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Emergency Regulation and Notice of Intended Regulatory Action Agency Background Document

Agency name	Board of Dentistry, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC60-21-10 et seq.
Regulation title(s)	Regulations Governing the Practice of Dentistry
Action title	Prescribing of opioids
Date	3/13/17

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

Emergency regulations for dentists prescribing of medications containing opioids and for continuing education for prescribers of controlled substances are being promulgated as emergency regulations to address the opioid abuse crisis in Virginia. Regulations for the management of acute pain include requirements for the evaluation of the patient, limitations on quantity and dosage, and record-keeping. Management of chronic pain requires either referral to a pain management specialist or adherence to regulations of the Board of Medicine. All dentists who prescribe Schedule II through IV drugs will be required to take two hours of continuing education on pain management during the renewal cycle following the effective date of these regulations.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the “Definition” section of the regulations.

PMP = Prescription Monitoring Program

Emergency Authority

The APA (Code of Virginia § 2.2-4011) states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of subdivision A. 4. of § 2.2-4006. Please explain why this is an emergency situation as described above, and provide specific citations to the Code of Virginia or the Appropriation Act, if applicable.

On November 16, 2016, State Health Commissioner Marissa Levine declared the opioid addiction crisis to be a public health emergency in Virginia. In his news conference about the opioid crisis, Governor McAuliffe noted that the Declaration would “provide a framework for further actions to fight it, and to save Virginians’ lives.” One of those “further actions” is adoption of emergency regulations by the Board of Medicine setting out rules for prescribing of opioids and buprenorphine.

The authority in § 2.2-4011 authorizes an agency to adopt emergency regulations when they “are necessitated by an emergency situation.” The Declaration by Commissioner Levine is indeed evidence that such an emergency situation exists in the Commonwealth.

Additionally, Chapter 291 of the 2017 Acts of the Assembly became effective on March 3, 2017 requiring the Board of Dentistry to promulgate regulations for prescribing of opioids.

Legal basis

Other than the emergency authority described above, 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) the promulgating entity, i.e., agency, board, or person.

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 Dentistry 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. ...

In addition, the Board has been mandated to adopt regulations by passage of HB2167 and SB1180 in the 2017 General Assembly:

§ 54.1-2708.4. Board to adopt regulations related to prescribing of opioids.

The Board shall adopt regulations for the prescribing of opioids, which shall include guidelines for:

1. The treatment of acute pain, which shall include (i) requirements for an appropriate patient history and evaluation, (ii) limitations on dosages or day supply of drugs prescribed, (iii) requirements for appropriate documentation in the patient's health record, and (iv) a requirement that the prescriber request and review information contained in the Prescription Monitoring Program in accordance with § 54.1-2522.1;
2. The treatment of chronic pain, which shall include, in addition to the requirements for treatment of acute pain set forth in subdivision 1, requirements for (i) development of a treatment plan for the patient, (ii) an agreement for treatment signed by the provider and the patient that includes permission to obtain urine drug screens, and (iii) periodic review of the treatment provided at specific intervals to determine the continued appropriateness of such treatment; and
3. Referral of patients to whom opioids are prescribed for substance abuse counseling or treatment, as appropriate.

Both bills have emergency enactments that provide: *That an emergency exists and this act is in force from its passage.* HB2167 has been signed by the Governor, and the Act was in force on March 3, 2017.

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 regulatory action is the establishment of requirements for prescribing of controlled substances containing opioids to address the overdose and addiction crisis in the Commonwealth. The goal is to provide dentists with definitive rules to follow so they may feel more assured of their ability to treat pain in an appropriate manner to avoid under-prescribing or over-prescribing.

