Virginia Regulatory Town Hall

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Proposed Regulation
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	Treatment of pain with controlled substances
Document preparation date	6/27/08

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.*

Brief summary

In a short paragraph, please summarize all substantive changes that are being proposed in this regulatory action.

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.

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., the 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.

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal and the problems the proposal is intended to solve.

The purpose of the proposed regulatory action is to establish in regulation the practice standards for treatment and management of acute and chronic pain with the use of controlled substances. By clarifying the Board's position on pain control, as related to the use of controlled substances, may alleviate physician uncertainty and encourage better pain management. 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.

Likewise, the Board believes that the use of opioids for other than legitimate medical purposes poses a threat to the individual and the community. Inappropriate prescribing of controlled substances may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Accordingly, the Board proposes to set standards for physicians to follow in their practices to minimize the potential for the abuse and diversion of controlled substances.

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.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (More detail about these changes is requested in the "Detail of changes" section.)

Section 95 is added in Part II on professional conduct to establish standards for treatment of pain with controlled substances. The definition subsection differentiates between acute and chronic pain, as there are different requirements for treatment. With acute pain, it is necessary to perform an appropriate history and physical (to the extent warranted) and to record the reason for the prescription and information about what was prescribed.

For the management of chronic pain, a more complete evaluation of the patient is necessary to include such things and the nature and intensity of the pain, underlying diseases or conditions, and any history of addiction in the patient or his family. The medical record must include a treatment plan that states measures to be used to determine progress in treatment, including but not limited to pain relief and improved physical and psychosocial function. The prescriber must also document in the medical record informed consent, to include risks, benefits and alternative approaches, prior to the initiation of opioids for chronic pain. There must be a written treatment agreement in the medical record that addresses the parameters of treatment, including those behaviors which will result in a cessation of treatment or dismissal from care and permission to query and receive reports from the Prescription Monitoring Program and consult with other prescribers or dispensing pharmacists for the patient.

The prescriber has to review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health at least every six months, and when necessary to achieve treatment goals, the prescriber shall refer the patient for additional evaluation and treatment. The prescriber is required to keep current, accurate and complete records in an accessible manner and readily available for review.

Issues

Please identify the issues associated with the proposed regulatory action, including:
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 the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.

1) The primary advantage to the public may be improved access to opioid medication for patients with legitimate medical needs and, conversely, more control over the availability of those drugs for diversion and abuse. 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.

The Board believes that the use of opioids for other than legitimate medical purposes poses a threat to the individual and the community. Inappropriate prescribing of controlled substances may lead to drug diversion and abuse by individuals who seek them for other than legitimate medical use. Such abuse of prescription drugs has had tragic results in some Virginia communities and many families. If a more definitive standard can prevent prescribing for illegitimate purposes, it will be of benefit to the public.

There are no disadvantages to the patients with medical needs in having more standards for physician in the management of chronic pain.

2) The primary advantage to the agency is consistency and clarity in the rules; it may alleviate the number of calls received by the Board asking for interpretations of the law and regulations. There are no disadvantages.

3) There are no other pertinent matters of interest.

Economic impact

Please identify the anticipated economic impact of the proposed regulation.

Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures	a) 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; b) The agency will incur some one-time costs (less than $1,000) for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities. Notices to the PPG list are typically sent by email so there is no cost involved. There are no on-going expenditures.
Projected cost of the regulation on localities	None
Description of the individuals, businesses or other entities likely to be affected by the regulation	The entities that are likely to be affected by these regulations would be doctors of medicine, osteopathic medicine or podiatry.
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	The number of entities impacted by this regulation would be: 26,982 active doctors of medicine 816 active doctors of osteopathic medicine 414 active doctors of podiatric medicine It is not known how many of doctors practice within a large medical center or as an employee of a governmental or other entity. To the extent a doctor practices independently or within a group practice, he would be included as a small business.
All projected costs of the regulation for affected individuals, businesses, or other entities. Please be specific. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses.	There are no projected costs for compliance since the focus of the regulation is medical care and recordkeeping consistent with current standards. If a patient is at high risk for medication abuse or has a history of substance abuse, the physician may consider the use of a urine drug screen, and a charge that would be passed on to the patient. According to testimony, a simple drug screen could be performed in the office for as little as $6 (Redwood Labs). If a complex drug screen was warranted because of suspected abuse or diversion,

	the cost could be substantially higher. Again, a drug screen is commonly used by physicians who treat chronic pain, so it would not be an additional burden required by these amendments.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action.

To assist state medical boards in guidelines for treatment of pain and to encourage adequate pain treatment, the Federation of State Medical Boards (the Federation) adopted *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain* in April of 1998. In 2004, the Federation updated its guidelines to assure currency and adequate attention to the undertreatment of pain. The goal of the revised "*Model Policy*" was to provide state medical boards with an updated template regarding the appropriate management of pain in compliance with applicable state and federal laws and regulations.

