing bodies but recommended that the Board not tie its regulations to any of those. Any practice that is accredited for office-based surgery by JCAHO would meet the requirements of the Board.*

From the Medical Society of Virginia:
Noted that regulations should not impede safe practices or clinical and technological advances; concurs with the recommendations and comments of the gastroenterologists.

Board response: *See response to comments above.*

A Public Hearing before the Board was held on October 10, 2002, at which time there was comment from two persons on the proposed rules.

Representative of the Virginia Association of Nurse Anesthetists:
Objected to regulation requiring doctor to remain physically present or immediately available to diagnose and treat anesthesia-related problems or complications (320 B 6). The implication is that all physicians (even though with a nurse anesthetists in charge of the anesthesia) would have to have training in diagnosing and treating anesthesia related problems. Suggested amendment to require that the physician ensure that appropriate anesthesia trained personnel remain available to diagnose and treat complications.

Board response: See response to comments above.

Representative of University of Virginia Medical Center:
Expressed concern that clinics associated with and contiguous to hospitals might fall under these regulations. Suggested that the Board add after hospitals in the definition of "office-based" the following language: "and their associated, contiguous clinics with immediate access to anesthesia services available within two minutes."

Board response: *In the adoption of emergency regulations on December 13, 2002, the Board voted to include such language. However, the Committee did not recommend that change in the proposed regulation based on three factors: 1) the clinics should be able to meet the minimal requirements of these regulations; 2) not all hospitals have anesthesia or emergency services available at all times; and 3) the proximity to the main hospital could be applicable to any facility, related or non-related. For consistency and patient safety, the Board did not change the proposed definition of "office-based."*

Detail of Changes

Please detail any changes, other than strictly editorial changes, that are being proposed. Please detail new substantive provisions, all substantive changes to existing sections, or both where appropriate. This statement should provide a section-by-section description - or crosswalk - of changes implemented by the proposed regulatory action. Include citations to the specific sections of an existing regulation being amended and explain the consequences of the changes.

The following new sections of regulation for Part VII, Office-Based Anesthesia are being promulgated:

18 VAC 85-20-310. Definitions.

Terms used in Part VII are defined as necessary for clarity and compliance with the requirements of these regulations. They include the following: *advanced resuscitative techniques; deep sedation; general anesthesia; local anesthesia; minimal sedation/anxiolysis; moderate sedation /conscious sedation; monitoring; office-based;* p*hysical status classification; regional anesthesia*; *minor conductive block; major conductive block; and topical anesthesia.* The definition of "office-based" clarifies that these regulations do not apply to licensed hospitals or facility directly maintained or operated by the federal government.

18 VAC 85-20-320. General provisions.

General provisions establish the applicability of requirements for office-based anesthesia to exclude 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 pre-operative tranquilization. The administration of moderate sedation/ conscious sedation, deep sedation, general anesthesia, or regional anesthesia consisting of a major conductive block are subject to requirements for office-based anesthesia.

The general responsibilities of a doctor of medicine, osteopathic medicine, or podiatry administering office-based anesthesia or supervising such administration are set forth, and a requirement is established for written policies, procedures and protocols office-based anesthesia to be maintained and available for inspection at the facility.

Subsection A was amended to add a number 3 in order to clarify that the applicability of the regulation relates to the level of anesthesia or sedation intended by a practitioner in the anesthesia plan for each patient.

Subsection B 6 was amended to clarify that the doctor must be physically present or immediately available to manage complications or emergencies until the patient is discharged. A licensed anesthesia provider may be responsible for the diagnosis and treatment of anesthesia-related problems, but the doctor remains responsible for the patient until discharge.

18 VAC 85-20-330. Qualifications of providers.

Doctors who utilize office-based anesthesia must ensure that all medical personnel assisting in providing patient care are appropriately trained, qualified and supervised, are sufficient in numbers to provide adequate care, and maintain training in basic cardiopulmonary resuscitation. Providers of office-based anesthesia must hold the appropriate license and have the necessary training and skills to deliver the level of anesthesia being provided. If deep sedation, general anesthesia or a major conductive block is being administered, it must be by an anesthesiologist or by a certified registered nurse anesthetist. Moderate sedation/conscious sedation may be administered by the operating doctor with the assistance of and monitoring by a licensed nurse, a physician assistant or a licensed intern or resident.

There are also requirements for additional training for the doctor who provides office-based anesthesia or who supervises the administration of anesthesia. They are required to maintain current certification in advanced resuscitation techniques, and any doctor who administers office-based anesthesia without the use of an anesthesiologist or certified registered nurse anesthetist is required to obtain four hours of continuing education in anesthesia each biennium (out of the 60 hours already required for renewal of licensure).

