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Emergency Regulation and Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Boards of Medicine, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC85-21
Regulation title(s)	Regulations Governing Prescribing of Opioids and Buprenorphine
Action title	Waiver for electronic prescribing of opioids
Date this document prepared	8-5-19

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 (preferably no more than 2 or 3 paragraphs) of the subject matter, intent, and goals of this this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an 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 from the requirement if the practitioner can demonstrate economic hardship technological limitations or other exceptional circumstances beyond the practitioner's control.

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

Mandate and Impetus (Necessity for Emergency)

Please explain why this rulemaking is an emergency situation in accordance with Virginia Code § 2.2-4011 A and B. In doing so, please either:

a) *Indicate whether the Governor's Office has already approved the use of emergency regulatory authority for this regulatory change.*
b) *Provide specific citations to Virginia statutory law, the appropriation act, federal law, or federal regulation that require that a regulation be effective in 280 days or less from its enactment.*

As required by § 2.2-4011, please also describe the nature of the emergency and of the necessity for this regulatory change. In addition, delineate any potential issues that may need to be addressed as part of this regulatory change.

The Board of Medicine is complying with the second enactment of HB2559 of the 2019 General Assembly, which specified:

2. That the Board of Medicine, the Board of Nursing, the Board of Dentistry, and the Board of Optometry shall promulgate regulations to implement the provisions of this act regarding prescriber waivers to be effective within 280 days of its enactment..

An "emergency" exists because the Board is required to have regulations in effect within 280 days of enactment or by December 24, 2019.

Legal Basis

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

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

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

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.

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.

Issues

Please 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.

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 are no viable alternatives to the proposed regulatory action, the conditions on which the Board may grant a waiver are identical to the provisions in subsection D of § 54.1-3408.02.

Public Participation

The Board of Medicine is seeking comments on this regulation, including but not limited to: ideas to be considered in the development of this regulation, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation. Also, the agency/board is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the *Code of Virginia*. Information may include: 1) projected reporting, recordkeeping, and other administrative costs; 2) the probable effect of the regulation on affected small businesses; and 3) the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit written comments for the public comment file may do so through the Public Comment Forums feature of the Virginia Regulatory Town Hall web site at https://www.townhall.virginia.gov. Written comments must include the name and address of the commenter. Comments may also be submitted by mail, email or fax to Elaine Yeatts, Senior Policy Analyst; 9960 Mayland Drive, Henrico, VA 23233; elaine.yeatts@dhp.virginia.gov; FAX (804) 527-4434. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action, and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (https://www.townhall.virginia.gov) and on the Commonwealth Calendar website (https://www.virginia.gov/connect/commonwealth-calendar). Both oral and written comments may be submitted at that time.