As the basis for regulations, the Board utilized several source documents, including the Federation's "*Model Policy for the Use of Controlled Substances for the Treatment of Pain,*" which was adopted as a Guidance Document (85-24) in June of 2004. In addition, "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, was adopted by the Board as a Guidance Document in 1998 (85-9). While policy statements provide some guidance to licensees, they are not 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 controlled substances, they cannot be cited in a disciplinary case involving a physician who does not follow the recommended guidelines for treatment, has unnecessarily 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.

To that end, the President of the Board appointed an ad hoc committee of persons with varying expertise and practice to recommend amendments to regulations. The committee includes two medical doctors who are pain management specialists (one of whom assisted the Federation in the development of the Model Policy), two MD members of the Board (an anesthesiologist and a family practitioner), an internist from rural Virginia (who observed first hand the effects of Oxycontin abuse in a community), a nurse practitioner, a physician assistant, the Executive Director of the Board of Pharmacy and the Director of the Prescription Monitoring Program.

The committee met on two occasions and discussed several issues extensively related to pain management, including, but not limited to, the reason for the need for regulations, statistics given regarding the increase in nonmedical use of prescription pain relievers, the lack of consensus among physicians as to all the circumstances that warrant the use of opioids to treat pain, and

what may be fueling the increase in prescription drug abuse. Throughout the review, the members made comments and recommendations for consideration in the draft language. It was noted that the issuance of a prescription for a legitimate medical purpose by a licensed physician acting within the usual course of professional practice cannot be emphasized enough.

Public comment

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

The Notice of Intended Regulatory Action was published in the Register on April 3, 2006 and sent to the Public Participation Guidelines list with comment requested until May 3, 2006. There were no comments on the NOIRA.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability.

There is no impact on the institution of the family and family stability.

Detail of changes

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail all new provisions and/or all changes to existing sections.

Proposed new section number, if applicable	Proposed change and rationale
95	**Section 95, entitled "Treatment of pain with controlled substances" is added to Part II. Standards of Professional Conduct, immediately following a section on pharmacotherapy for weight loss.** Subsection A sets out the definitions. For purposes of this section, the following words and terms shall have the following meanings: "Acute pain" shall mean pain that occurs within the normal course of a disease or condition or as the result of surgery for which controlled substances may be prescribed for no more than six months. "Chronic pain" shall mean non-malignant pain that goes beyond the normal course of a disease or condition for which controlled substances may be prescribed for a period greater than six months.

	"Controlled substance" shall mean drugs listed in The Drug Control Act of the Code of Virginia in Schedules II through IV. "Prescription Monitoring Program" shall mean the electronic system within the Department of Health Professions that monitors the dispensing of certain controlled substances. *The primary issue that this section addresses is the definition of "acute" versus "chronic" pain. Acute pain is typically episodic, short-term and related to an acute illness, injury or surgery. Treatment for acute pain typically last from a few days to three months. In order to ensure that physicians were allowed to use their judgment about whether the requirements for treatment of chronic pain were necessary in order to continue prescribing for a patient beyond 90 days, the Board decided to extend the definition of "acute" pain to six months. There was general agreement that prescribing pain medicine beyond that time would be considered treatment of "chronic pain."* Subsection B sets out the requirements for treatment of acute pain. 1. Evaluation of the patient. Prior to initiating treatment with a controlled substance for a complaint of acute pain, the prescriber shall perform a history and physical examination appropriate to the complaint. 2. Medical records. The medical record shall include a description of the pain, a presumptive diagnosis for the origin of the pain, an examination appropriate to the complaint, a treatment plan and the medication prescribed (including date, type, dosage and quantity prescribed). *Requirements for treatment of acute pain should be standard notes in a patient record. A basic history and physical examination, as appropriate to the complaint would be necessary to determine the proper course of treatment. Likewise, the record should indicate the cause of the pain, the plan for treatment and the medication prescribed.* Subsection C sets out the requirements for management of chronic pain. *Management of chronic pain should be based on sound clinical judgment and clear documentation of unrelieved pain. The purpose of subsection C is to give the physician regulatory guidance on the evaluation and documentation that should occur.* 1. Evaluation of the patient Prior to initiating management of chronic pain with a controlled substance, a medical history and physical examination shall be performed and documented in

