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Final Regulation
Agency Background Document

Agency name	Boards of Medicine, Department of Health Professions
Virginia Administrative Code (VAC) Chapter citation(s)	18VAC85-21
VAC Chapter title(s)	Regulations Governing Prescribing of Opioids and Buprenorphine
Action title	Waiver for electronic prescribing of opioids
Date this document prepared	12/4/20

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1VAC7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

Section 21 is added to Chapter 21 to: 1) reiterate the requirement that takes effect on July 1, 2020 that a prescription for a controlled substance that contains an opioid must be issued as an electronic prescription; and 2) provide for a one-year extension from the requirement if the practitioner can demonstrate economic hardship technological limitations or other exceptional circumstances beyond the practitioner's control.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.

N/A

Statement of Final Agency Action

Provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

On December 4, 2020, the Board of Medicine adopted final amendments to 18VAC85-21-10 et seq., Regulations Governing Prescribing of Opioids and Buprenorphine.

Mandate and Impetus

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding the mandate for this regulatory change, and any other impetus that specifically prompted its initiation. If there are no changes to previously reported information, include a specific statement to that effect.

The Board of Medicine is complying with provisions of HB2559 of the 2019 General Assembly and is replacing emergency regulations adopted pursuant to the second enactment of the Acts.

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia and Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

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. …*

The specific statutory for electronic prescribing and the authority for granting a waiver are found in:

§ 54.1-3408.02. (Effective July 1, 2020) Transmission of prescriptions.

A. Consistent with federal law and in accordance with regulations promulgated by the Board, prescriptions may be transmitted to a pharmacy as an electronic prescription or by facsimile machine and shall be treated as valid original prescriptions.

B. Any prescription for a controlled substance that contains an ~~opiate~~ opioid shall be issued as an electronic prescription.

C. The requirements of subsection B shall not apply if:

1. The prescriber dispenses the controlled substance that contains an opioid directly to the patient or the patient's agent;

2. The prescription is for an individual who is residing in a hospital, assisted living facility, nursing home, or residential health care facility or is receiving services from a hospice provider or outpatient dialysis facility;

3. The prescriber experiences temporary technological or electrical failure or other temporary extenuating circumstance that prevents the prescription from being transmitted electronically, provided that the prescriber documents the reason for this exception in the patient's medical record;

4. The prescriber issues a prescription to be dispensed by a pharmacy located on federal property, provided that the prescriber documents the reason for this exception in the patient's medical record;

5. The prescription is issued by a licensed veterinarian for the treatment of an animal;

6. The FDA requires the prescription to contain elements that are not able to be included in an electronic prescription;

7. The prescription is for an opioid under a research protocol;

8. The prescription is issued in accordance with an executive order of the Governor of a declared emergency;

9. The prescription cannot be issued electronically in a timely manner and the patient's condition is at risk, provided that the prescriber documents the reason for this exception in the patient's medical record; or

10. The prescriber has been issued a waiver pursuant to subsection D.

D. The licensing health regulatory board of a prescriber may grant such prescriber, in accordance with regulations adopted by such board, a waiver of the requirements of subsection B, for a period not to exceed one year, due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the prescriber, or other exceptional circumstances demonstrated by the prescriber.

Purpose

Explain the need for the regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it's intended to solve.

The purpose of this regulatory action is compliance with a statutory requirement to promulgate regulations setting out the conditions upon which the Board may grant a one-year waiver from the requirement for e-prescribing of a controlled substance containing an opioid. Since the circumstances may vary from practitioner to practitioner, the Board has used the conditions set forth in the Code as the basis for the regulation and will take into consideration in making a case-by-case decision on a waiver the health, safety, and welfare of a practitioner's patients.

Substance

Briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of Changes" section below.

Section 21 is added to Chapter 21 to: 1) reiterate the requirement that takes effect on July 1, 2020 that a prescription for a controlled substance that contains an opioid must be issued as an electronic prescription; and 2) provide for a one-year from the requirement if the practitioner can demonstrate economic hardship technological limitations or other exceptional circumstances beyond the practitioner's control.

