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

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) Chapter citation(s)	18VAC110-21
VAC Chapter title(s)	Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians
Action title	2023 Pharmacists Initiating Treatment
Date this document prepared	March 30, 2023

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 19 (2022) (EO 19), any instructions or procedures issued by the Office of Regulatory Management (ORM) or the Department of Planning and Budget (DPB) pursuant to EO 19, the Regulations for Filing and Publishing Agency Regulations (1 VAC 7-10), 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 the subject matter, intent, and goals 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 or changes. If applicable, generally describe the existing regulation.

Chapters [171](#) and [172](#) of the 2023 Acts of Assembly expanded the conditions for which pharmacists can initiate treatment. The legislation additionally required that the Board of Pharmacy promulgate emergency regulations to be effective within 280 days of enactment. These emergency regulations amend existing effective and emergency regulations promulgated pursuant to 2020, 2021, and 2022 legislation regarding pharmacists initiating treatment.

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

Mandate and Impetus (Necessity for Emergency)

Explain why this rulemaking is an emergency situation in accordance with § 2.2-4011 A and B of the Code of Virginia. In doing so, 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, 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.

Enactment clause 3 of Chapters [171](#) and [172](#) of the 2023 Acts of Assembly required the Board to promulgate emergency regulations. Although the General Assembly determined that this legislation required emergency regulations, rather than the Board making such a determination, the emergency is likely the provision of healthcare services at a wider variety of locations for the general public, including pharmacies.

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 or Acts and 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 of the Board of Pharmacy are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Virginia Code § 54.1-2400(6) specifically states that the general powers and duties of health regulatory boards shall be "[t]o promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) that are reasonable and necessary to administer effectively the regulatory system."

Virginia Code § 54.1-3303.1 sets forth the ability for pharmacists to initiate treatment for certain diseases and conditions "in accordance with a statewide protocol developed by the Board in collaboration with the Board of Medicine and the Department of Health and set forth in regulations of the Board."

Purpose

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, explain any potential issues that may need to be addressed as the regulation is developed.

The purpose of the emergency regulations is to ensure that a pharmacist who initiates treatment for patients follows protocols that would render such treatment to be a low risk for patient harm. The rules establishing treatment protocols are necessary to ensure the health and safety of patients who receive treatment from pharmacists.

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.

The changes add group A streptococcus bacteria infections, influenza virus infections, COVID-19 infections, and urinary tract infections as diseases or conditions for which pharmacists can initiate treatment with controlled substances or devices for persons 18 and older. These additions are identical to the additions made to Virginia Code § 54.1-3303.1 by the General Assembly.

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) The primary advantages to the public are access to healthcare for certain diseases and conditions at more locations, including patients' local pharmacy. There are no disadvantages to the public.
- 2) There are no primary advantages or disadvantages to the agency or the Commonwealth.
- 3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. Any restraint on competition as a result of promulgating these regulations is a foreseeable, inherent, and ordinary result of the statutory obligation of the Board to protect the safety and health of citizens of the Commonwealth. The Board is authorized under § 54.1-2400 "[t]o 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." The promulgated regulations do not conflict with the purpose or intent of Chapters 1 or 25 of Title 54.1.

Alternatives to Regulation

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.

The General Assembly issued a mandate to the Board to promulgate emergency regulations to permit pharmacists to initiate treatment as provided in the 2023 legislation to be effective within 280 days of enactment. There is no alternative to regulation, therefore none were considered.

Periodic Review and Small Business Impact Review Announcement

This NOIRA is not being used to announce a periodic review or small business impact review.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below. In addition, as required by § 2.2-4007.02 of the Code of Virginia describe any other means that will be used to identify and notify interested parties and seek their input, such as regulatory advisory panels or general notices.

The Board of Pharmacy is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal, (ii) any alternative approaches, (iii) the potential impacts of the regulation, and (iv) the agency’s regulatory flexibility analysis stated in that section of the background document.

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 Erin Barrett, Agency Regulatory Coordinator, 9960 Mayland Drive, Henrico, VA 23233 or erin.barrett@dhp.virginia.gov or by fax to (804) 915-0382. 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 (<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

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. 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. Use all tables that apply, but delete inapplicable tables.

If an existing VAC Chapter(s) is being amended or repealed, use Table 1 to describe the changes between existing VAC Chapter(s) and the emergency regulation. If existing VAC Chapter(s) or sections are being repealed and replaced, ensure Table 1 clearly shows both the current number and the new number for each repealed section and the replacement section.

Table 1: Changes to Existing VAC Chapter(s)

Current chapter-section number	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
21-46	(A) lists the diseases and conditions for which pharmacists can initiate treatment in persons 18 or older using controlled substances or devices.	<p>(A)(11) is added to include group A streptococcus bacteria infections, influenza virus infections, COVID-19 virus infections, and urinary tract infections. These were the four diseases and conditions added by Chapters 171 and 172 of the 2023 Acts of Assembly.</p> <p>Clinical decision-making for these four diseases and conditions can be guided by a clinical test that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. 263a, known as “CLIA-waived tests.”</p> <p>Note: Because these emergency regulations amend existing emergency regulations, the Registrar has requested that the RIS project only list the amendment to the existing language of 18VAC110-21-46. That makes the new section (A)(7). The actual regulation will be (A)(11) once all emergency regulations are final regulations.</p>