Virginia Regulatory Town Hall

Proposed 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:	6/20/02

This information is required pursuant 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*. Please refer to these sources for more information and other materials required to be submitted in the regulatory review package.

Summary

Please provide a brief summary of the proposed new regulation, proposed amendments to an existing regulation, or the regulation proposed to be repealed. There is no need to state each provision or amendment or restate the purpose and intent of the regulation; instead give a summary of the regulatory action and alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

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 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.

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 must be provided. Please state that the Office of the Attorney General has certified that the agency has the statutory authority to promulgate the proposed 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 proposed 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 providing detail of the regulatory action's changes.

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 proposed regulatory action. The term "issues" means: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If 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.

Fiscal Impact

Please identify the anticipated fiscal impacts and at a minimum include: (a) the projected cost to the state to implement and enforce the proposed regulation, including (i) fund source / fund detail, (ii) budget activity with a cross-reference to program and subprogram, and (iii) a delineation of one-time versus on-going expenditures; (b) the projected cost of the regulation on localities; (c) a description of the individuals, businesses or other entities that are likely to be affected by the regulation; (d) the agency's best estimate of the number of such entities that will be affected; and e) the projected cost of the regulation for affected individuals, businesses, or other entities.

Projected cost to the state to implement and enforce:

(i) Fund source: As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners for necessary functions of regulation.

(ii) Budget activity by program or subprogram: There is no change required in the budget of the Commonwealth as a result of this program.

(iii) One-time versus ongoing expenditures: The agency will incur some one-time costs (less than $5,000) for meetings of the advisory committee, mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending copies of final regulations to regulated entities. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled.

Projected cost on localities:

There are no projected costs to localities.

Description of entities that are likely to be affected by regulation:

The entities that are likely to be affected by these regulations would be licensed doctors of medicine, osteopathy, or podiatry who administer anesthesia in an office-based setting.

Estimate of number of entities to be affected:

Currently, there are 28,283 persons licensed doctors of medicine and surgery, 886 licensed as doctors of osteopathic medicine, and 494 licensed as doctors of podiatry.

Projected costs to the affected entities:

The cost for compliance will vary depending on the practitioner and the level of anesthesia administered in an office-based setting. The regulations will have no effect on the vast majority of doctors who do not use anesthesia in their practice, administer anesthesia or supervise the administration of anesthesia only in a hospital, or only utilize minimal sedation, local or topical anesthesia or minor conductive blocks. For most practitioners covered by these regulations, there should be no additional cost. Many out-patient surgery centers or physician practices are accredited or in the process of seeking accreditation by national credentialing agencies for out-patient surgery (such as Joint Commission (JACHO) for ambulatory accreditation under the Office-Based Surgery standards, 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 such accreditation are more stringent than those set forth in these regulations, so any doctor practicing in an accredited facility could comply with regulations with no additional expense.

Doctors who utilize office-based moderate sedation, deep sedation or general anesthesia may have some added cost if their practices are not appropriately equipped. If a doctor does not currently maintain the basic equipment required for monitoring patients under deep sedation or general anesthesia, he may not be practicing according to an accepted standard for anesthesia care. It would be necessary for such a practitioner to acquire the necessary drugs, equipment or supplies to comply with these regulations, but patients would be better protected and unfortunate consequences may be avoided.

Doctors who are required to obtain four hours of continuing education in anesthesia would incur no additional cost, because those hours are included in the 60 hours per biennium already required for licensure. They may have to redirect some of their hours to the subject of anesthesia, but no additional hours are required. Most doctors already maintain training in advanced resuscitative techniques, whether they perform surgery or not. If not certified in ACLS or PALS, the cost for training is minimal and is usually available through the local hospital. Finally, it may be necessary for a doctor who supervises or administers anesthesia to develop written policies and procedures, but such an exercise is necessary to ensure steps have been taken before, during and after the delivery of anesthesia to follow acceptable standards of care.

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 cross-walk - of changes implemented by the proposed regulatory action. Where applicable, include citations to the specific sections of an existing regulation being amended and explain the consequences of the proposed 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.

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).

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.

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.

Alternatives

Please describe the specific 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.

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.

The initial approach to adoption of regulation for outpatient (office-based) anesthesia 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.

Public Comment

Please summarize all public comment received during the NOIRA comment period and provide the agency response.

An announcement of the board's intent to amend its regulations was posted on the Virginia Regulatory Townhall, sent to the Registrar of Regulations, and sent to persons on the PPG mailing list for the board. Public comment was received from November 19, 2001 through December 19, 2001. During the 30-day comment period, the following comments were received:

Virginia Society of Anesthesiologists (Brian Ball) provided a substantial amount of information on anesthesia standards and offered assistance in the development of regulations.

Virginia Association of Nurse Anesthetists (Lorraine Christ, CRNA) provided information on the standards for office-based practice developed by the American Association of Nurse Anesthetists and encouraged the board to consider valid patient safety issues, access to care and cost of care in developing regulations. The commenter also offered assistance in the development of regulations.

Clarity of the Regulation

Please provide a statement indicating that the agency, through examination of the regulation and relevant public comments, has determined that the regulation is clearly written and easily understandable by the individuals and entities affected.

An advisory committee, comprised of the President of the Board (who is a doctor with a specialty in gynecology), a doctor of podiatry, a certified registered nurse anesthetist, a doctor of osteopathy and a doctor of medicine who are anesthesiologists, and a doctor of medicine who is a plastic surgeon met on four occasions to work on draft regulations. In addition, representatives of various practice groups/associations were involved in the development of regulations and circulated working drafts throughout the process. Proposed regulations adopted by the Board had been edited and modified numerous times during development of proposed regulations. The Assistant Attorney General who provides counsel to the Board has been involved during the discussion on adoption of proposed regulations to ensure clarity and compliance with law and regulation.

Periodic Review

Please supply a schedule setting forth when the agency will initiate a review and re-evaluation to determine if the regulation should be continued, amended, or terminated. The specific and measurable regulatory goals should be outlined with this schedule. The review shall take place no later than three years after the proposed regulation is expected to be effective.

Public participation guidelines require the Board to review regulations each biennium or as required by Executive Order. Regulations will be reviewed again during the 2004-05 fiscal year.

Family Impact Statement

Please provide an analysis of the proposed regulatory action that assesses the potential 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.

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.