Issues

Identify the issues associated with the regulatory change, 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 there are no disadvantages to the public or the Commonwealth, include a specific statement to that effect.

1) There are no advantages or disadvantages to the public apart from those in the statutory language. Submitting opioid prescriptions electronically has been shown to reduce prescription fraud and thereby reduce the volume of opioids available for abuse or misuse. The waiver provision (in addition to the specific exemptions to electronic prescribing) will allow for continued prescribing for practitioners who are not able to comply for exceptional circumstances beyond their control.
2) There are no particular advantages or disadvantages to the agency; there may be an advantage to the Commonwealth by a reduction in fraudulent prescriptions.
3) Other matters interest revolve around the implementation and application of statutory and regulatory provisions. Some prescribers are concerned about the requirement for electronic prescribing, as required by statute by July 1, 2020.

The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. The Board is authorized under § 54.1-2400 to "*To promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 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.*" Any restraint on competition as a result of promulgating this regulation is a foreseeable result of the statute.

Requirements More Restrictive than Federal

List all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any requirement of the regulatory change which is more restrictive than applicable federal requirements. If there are no changes to previously reported information, include a specific statement to that effect.

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Please identify any other state agencies, localities, or other entities particularly affected by the regulatory change. "Particularly affected" are those that are likely to bear any identified disproportionate material impact which would not be experienced by other agencies, localities, or entities. "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulation or regulatory change are most likely to occur. If no agency, locality, or entity is particularly affected, include a specific statement to that effect.

Other State Agencies Particularly Affected - None

Localities Particularly Affected - None

Other Entities Particularly Affected - None

Public Comment

Summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency response. Include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency. If no comment was received, enter a specific statement to that effect.

Public comment was requested from 9/14/20 to 11/13/20. A public hearing was conducted on 11/4/20. There was no comment at the hearing; there were 2 comments on Townhall.

Regan Price Victoria McNiff	Commented in support of the proposed regulations.	The Board appreciated the support of this action.

Virginia Tech MPA Graduate programs		

Detail of Changes Made Since the Previous Stage

*List all changes made to the text since the previous stage was published in the Virginia Register of Regulations and the rationale for the changes. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Put an asterisk next to any substantive changes.*

Current chapter-section number	New requirement from previous stage	Updated new requirement since previous stage	Change, intent, rationale, and likely impact of updated requirements
21-21	Subsection A reiterates the requirement stated in the Code that beginning July 1, 2020, a prescription for a controlled substance containing an opioid must be issued electronically	The phrase "*unless the prescription qualifies for an exemption as set forth in subsection C of that section*" was added to subsection A point the prescriber to language in the Code that lists exemptions to the requirement for electronic prescribing.	The intent is to clarify that there are exemptions provided in the statute.

Detail of All Changes Proposed in this Regulatory Action

*List all changes proposed in this action and the rationale for the changes. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Put an asterisk next to any substantive changes.*

Current section number	New section number, if applicable	Change, intent, rationale, and likely impact of new requirements
N/A	21	Subsection A of section 21 will reiterate the law that becomes effective on July 1, 2020, which requires that a prescription containing an opioid must be issued as an electronic prescription as consistent with 54.1-3408.02 of the Code. *While reiteration of the law is not necessary in regulation, this provision is included in the chapter on prescribing of opioids*

		because it is necessary for the regulations to be consistent with the law. Subsection B of section 21 sets out the conditions on which the Board may grant a waiver from the e-prescribing requirement. The Code provides that: *The licensing health regulatory board of a prescriber may grant such prescriber, in accordance with regulations adopted by such board, a waiver of the requirements of subsection B, for a period not to exceed one year, due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the prescriber, or other exceptional circumstances demonstrated by the prescriber.* It will be necessary for a practitioner to present evidence to the Board on how he or she meets one of the stated conditions. Based on such evidence, the Board will make a decision on whether to grant a one-year waiver. Much like a licensing decision, a practitioner will have the right to appeal the Board's decision through an administrative process.