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# Emergency Regulation
# Agency Background Document

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| **Agency name** | Board of Medicine, Department of Health Professions |
| **Virginia Administrative Code (VAC) citation(s)** | 18VAC10-21 |
| **Regulation title(s)** | Regulations Governing Prescribing of Opioids and Buprenorphine |
| **Action title** | Re-adoption of emergency regulations |
| **Date** | 6/29/17 |

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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 of Medicine has re-adopted emergency regulations to address a major concern with the current emergency regulations. According to numerous comments and testimony from patients and physicians, the restriction on prescribing the mono-product was highly problematic for a small number of patients who have demonstrated an intolerance to naloxone. While the literature does not validate the existence of allergies to naloxone, physicians on the Regulatory Advisory Panel and others have observed the physical manifestations of intolerance, estimated to be within 3% of their patients. **In order to provide these patients with access to buprenorphine in the treatment of substance abuse as soon as possible, it was essential to readopt the emergency regulations.**

Two other changes were deemed important enough to include in the re-adoption of emergency regulations: 1) Clarity about the prohibition on prescribing of the buprenorphine mono-product for chronic pain; and 2) Allowance for prescribing of buprenorphine with naloxone for a pregnant woman, if medically indicated.

## 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.*

FDA = Food and Drug Administration
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.

## 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 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. ...*

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

***§ 54.1-2928.2. Board to adopt regulations related to prescribing of opioids and buprenorphine.***

*The Board shall adopt regulations for the prescribing of opioids and products containing buprenorphine. Such regulations 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. The use of buprenorphine in the treatment of addiction, including a requirement for referral to or consultation with a provider of substance abuse counseling in conjunction with treatment of opioid dependency with products containing buprenorphine.*

Both bills have emergency enactments that provide: *That an emergency exists and this act is in force from its passage.*

## 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 re-adoption of emergency regulations is to address some of the concerns with restrictions on prescribing buprenorphine. The goal is to provide prescribers 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 the re-adoption were recommended by a re-convened Regulatory Advisory Panel (RAP), comprised of specialists in pain management and addiction medicine, which met on May 15, 2017. Extensive comment, both in writing and oral, was received by the RAP, the Legislative Committee of the Board, and the full Board of Medicine prior to re-adoption of emergency regulations. To the extent deemed consistent with public health and safety, recommendations from RAP were incorporated into the re-adopted 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.*

For changes to existing emergency regulations:

| Current section number | Emergency requirement currently if effect | Proposed change and rationale |
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| 30, 40, 60, 70, 80, 130, 140, 150 | Use of the term “substance abuse” | The term substance “abuse” is used in several sections of regulation; the RAP recommended that the more acceptable terminology is substance “misuse.” Those sections were amended accordingly. |
| 70 | Buprenorphine may be prescribed or administered for chronic pain in formulation and dosages that are FDA-approved for that purpose. | Buprenorphine mono-product in tablet form shall not be prescribed for chronic pain.<br>The RAP recommended this change to the emergency regulation to specify that the mono-product (without naloxone) cannot |

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| | | be used for chronic pain. FDA does not approve such usage, but there seemed to be some confusion in that regulation, so specificity was recommended. |
| 150 | In current emergency regulations, the buprenorphine mono-product may only be prescribed when a patient is pregnant, when converting a patient from methadone to buprenorphine for a period of seven days, or in formulations other than tablet form as approved by the FDA. | The Board added a fourth allowance for prescribing the buprenorphine mono-product: *For patients who have a demonstrated intolerance to naloxone; such prescriptions for the mono-product shall not exceed 3% of the total prescriptions for buprenorphine written by the prescriber, and the exception shall be clearly documented in the patient's medical record.*<br>According to numerous comments and testimony from patients and physicians, the restriction on prescribing the mono-product was highly problematic to a small number of patients who have demonstrated an intolerance to naloxone. While the literature does not validate the existence of allergies to naloxone, physicians on the RAP and others have observed the physical manifestations of intolerance, estimated to be within 3% of their patients. **To provide these patients with access to buprenorphine in the treatment of substance abuse as soon as possible, it was essential to readopt the emergency regulations.** |
| 160 | In current regulations, it is required that the buprenorphine mono-product be prescribed for pregnant women. | The RAP noted that a small number of pregnant women who have a history of substance misuse may need to have buprenorphine with naloxone. It was recommended that the word "shall" be changed to "may" to allow such prescribing based on the medical history of the patient and the professional judgment of the prescriber. |

## 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.*

To address numerous concerns expressed by patients and physicians about the emergency regulations for management of pain and buprenorphine for addiction, the Board of Medicine re-convened a Regulatory Advisory Panel (RAP). The recommendations of the RAP were considered by the Legislative Committee on May 19, 2017 and then by the full Board on June 22, 2017. It was determined that the changes needed should be re-adopted as emergency regulations rather than just promulgated through the more lengthy APA process.

## 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 practitioners in the appropriate prescribing of opioids to manage pain in such a manner as to prevent addiction and diversion.