	the medical record, including: a) the nature and intensity of the pain; b) current and past treatments for pain; c) underlying or coexisting diseases or conditions; d) the effect of the pain on physical and psychological and social function; and e) psychiatric, addiction and substance abuse history of the patient and his family. The medical record also shall document the presence of one or more recognized medical indications for the use of a controlled substance. 3. Treatment plan. The medical record shall include a treatment plan that states measures to be used to determine progress in treatment, including but not limited to pain relief and improved physical and psychosocial function. The treatment plan shall include further diagnostic evaluations and other treatment modalities or rehabilitation that may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. The prescriber shall record in the patient records the presence or absence of any indicators for medication misuse, abuse or diversion. 4. Informed consent and agreement for treatment. The prescriber shall document in the medical record informed consent, to include risks, benefits and alternative approaches, prior to the initiation of opioids for chronic pain. There shall be a written treatment agreement in the medical record that addresses the parameters of treatment, including those behaviors which will result in a cessation of treatment or dismissal from care. The treatment agreement shall include, but not be limited to permission for the practitioner to query and receive reports from the Prescription Monitoring Program and consult with other prescribers or dispensing pharmacists for the patient. If the patient is at high risk for medication abuse or has a history of substance abuse, the prescriber should consider the inclusion of a written agreement between the prescriber and the patient outlining patient responsibilities, including: 1) urine/serum medication levels screening, when requested; 2) number and frequency of all prescription refills; and 3) reasons for which drug therapy may be discontinued (e.g., violation of agreement). 5. Periodic review. The prescriber shall review the course of pain treatment and any new information about the etiology of the pain or the patient's state of health at least every 90 days. Continuation of treatment with controlled substances shall be supported by documentation of continued benefit by the prescriber. If the patient's progress is unsatisfactory, the prescriber shall assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities. 6. Consultation. When necessary to achieve treatment goals, the prescriber shall refer the patient

	for additional evaluation and treatment. 7. Medical records. The prescriber shall keep current, accurate and complete records in an accessible manner and readily available for review to include: a. The medical history and physical examination; b. Past medical history; c. Records from prior treatment providers; d. Diagnostic, therapeutic and laboratory results; e. Evaluations and consultations; f. Treatment goals; g. Discussion of risks and benefits; h. Informed consent and agreement for treatment; i. Treatments; j. Medications (including date, type, dosage and quantity prescribed). During the course of treatment, the physician shall adjust drug therapy to the individual medical needs of the patient and record the rationale for adjustments. Records shall document the medical necessity for any prescriptions in excess of recommended dosage in accordance with §§ 54.1-2971.01 and 54.1-3408.1 of the Code of Virginia; k. Instructions and agreements; and l. Periodic reviews. *The Model Policy for the Use of Controlled Substances for the Treatment of Pain adopted by the Federation of State Medical Boards sets out the criteria that the Board of Medicine has included in subsection C for evaluation of the patient, establishment of a treatment plan, informed consent and agreement for treatment, periodic reviews, consultation, and documentation in the medical record. Utilizing the expertise of a nationally-recognized panel of doctors who developed the Model Policy for the Federation, the Ad Hoc Committee and the Board closely followed the recommended criteria in the development of these regulations.* *Two aspects of the criteria for treatment that were debated were requirements for urine drug screens and a query of the Prescription Monitoring Program. The Board determined that both should be included in the proposal, but subsequently revised proposal to make urine drug screens discretionary if indicated. Two illustrations that follow demonstrate the necessity for their inclusion.* *The following scenario is presented as a strong argument for drug screens. A physician*

	made the decision to screen patients being treated at a pain clinic in which prescriptions for opioids had been written for a period of time without requiring drug screens of the patients. Of the 15 patients who were administered drug screens, only one had the expected result. The others either had multiple drugs in their system (beyond what had been prescribed in the clinic) or had no drugs in their system (which meant they may have been diverting and selling their prescribed medications). Without a drug screen, there would be no way for a practitioner to discern these important clinical facts about the patients. *At the Advisory Committee for the Prescription Monitoring Program on July 25, 2007, it was reported that a single individual had visited 23 doctors in one month, obtaining 450 pills of opioids, which he had apparently been selling to dealers. A quick check of that individual on the PMP System would have alerted the prescribers that he was doctor-shopping and obtaining multiple prescriptions. Currently a request for information can produce results in approximately 30 minutes without charge to the requester or the patient. Software will be installed in 2008 that will provide automated responses 24 hours a day, practically instantaneously. Having this capability in the emergency department in the middle of the night will be a great help to practitioners at the point of care.* *The Board originally proposed to require a periodic review of prescribing opioids at least once every six months, but it was noted that the Drug Enforcement Administration (DEA) has amended its rules to allow a prescriber to issue multiple prescriptions in a single visit for up to a 90-day supply of Schedule II drugs (the previous rule specified a single prescription with no more than a 30 day supply). Therefore, the Board changed its proposed rule to be consistent with the DEA to allow prescribing for 90 days with a review of the patient before additional drugs could be prescribed.*