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Notice of Intended Regulatory Action Agency Background Document

Agency Name:	Board of Medicine, Department of Health Professions
VAC Chapter Number:	18 VAC 85-20-10 et seq.
Regulation Title:	Regulations Governing the Practice of Medicine, Osteopathy, Podiatry, Chiropractic and Physician Acupuncture
Action Title:	Anesthetic services in physician's offices
Date:	02/23/2000

This information is required prior to the submission to the Registrar of Regulations of a Notice of Intended Regulatory Action (NOIRA) pursuant to the Administrative Process Act § 9-6.14:7.1 (B). Please refer to Executive Order Twenty-Five (98) and Executive Order Fifty-Eight (99) for more information.

Purpose

Please describe the subject matter and intent of the planned regulation. This description should include a brief explanation of the need for and the goals of the new or amended regulation.

The Board of Medicine is seeking to respond to a petition for rule-making concerning the use of anesthesia in physician offices, ambulatory surgery centers and other non-hospital settings. At its annual meeting in 1999, the Medicine Society of Virginia adopted a resolution requesting the Board to define as unprofessional conduct "the practice of delivering certain anesthetic services (i.e., general or IV conscious sedation) in the physician's office without the necessary monitoring and resuscitation equipment, drugs and personnel consistent with the prevailing practice in the Commonwealth." The letter from MSV stated that there is a growing concern for patients and that the Board of Medicine is the appropriate agency to ensure that anesthetic services delivered in non-hospital settings are delivered in the safest environment possible. It is their position that such regulations would provide the necessary oversight without the burdensome requirement of licensure under a state agency.

In addition, the Board has received a letter from a law firm representing a group of physicians who want to perform a variety of minor surgical procedures in an office setting. They have been informed by the Department of Health that they must demonstrate assurances that the surgical procedures they wish to perform without licensure as an outpatient surgical hospital are

considered by the Board of Medicine to be able to be safely performed within the context of a physician office setting. Since the Board of Medicine has no regulations on procedures that may safely be performed by outpatient surgery or on the use of anesthesia in physician's offices, it was unable to provide such guidance or assurances. Consequently, the Board seeks to publish a Notice of Intended Regulatory Action to address the concerns of the Medical Society and to consider regulations which will provide guidance on the delivery of outpatient surgical services in physicians' offices.

Basis

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Please identify the state and/or federal source of legal authority to promulgate the contemplated regulation. The discussion of this authority should include a description of its scope and the extent to which the authority is mandatory or discretionary. The correlation between the proposed regulatory action and the legal authority identified above should be explained. Full citations of legal authority and, if available, web site addresses for locating the text of the cited authority must be provided.

18 VAC 85-20-10 et seq. Regulations Governing the Practice of Medicine, Osteopathy, Podiatry, Chiropractic and Physician Acupuncture were promulgated under the general authority of Title 54.1 of the Code of Virginia.

Chapter 24 establishes the general powers and duties of health regulatory boards including the responsibility to promulgate regulations.

§ 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.

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- 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 statutory authority for the Board to determine unprofessional conduct is found in:

§ 54.1-2914. Unprofessional conduct.

- A. Any practitioner of the healing arts regulated by the Board shall be considered guilty of unprofessional conduct if he:
- 1. Undertakes in any manner or by any means whatsoever to procure or perform or to aid or abet in procuring or performing a criminal abortion;

2. Engages in the practice of any of the healing arts under a false or assumed name, or impersonates another practitioner of a like, similar or different name;