Subsection C 1 was amended to give licensees six months from the effective date of the regulations to become certified in advanced resuscitation techniques.

Subsection C 2 was amended to specify that the four hours of continuing education must be in topics “related” to anesthesia, that the hours are a part of the 60 hours required for renewal, and that all hours are subject to a random audit by the Board.

18 VAC 85-20-340. Procedure/anesthesia selection and patient evaluation.

A written protocol is required for procedure selection to include but not be limited to a provision stating that the doctor providing or supervising the anesthesia is responsible for ensuring that the procedure to be undertaken is within the scope of practice of the health care practitioners and the capabilities of the facility; that the procedure is of a duration and degree of complexity that will permit the patient to recover and be discharged from the facility in less than 24 hours; and that the level of anesthesia used is appropriate for the patient, the surgical procedure, the clinical setting, the education and training of the personnel, and the equipment available.

A written protocol for patient evaluation is also required to include but not be limited to the performance of a pre-operative anesthesia evaluation of a patient by the health care practitioner administering the anesthesia or supervising the administration of anesthesia, consisting of an appropriate history and physical examination, a determination of the patient's physical status classification, development of a plan of anesthesia care, and making the patient or the responsible individual familiar with the proposed plan and the risks and benefits of anesthesia.

The condition of the patient, specific morbidities that complicate anesthetic management, the specific intrinsic risks involved, and the nature of the planned procedure must be considered in evaluating a patient for office-based anesthesia. Patients who have pre-existing medical or other conditions that may be of particular risk for complications must be referred to a facility appropriate for the procedure and administration of anesthesia. Office-based anesthesia can only be provided for patients in physical status classifications for Classes I, II and III. Patients in Classes IV and V cannot be provided anesthesia in an office-based setting.

18 VAC 85-20-350. Informed consent.

Prior to administration, the anesthesia plan must 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 and the name of the anesthesia providers must be in writing and obtained from the patient or responsible party before the procedure is performed.

18 VAC 85-20-360. Monitoring.

Section 360 establishes requirements for monitoring, including equipment that is appropriate for the type of anesthesia and the nature of the facility. At a minimum, provisions shall be made for a reliable source of oxygen, suction, resuscitation equipment and emergency drugs. All equipment must be maintained, tested and inspected according to manufacturer's specifications with back-up power sufficient to ensure patient protection in the event of an emergency. When anesthesia services are provided to infants and children, the required equipment, medication and resuscitative capabilities must be appropriately sized and calibrated for children.

To administer office-based moderate sedation/ conscious sedation, the regulations list the minimal equipment, supplies and pharmacological agents required. In addition to those requirements, there are requirements equipment, supplies and pharmacological agents for the administration of general anesthesia, deep sedation or major conductive blocks.

A written protocol must be developed for monitoring procedures to include physiologic monitoring of patients appropriate for the type of anesthesia and individual patient needs. Intra-operative patient evaluation must include continuous clinical observation and continuous anesthesia monitoring. A health care practitioner administering general anesthesia or deep sedation is required to remain present and available in the facility to monitor a patient until the patient meets the discharge criteria. A health care practitioner administering moderate sedation/conscious sedation is required to routinely monitor a patient according to procedures consistent with such administration.

Subsection B 6 was amended to eliminate the requirement for a paper recorder with a continuous electrocardiograph.

18 VAC 85-20-370. Emergency and transfer protocols.

There is a requirement for written protocols for handling emergency situations, including medical emergencies and internal and external disasters. All personnel must be appropriately trained in and regularly review the protocols and the equipment and procedures for handing emergencies. There must also be written protocols for the transfer of patients to a pre-specified hospital or hospitals within a reasonable proximity and a transfer agreement with such hospital or hospitals.

18 VAC 85-20-380. Discharge policies and procedures.

Section 380 requires written policies and procedures outlining discharge criteria to include stable vital signs, responsiveness and orientation, ability to move voluntarily, controlled pain, and minimal nausea and vomiting. Discharge from anesthesia care is the responsibility the health care practitioner providing the anesthesia care and may only occur when patients have met specific physician-defined criteria. Patients must be given written instructions and an emergency phone number and only discharged with a responsible individual who has been instructed with regard to the patient's care. At least one person trained in advanced resuscitative techniques must be immediately available until all patients are discharged.

18 VAC 85-20-390. Reporting requirements.

The doctor administering the anesthesia or supervising such administration is required to report to the board within 30 days any incident relating to the administration of anesthesia that results in patient death, either intraoperatively or within the immediate 72-hour postoperative period or in transport of a patient to a hospital for a stay of more than 24 hours.

Family Impact Statement

Please provide an analysis of the regulatory action that assesses the impact on the institution of the family and family stability including the extent to which 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.

This regulatory action will 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.