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Proposed Regulation
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	12/6/19

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 (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations.*

Brief Summary

Please 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 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

Please identify the mandate for this regulatory change, and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, board decision, etc.). For purposes of executive branch review, "mandate" has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

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

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 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

Please 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

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.

Requirements More Restrictive than Federal

Please identify and describe any requirement of the regulatory change which is more restrictive than applicable federal requirements. Include a specific citation for each applicable federal requirement, and a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements, or no requirements that exceed applicable federal requirements, 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

Economic Impact

Pursuant to § 2.2-4007.04 of the Code of Virginia, please identify all specific economic impacts (costs and/or benefits), anticipated to result from the regulatory change. When describing a particular economic impact, specify which new requirement or change in requirement creates the anticipated economic impact. Please keep in mind that this is change versus the status quo.

Impact on State Agencies

For your agency: projected costs, savings, fees or revenues resulting from the regulatory change, including: a) fund source / fund detail; b) delineation of one-time versus on-going expenditures; and c) whether any costs or revenue loss can be absorbed within existing resources	As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners or entities for necessary functions of regulation. All notifications will be done electronically. There are no on-going expenditures.
For other state agencies: projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.	There are no costs to other agencies.
For all agencies: Benefits the regulatory change is designed to produce.	There are no specific benefits.

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	There are no costs.
Benefits the regulatory change is designed to produce.	No benefits

Impact on Other Entities

Description of the individuals, businesses, or other entities likely to be affected by the regulatory change. If no other entities will be affected, include a specific statement to that effect.	Practitioners with prescriptive authority under the Board of Medicine – MDs, DOs, DPMs, and PAs
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	Total licensure counts are: Doctors of Medicine & Surgery – 38,947 Doctors of Osteopathic Medicine – 3,834 Doctors of Podiatry – 553 Physician Assistants – 4,224 There is no information on how many of the total number of licensees prescribe drugs containing an opioid, would be unable to comply with the statutory mandate, and would request a waiver. It is not known how many are small businesses.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. Please be specific and include all costs including, but not limited to: a) projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the regulatory change; c) fees; d) purchases of equipment or services; and e) time required to comply with the requirements.	There are no costs associated with requesting a waiver; no fee will be applied.
Benefits the regulatory change is designed to produce.	There may be a benefit to those prescribers will be granted a waiver for up to 12 months after July 1, 2020 to comply with the law.

Alternatives

Please describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulatory change.

There are no viable alternatives to the proposed regulatory action, which is conforming to statutory provisions for granting a waiver for the requirement of electronic prescribing of a drug containing an opioid that takes effect July 1, 2020. The conditions on which the Board may grant a waiver are identical to the provisions in subsection D of § 54.1-3408.02.

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) establishing less stringent compliance or reporting requirements; 2) establishing less stringent schedules or deadlines for compliance or reporting requirements; 3) consolidation or simplification of compliance or reporting requirements; 4) establishing performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the regulatory change.

There are no alternative regulatory methods consistent with the mandate of the Code and public health and safety.

Public Comment

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

There was a public comment period on the Notice of Intended Regulatory Action from 9/30/19 to 10/30/19; no comment was received.

Public Participation

Please include a statement that in addition to any other comments on the regulatory change, the agency is seeking comments on the costs and benefits of the regulatory change and the impacts of the regulated community. Also, indicate whether a public hearing will be held to receive comments.

In addition to any other comments, the Board of Medicine is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is 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) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments for the public comment file may do so by mail, email or fax to Elaine Yeatts at elaine.yeatts@dhp.virginia.gov or at 9960 Mayland Drive, Henrico, VA

23233 or by fax at (804) 527-4434.. Comments may also be submitted through the Public Forum feature of the Virginia Regulatory Town Hall web site at: http://www.townhall.virginia.gov. Written comments must include the name and address of the commenter. 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 this stage and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (**http://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.

Detail of Changes

Please list all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation.

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.