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- 3. Prescribes or dispenses any controlled substance with intent or knowledge that it will be used otherwise than medicinally, or for accepted therapeutic purposes, or with intent to evade any law with respect to the sale, use or disposition of such drug;
- 4. Violates provisions of this chapter on division of fees or practices any branch of the healing arts in violation of the provisions of this chapter;
- 5. Being a practitioner of physical therapy, undertakes to practice physical therapy, independently of the referral and direction of a duly licensed doctor of medicine, osteopathy, chiropractic, podiatry, or dental surgery;
- 6. Being a licensed physical therapist assistant, undertakes to practice independently without direction of a physical therapist or under his supervision or control;
- 7. Knowingly and willfully commits any act which is a felony under the laws of this Commonwealth or the United States, or any act which is a misdemeanor under such laws and involves moral turpitude;
- 8. Aids or abets, has professional connection with, or lends his name to any person known to him to be practicing illegally any of the healing arts;
- 9. Conducts his practice in a manner contrary to the standards of ethics of his branch of the healing arts; 10. Conducts his practice in such a manner as to be a danger to the health and welfare of his patients or to the public;
- 11. Is unable to practice with reasonable skill or safety because of illness or substance abuse;
- 12. Publishes in any manner an advertisement relating to his professional practice which contains a claim of superiority or violates Board regulations governing advertising;
- 13. Performs any act likely to deceive, defraud or harm the public;
- 14. Violates any provision of statute or regulation, state or federal, relating to the manufacture, distribution, dispensing or administration of drugs;
- 15. Violates or cooperates with others in violating any of the provisions of this chapter or regulations of the Board; or
- 16. Engages in sexual contact with a patient concurrent with and by virtue of the practitioner/patient relationship or otherwise engages at any time during the course of the practitioner/patient relationship in conduct of a sexual nature that a reasonable patient would consider lewd and offensive.
- B. A practitioner of the healing arts shall not engage in selling controlled substances unless he is licensed to do so by the Board of Pharmacy. However, this prohibition shall not apply to a doctor of medicine, osteopathy or podiatry who administers controlled substances to his patients or provides controlled substances to his patient in a bona fide medical emergency or when pharmaceutical services are not available. Practitioners who sell or dispense controlled substances shall be subject to inspection by the Department of Health Professions to ensure compliance with Chapters 33 (§ 54.1-3300 et seq.) and 34 (§ 54.1-3400 et seq.) of this title and the Board of Pharmacy's regulations. This subsection shall not apply to physicians acting on behalf of the Virginia Department of Health or local health departments.
- C. A practitioner of the healing arts who may lawfully sell medical appliances or devices shall not sell such appliances or devices to persons who are not his own patients and shall not sell such articles to his own patients either for his own convenience or for the purpose of supplementing his income. This subsection shall not apply to physicians acting on behalf of the Virginia Department of Health or local health departments.
- D. A practitioner of the healing arts may, from within the practitioner's office, engage in selling or promoting the sale of eyeglasses and may dispense contact lenses. Only those practitioners of the healing arts who engage in the examination of eyes and prescribing of eyeglasses may engage in the sale or promotion of eyeglasses. Practitioners shall not employ any unlicensed person to fill prescriptions for eyeglasses within the practitioner's office except as provided in subdivision 6 of § 54.1-2901. A practitioner may also own, in whole or in part, an optical dispensary located adjacent to or at a distance from his office.

E. Any practitioner of the healing arts engaging in the examination of eyes and prescribing of eyeglasses shall give the patient a copy of any prescription for eyeglasses and inform the patient of his right to have the prescription filled at the establishment of his choice. No practitioner who owns, in whole or in part, an establishment dispensing eyeglasses shall make any statement or take any action, directly or indirectly, that infringes on the patient's right to have a prescription filled at an establishment other than the one in which the practitioner has an ownership interest.

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Disclosure of ownership interest by a practitioner as required by § 54.1-2964 or participation by the practitioner in contractual arrangements with third-party payors or purchasers of vision care services shall not constitute a violation of this subsection.

§ 54.1-2915. Refusal; suspension or revocation; other disciplinary actions.

- A. The Board may refuse to admit a candidate to any examination, refuse to issue a certificate or license to any applicant, and may suspend for a stated period of time or indefinitely, or revoke any certificate or license or censure or reprimand any person or place him on probation for such time as it may designate for any of the following causes:
- 1. False statements or representations or fraud or deceit in obtaining admission to the practice, or fraud or deceit in the practice of any branch of the healing arts;
- 2. Substance abuse rendering him unfit for the performance of his professional obligations and duties;
- 3. Unprofessional conduct as defined in this chapter;
- 4. Gross ignorance or carelessness in his practice, or gross malpractice;
- 5. Mental or physical incapacity or incompetence to practice his profession with safety to his patients and the public;
- 6. Restriction of a license to practice a branch of the healing arts in another state, the District of Columbia, a United States possession or territory, or a foreign jurisdiction.

The Board shall refuse to admit a candidate to any examination and shall refuse to issue a certificate or license to any applicant if the candidate or applicant has had his certificate or license to practice a branch of the healing arts revoked or suspended, and has not had his certificate or license to so practice reinstated, in another state, the District of Columbia, a United States possession or territory, or a foreign jurisdiction.