Need

Please describe the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

As noted above, the opioid addiction crisis was declared to be a public health emergency in Virginia on November 21, 2016. In the declaration announcement, it was noted that by the end of 2016, the numbers of fatal opioid overdose deaths were expected to increase by 77 percent, compared to five years ago. In 2014, for the first time in Virginia, more people died from opioid overdoses than fatal car accidents. Emergency department visits for heroin overdose for January-September 2016 increased 89 percent, compared to the same nine-month period in 2015. In the first half of 2016, the total number of fatal drug overdoses in Virginia increased 35 percent, when compared to the same time period in 2015, and in 2013, fatal drug overdoses became the number one cause of unnatural death. In addition to overdoses from opioids, overdoses from heroin and other illicit drugs continue to soar. Many of those who become addicted to heroin started with an addiction to prescription drugs. In order to stem the tide of addiction, practitioners need enforceable rules for proper prescribing of drugs containing opioid in treatment of pain to protect the public health and safety.

Regulations in this chapter were drafted by a Regulatory Advisory Panel (RAP), comprised of two members of the Board and two members of the faculty at the VCU School of Dentistry. To the extent consistent with public health and safety, recommendations from interested parties were incorporated into the regulations.

Substance

Please describe any changes that are proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate. Set forth the specific reasons the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of Virginians.

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
101	Section 101 sets out definitions for words and terms used in this chapter. They include a definition for acute pain to 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 three months. The definition for chronic pain means 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 three months.	18VAC60-21-10	The Board adopted definitions identical to those adopted by the Board of Medicine for consistency.
102	Section 102 sets out the rules for evaluation of a patient. Subsection A requires that non-	§§ 54.1-3303 and 54.1-2522.1	The intent of this section is to ensure that dentists prescribe

	<p>pharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids. If an opioid is considered necessary for the treatment of acute pain, the practitioner shall give a short-acting opioid in the lowest effective dose for the fewest possible days.</p> <p>Subsection B requires that prior to initiating treatment with a controlled substance for a complaint of acute pain, the prescriber must perform a history and physical examination appropriate to the complaint, query the Prescription Monitoring Program as set forth in the Code of Virginia and conduct an assessment of the patient’s history and risk of substance abuse.</p>		<p>opioids only when absolutely necessary, rather than as a routine treatment and that the prescription be limited in quantity and dosage.</p> <p>Prior to prescribing a controlled substance for pain, the dentist has legal obligations in the establishment of a practitioner/patient relationship and in checking the PMP and also a professional obligation to assess the patient’s risk.</p>
<p>103</p>	<p>Section 103 establishes the requirements for treatment of acute pain with opioids.</p> <p>Subsection A specifies that initiation of opioid treatment for patients with acute pain shall be with short-acting opioids. When prescribing a controlled substance containing an opioid, a practitioner is limited to a quantity that do not exceed a seven-day supply as determined by the manufacturer’s directions for use, unless extenuating circumstances are clearly documented in the patient record.</p> <p>Subsection A also sets the following limits on dosages:</p> <ol style="list-style-type: none"> 1. The dentist must carefully consider and document in the patient record the reasons to exceed 50 MME/day. 2. Prior to exceeding 120 MME/day, the dentist must document in the patient record the reasonable justification for such doses and shall refer to or consult with a pain management specialist. 3. Naloxone must be prescribed for any patient when risk factors of prior overdose, substance abuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present. <p>Subsection B provided that when an opioid is prescribed for more than 7 days, the patient must be re-evaluated, the need for continued prescribing must be documented in the patient record, and the dentist must check the PMP.</p> <p>Subsection C limits co-prescribing of certain substances. Due to a higher risk of fatal</p>	<p>§§ 54.1-2706 (13) and 54.1-3408</p>	<p>Legislation introduced in the General Assembly would have limited prescribing for acute pain to 7 days and for emergency room discharge to 3 days. The medical and dental communities requested that the boards make the decision about prescribing limitation through regulation, and the Boards of Dentistry and Medicine determined that a consistent 7-day limit was advisable. In each case, the prescriber can document circumstances that would warrant prescribing outside the limits. A specified limitation on days of prescribing will reduce the amount of unused or unnecessary opioids available for abuse or diversion. It will also encourage practitioners to prescribe non-opioid controlled substances that may be just as effective but not addictive.</p> <p>Regulations for Medicine allow prescribing for 14 days following a surgical procedure, but dentists believe it is important to re-evaluate a dental patient if there is pain to the extent an opioid is necessary beyond seven days.</p> <p>Since there are many controlled substances containing opioids, the acceptable limitation on dosage is translated into morphine milligram equivalency (MME). Typically, a patient should not be prescribed a</p>

