Virginia Regulatory Town Hall

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Notice of Intended Regulatory Action (NOIRA)
Agency Background Document

Agency name	Board of Medicine, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC85-20-10 et seq.
Regulation title	Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry and Chiropractic
Action title	Practice standards for pain management
Document preparation date	12/30/05

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Purpose

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

The purpose of the proposed regulatory action is to establish in regulation the practice standards for treatment and management of chronic pain with the use of opioids. The goal of the action would be to set basic standards for assessment, documentation, treatment, and follow-up care by physicians whose patients may need controlled substances to manage chronic pain.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Medicine the authority to promulgate regulations to administer the regulatory system:

§ 54.1-2400 -General powers and duties of health regulatory boards
The general powers and duties of health regulatory boards shall be:
…
6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title. …

Provisions in the Medical Practice Act and the Drug Control Act authorize a physician to prescribe pain medications in excessive dosages for the treatment of chronic pain in for recognized medicinal or therapeutic purposes:

§ 54.1-2971.01. Prescription in excess of recommended dosage in certain cases.
A. Consistent with § 54.1-3408.1, a physician may prescribe a dosage of a pain-relieving agent in excess of the recommended dosage upon certifying the medical necessity for the excess dosage in the patient's medical record. Any practitioner who prescribes, dispenses or administers an excess dosage in accordance with this section and § 54.1-3408.1 shall not be in violation of the provisions of this title because of such excess dosage, ***if such excess dosage is prescribed, dispensed or administered in good faith for recognized medicinal or therapeutic purposes****.*
B. The Board of Medicine shall advise physicians of the provisions of this section and § 54.1-3408.1.
§ 54.1-3408.1. Prescription in excess of recommended dosage in certain cases.
In the case of a patient with intractable pain, a physician may prescribe a dosage in excess of the recommended dosage of a pain relieving agent if he certifies the medical necessity for such excess dosage in the patient's medical record. Any person who prescribes, dispenses or administers an excess dosage in accordance with this section shall not be in violation of the provisions of this title because of such excess dosage, ***if such excess dosage is prescribed, dispensed or administered in good faith for accepted medicinal or therapeutic purposes.***
Nothing in this section shall be construed to grant any person immunity from investigation or disciplinary action based on the prescription, dispensing or administration of an excess dosage in violation of this title.

In § 54.1-2915, the Medical Practice Act authorizes the Board to take disciplinary action on a license. Adoption of regulations for pain management by physicians will give the Board specificity in the enforcement of § 54.1-2915, especially unprofessional conduct in "*Conducting his practice in a manner contrary to the standards of ethics of his branch of the healing arts" or " Conducting his practice in such a manner as to be a danger to the health and welfare of his patients or to the public."*

§ 54.1-2915. Unprofessional conduct; grounds for refusal or disciplinary action.
A. The Board may refuse to admit a candidate to any examination; refuse to issue a certificate or license to any applicant; reprimand any person; place any person on probation for such time as it may designate; suspend any license for a stated period of time or indefinitely; or revoke any license for any of the following acts of unprofessional conduct:

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. Intentional or negligent conduct in the practice of any branch of the healing arts that causes or is likely to cause injury to a patient or patients;
4. Mental or physical incapacity or incompetence to practice his profession with safety to his patients and the public;
5. 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;
6. Undertaking in any manner or by any means whatsoever to procure or perform or aid or abet in procuring or performing a criminal abortion;
7. Engaging in the practice of any of the healing arts under a false or assumed name, or impersonating another practitioner of a like, similar, or different name;
8. Prescribing or dispensing 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;
9. Violating provisions of this chapter on division of fees or practicing any branch of the healing arts in violation of the provisions of this chapter;
10. Knowingly and willfully committing an act that is a felony under the laws of the Commonwealth or the United States, or any act that is a misdemeanor under such laws and involves moral turpitude;
11. Aiding or abetting, having professional connection with, or lending his name to any person known to him to be practicing illegally any of the healing arts;
12. Conducting his practice in a manner contrary to the standards of ethics of his branch of the healing arts;
13. Conducting his practice in such a manner as to be a danger to the health and welfare of his patients or to the public;
14. Inability to practice with reasonable skill or safety because of illness or substance abuse;
15. Publishing in any manner an advertisement relating to his professional practice that contains a claim of superiority or violates Board regulations governing advertising;
16. Performing any act likely to deceive, defraud, or harm the public;
17. Violating any provision of statute or regulation, state or federal, relating to the manufacture, distribution, dispensing, or administration of drugs;
18. Violating or cooperating with others in violating any of the provisions of Chapters 1 (§ 54.1-100 et seq.), 24 (§ 54.1-2400 et seq.) and this chapter or regulations of the Board;
19. Engaging in sexual contact with a patient concurrent with and by virtue of the practitioner and patient relationship or otherwise engaging at any time during the course of the practitioner and patient relationship in conduct of a sexual nature that a reasonable patient would consider lewd and offensive;
20. Conviction in any state, territory, or country of any felony or of any crime involving moral turpitude; or
21. Adjudication of legal incompetence or incapacity in any state if such adjudication is in effect and the person has not been declared restored to competence or capacity.

B. The commission or 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 or commission under this section regardless of its designation in the other state, territory, or country.
C. 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.

Substance

Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed. Include the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. Delineate any potential issues that may need to be addressed as the regulation is developed.

Provisions in the Medical Practice Act and the Drug Control Act authorize a physician to prescribe pain medications in excessive dosages for the treatment of chronic pain provided "such excess dosage is prescribed, dispensed or administered in good faith for recognized medicinal or therapeutic purposes." The Board proposes to set out the basic criteria by which a doctor may determine the appropriateness of prescribing for pain management and the steps that should be taken to evaluate the patient, obtain informed consent, periodically review and document thoroughly in the medical record. With a regulatory standard to follow, physicians who want to improve the quality of life for patients with chronic pain may be more inclined to treat appropriately, which can reduce the morbidity and costs associated with untreated or inappropriately treated pain. The Board believes that regulatory action may alleviate the uncertainty that many physicians have and encourage better pain management to the benefit of the health and safety of patients in Virginia.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action.

As the basis for regulations, the Board will utilize several sources documents, including the "Guidelines for the Use of Opioids in the Management of Chronic, Noncancer Pain," offered by the Medical Society of Virginia in 1997, at the request of a Joint Subcommittee of the General Assembly following passage of Chapter 277 in 1995, and adopted by the Board as a Guidance Document in 1998 (85-9). In addition, the "Model Policy for the Use of Controlled Substances for the Treatment of Pain" from the Federation of State Boards of Medicine was issued in 2004 and adopted by the Board as a Guidance Document (85-24) in June of 2004. While policy statements provide some guidance to licensees, they are not an enforceable documents and

therefore do not allow the Board to cite deviation from the guidance as grounds for disciplinary action when appropriate.

While the guidelines are effective for those practitioners who seek the Board's guidance on treatment of chronic pain with opioids, they cannot be cited in a disciplinary case involving a physician who does not follow the recommended guidelines for opioid treatment, has exceeded the prescribing limits or failed to follow the Board's guidance in other ways. For that reason, the Board believes it is now necessary to incorporate the guidance into regulation, so it has enforceability and accountability.

Family impact

Assess the potential impact of the proposed regulatory action on the institution of the family and family stability.

There is no potential impact of the proposed regulatory action on the institution of the family and family stability.