B. The Board may direct any licensee under a disciplinary order to furnish it at such intervals as it may require, evidence that he is not practicing his profession in violation of this chapter. In addition, when the Board has probable cause to believe the licensee unable to practice the healing arts with reasonable skill and safety to patients because of excessive use of alcohol or drugs or physical or mental illness, the Board, after preliminary investigation by informal conference, may direct that the licensee submit to a mental or physical examination by physicians designated by it. Failure of the licensee to submit to the examination shall constitute grounds for disciplinary action. Any licensee affected by this subsection shall be afforded reasonable opportunity to demonstrate that he is competent to practice the healing arts with reasonable skill and safety to patients.

§ 54.1-2916. Additional grounds for refusal; suspension or revocation.

- A. The Board may refuse to admit a candidate to any examination, refuse to issue a license or a certificate to any applicant, and suspend or revoke any certificate or license if it finds that the candidate, applicant or licensee:
- 1. Has been convicted in any state, territory or country of any felony or of any crime involving moral turpitude;
- 2. Has been adjudged legally incompetent or incapacitated in any state if such adjudication is in effect and the person has not been declared restored to competence or capacity.
- B. The conviction of an offense in another state, territory or country, which if committed in Virginia would be a felony, shall be treated as a felony conviction under this section regardless of its designation in the other state, territory or country.

Substance

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Please detail any changes that would be implemented: this discussion should include a summary of the proposed regulatory action where a new regulation is being promulgated; where existing provisions of a regulation are being amended, the statement should explain how the existing regulation will be changed. The statement should set forth the specific reasons the agency has determined that the proposed regulatory action would be essential to protect the health, safety or welfare of citizens. In addition, a statement delineating any potential issues that may need to be addressed as the regulation is developed shall be supplied.

The Board has not determined the exact nature of the regulatory action to be taken - it may consist of a statement about unprofessional conduct in Part II that reflects the wording in the petition from the Medical Society of Virginia. In order to respond to a concern by the Department of Health and other parties about the appropriateness of certain procedures for outpatient surgery and the necessary equipment and qualifications of those persons providing care, the Board may need to provide guidance about the standard of care for delivery of such services. The Board will consider the comments it receives from interested parties as a result of publication of the Notice of Intended Regulatory Action to determine the appropriate regulatory action.

Alternatives

Please describe, to the extent known, the specific alternatives to the proposal that have been considered or will be considered to meet the essential purpose of the action.

The Board of Medicine generally relies on provisions of §§ 54.1-2914, 54.1-2915 or 54.1-2916 in making a determination to take disciplinary action against a licensee. In those sections of the Code, there are specific actions listed which may warrant a finding of violation or the refusal to renew or grant a license. In addition, subsections 9 and 10 in § 54.1-2914 provide general authority for a finding of unprofessional conduct if the practitioner either "conducts his practice in a manner contrary to the standards of ethics of his branch of the healing arts" or "conducts his practice in such a manner as to be a danger to the health and welfare of his patients or to the public" While general statutory authority for disciplinary action by the Board may exist, the Board has also provided specific regulations for standards of conduct in certain areas of practice. Part II of 18 VAC 85-20-10 et seq. stipulates specific prohibited practices or guidance for performance of certain practices to include: a) advertising ethics; b) vitamins, minerals and food supplements; c) anabolic steroids; d) solicitation or remuneration for referrals; e) pharmacotherapy for weight loss; f) sexual contact with patients; and g) refusal to provide information or records. The contemplated regulatory action addressing concerns about outpatient surgery in physicians' offices would likely add a section to Part II of the regulations on Unprofessional Conduct.

In order to define as unprofessional conduct the practice of delivering certain anesthesia services in a physician's office without the necessary patient protection, the Board may need to adopt

some guidance or requirements for monitoring and resuscitation, administration of drugs, and training of personnel. It will consider the Guidelines for Office-Based Anesthesia approved by the House of Delegates of the American Society of Anesthesiologists (ASA) in October 13, 1999, as well as other guidelines adopted by health care organizations for the administration of intravenous analgesia. Rather than specifying such requirements in regulation, the Board may choose to incorporate by reference the guidelines of a professional society such as the ASA.

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A proposal in House Bill 1272 as amended in the 2000 General Assembly would have provided for licensure of such physician offices and would have required the Board of Medicine to develop regulations to determine the definition of "minor surgery" and the qualifications and minimum standards for licensure of specialized health care facilities. The Medical Society had concerns about the requirement for licensure and about breadth of the bill and the potential impact on many of the physicians practicing in Virginia. House Bill 1272 was defeated on the House floor by a vote of 30-Y, 66-N and 1-A. Regulatory action by the Board of Medicine may serve to alleviate some of the concerns for public safety that precipitated introduction of this legislation.

Family Impact Statement

Please provide a preliminary analysis of the potential impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

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.