	<p>overdose when opioids are prescribed with benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses if these medications are prescribed.</p>		<p>dosage in excess of 50 MME per day. If a prescriber exceeds 120 MME per day for a patient, there must be a clear justification or consultation with or referral to a pain specialist. Naloxone, an overdose antidote, should always be prescribed under the conditions listed in subsection A. A specified standard in regulation should assist practitioners in determining dosages that are consistent with the standard of care in prescribing for pain.</p> <p>Subsection C lists drugs, for which there is a high risk of overdose if co-prescribed with an opioid. Regulations require documentation of the circumstances necessitating co-prescribing and the tapering plan in place.</p>
104	<p>Section 104 requires that the patient record 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 or administered to include the date, type, dosage, and quantity prescribed.</p>	<p>§§ 54.1-3303 and 32.1-127.1:03 18VAC60-21-90</p>	<p>Requirements for the patient record in the treatment of a patient with are consistent with the establishment of a bona fide practitioner-patient relationship and Board regulations for complete records.</p>
105	<p>Section 105 sets out the requirements for prescribing opioids for treatment of the chronic pain patient.</p> <p>If a dentist treats a patient for whom an opioid prescription is necessary for chronic pain, he shall either:</p> <ol style="list-style-type: none"> 1. Refer the patient to a medical doctor who is pain management specialist; or 2. Comply with regulations of the Board of Medicine, 18VAC85-21-60 through 18VAC85-21-120, if he chooses to manage the chronic pain with an opioid prescription 	<p>§§ 54.1-3303 and 54.1-2522.1</p>	<p>Prescribing for chronic pain with a substance containing an opioid (longer than 30 days) requires a more in-depth evaluation of the patient because of the high risk of addiction.</p> <p>While it is possible that a small number of chronic pain conditions could be managed by dentists, the RAP and the Board believe that long-term prescribing of opioids is not appropriate in dentistry. Therefore, regulations specify that a patient should be referred to a pain management specialist; or if the dentist does choose to manage chronic pain, he or she must comply with Board of Medicine regulations.</p>
106	<p>Section 106 requires any dentist who prescribes any Schedule II through IV controlled substances during one renewal cycle shall obtain two hours of continuing education on pain management during the next renewal cycle following the effective</p>	<p>§ 54.1-2709</p>	<p>The requirement for continuing education is consistent with other boards that regulate prescribers or dispensers. The Board of Medicine is requiring prescribers to complete two hours of continuing education</p>

	<p>date of this regulation. Continuing education hours required for prescribing of controlled substances may be included in the 15 hours required for renewal of licensure.</p>	<p>(CE) in pain management, proper prescribing of controlled substances, and the diagnosis and management of addiction in the 24 months prior to the next biennial renewal.</p> <p>The Board of Pharmacy is requiring all pharmacists to obtain at least one hour of CE in 2017 in any of the following subject areas: proper opioid use, opioid overdose prevention, or naloxone administration.</p> <p>The two-hour requirement is part of the required 15 hours of CE that must be obtained during one renewal cycle and is not in addition to the required 15 hours, so it does not increase the burden on those dentists who prescribe scheduled drugs.</p>
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Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been considered to meet the essential purpose of the action. Also describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

The Board has a specific statutory mandate to adopt regulations for the prescribing of opioids in the management of acute and chronic pain. There are no alternatives to the essential purpose of this action.

Family impact

Please assess the impact of this 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 institution of the family and family stability is being severely impacted by the opioid addiction crisis in the Commonwealth. The impact of this action is intended to empower and instruct dentists in the appropriate prescribing of opioids to manage pain in such a manner as to prevent addiction and diversion.