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Emergency Regulation Agency Background Document

Agency name	Board of Dentistry, Department of Health Professions	
Virginia Administrative Code (VAC) citation(s)	18VAC60-20	
Regulation title(s)	Regulations Governing the Practice of Dentistry	
Action title Continuing education requirement		
Date	6/14/17	

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

The Board is submitting an amendment to the emergency regulations that became effective on April 24, 2017 for prescribing of opioids. The requirement in section 106 is amended to allow dentists to begin immediately fulfilling the continuing education requirement of two hours on pain management, rather than waiting until the next renewal cycle beginning March 31st of 2018.

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.

N/A

Emergency Authority

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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:

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- 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 \S 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 to encourage dentists to seek continuing education in prescribing opioids as soon as possible so they understand the crisis in the Commonwealth, their role in addressing the issue, and the requirements of the emergency regulations on prescribing. As re-written, the emergency regulation will allow dentists almost two years to obtain two hours of continuing education, beginning with the effective date of the emergency regulation on April 24, 2017.

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 an understanding of pain management for proper prescribing of drugs containing opioid in treatment of pain to protect the public health and safety.

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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.

For changes to existing regulations, use this chart:

Current section	Current requirement	Proposed change and rationale
number		
106	A dentist who prescribes Schedules II through IV controlled	Any dentist who prescribes Schedules II through IV controlled substances after April 24, 2017 shall
	substances during one license renewal	obtain two hours of continuing education on pain
	cycle shall obtain two hours of	management, which must be taken by March 31,
	continuing education on pain	2019. Thereafter, any dentist who prescribes
	management during the next renewal	Schedule II through IV controlled substances shall
	cycle following April 24, 2017.	obtain two hours of continuing education on pain
	Continuing education hours required	management every two years. Continuing
	for prescribing of controlled	education hours required for prescribing of
	substances may be included in the 15	controlled substances may be included in the 15
	hours required for renewal of	hours required for renewal of licensure.
	licensure.	
		After adoption of the emergency regulations, the Virginia Dental Association contacted the Board
		about offering a two-hour course in pain
		management in the fall of 2017. However, the
		language in the original emergency regulation
		would not allow dentists to use that course to fulfill
		the two-hour requirement of section 106.
		Since there is an urgent need for dentists to

	understand appropriate management of pain with opioids and the requirements for dentists in prescribing, it was determined that the emergency regulation should be amended by re-adoption of
	section 106.

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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.

There is no alternative that will meet 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 instruct dentists in the appropriate prescribing of opioids to manage pain in such a manner as to prevent addiction and diversion.