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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)	18VAC110-20
VAC Chapter title(s)	Regulations Governing the Practice of Pharmacy
Action title	Pharmacy working conditions
Date this document prepared	September 6, 2022

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 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.

Chapter 628 of the 2022 Acts of Assembly required that the Board of Pharmacy adopt emergency regulations related to work environments for pharmacy personnel that protect the health, safety, and welfare of patients. The Board has amended a section of Chapter 20 and added a new section to address the issues raised by Chapter 628 of the 2022 Acts of Assembly.

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.

PIC = pharmacist in charge

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.

Chapter 628 of the 2022 Acts of Assembly required that the Board of Pharmacy adopt emergency regulations related to work environments for pharmacy personnel that protect the health, safety, and welfare of patients. Enactment 2 of the legislation required that such emergency regulations be effective within 280 days of enactment. Although the General Assembly determined that this legislation required emergency regulations, rather than the Board, the emergency is likely related to concern for the safety of pharmacists, pharmacy staff, and patients given the current healthcare climate and increased workloads for pharmacists and other pharmacy personnel.

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 § 54.1-3307(A) requires the Board to "regulate the practice of pharmacy." That subsection explicitly requires such regulations to include criteria for "[m]aintenance of the integrity of, and public confidence in, the profession and improving the delivery of quality pharmaceutical services to the citizens of Virginia" (Va. Code § 54.1-3307(A)(4)) and "[s]uch other factors as may be relevant to, and consistent with, the public health and safety." (Va. Code § 54.1-3307(A)(9).

Chapter 628 of the 2022 Acts of Assembly directed the Board to promulgate emergency regulations related to pharmacy working conditions.

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 safeguard the health, safety, and welfare of patients by ensuring safe working environments exist for pharmacists and pharmacy personnel, ensuring a pharmacist's authority and control over the practice of pharmacy is not usurped by the pharmacy permit holder, and ensuring proper breaks are provided for pharmacists while protecting patient safety.

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.

In general, the substantive provisions: (i) ensure that the decisions of the pharmacist are not overridden by the pharmacy permit holder, including staffing decisions and the decision of whether pharmacy staff can safely provide vaccines at a given time; (ii) ensure that pharmacy permit holders provide sufficient staffing levels to avoid interference with a pharmacist's ability to practice with reasonable competence and safety; (iii) ensure that a pharmacist and pharmacy personnel are provided with proper and functioning equipment; (iv) ensure pharmacists and pharmacy staff are not burdened with external factors that may inhibit the ability to provide services to the public; (v) ensure staff are properly trained to provide the services they are tasked with; (vi) ensure pharmacists are provided appropriate breaks while maintaining drug stock integrity and providing required consultation services to the public; (vii) ensure pharmacists are provided adequate time to perform professional duties; and (viii) provide a reporting mechanism for staffing concerns.

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 provision of pharmacy services in a safe and efficient manner. 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 and the directive included in Chapter 628 of the 2022 Acts of Assembly. 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.

Chapter 628 of the 2022 Acts of Assembly requires the Board to promulgate regulations. There are no alternatives to regulatory action.

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	New chapter-section number, if applicable	Current requirements in VAC	Change, intent, rationale, and likely impact of new requirements
20-110		Pharmacy permit holders cannot require a pharmacist to work longer than 12 continuous hours except in an emergency. Pharmacists working longer than six continuous hours must be provided a 30-minute break.	Under the amendments, a pharmacist may volunteer to work longer than 12 continuous hours. Additionally, the amendments require that breaks be provided consistent with 18VAC110-20-113(B)(5). The amendments will permit pharmacists to volunteer for longer shifts, but keeps the prohibition on permit holders requiring that pharmacists work more than 12 continuous hours. Additionally the amendments refer back to the new section 20-113 to ensure breaks are provided appropriately.
	20-113	N/A	Subsection A requires that the pharmacy permit holder protect the health, safety, and welfare of patients by consulting with the PIC or pharmacist on duty and other staff to ensure services are safely provided. Subsection A prohibits the permit holder from overriding the control and decision-making of the PIC or pharmacist on duty regarding appropriate working environments. The rationale and likely impact of this provision is to guarantee that the decisions of the PIC or pharmacist on duty is not superseded by the permit holder at the expense of the safety of the public. Subsection B lists the minimum requirements for a permit holder to provide a safe pharmacy working environment. Those include: (i) sufficient staffing and appropriate management of staffing levels; (ii) provision of sufficient tools and equipment, and minimization of distractions to ensure a safe workflow for a pharmacist to practice; (iii) avoidance of external factors, such as production quotas; (iv) ensuring staff are sufficiently trained to perform assigned tasks and work with appropriate supervision; (v)

			provision of uninterrupted rest periods for pharmacists; (vi) provision of adequate time for pharmacists to complete professional duties; and (vii) assurance that pharmacy technicians do not perform duties restricted to pharmacists. The intent and rationale behind these provisions is creation of a baseline for safe working conditions for pharmacists and pharmacy staff, with the further intent of ensuring the pharmacist and pharmacy staff are able to provide services safely to the public. These minimum requirements address the subjects included in Chapter 628 of the 2022 Acts of Assembly. Subdivision (B)(5) additionally provides specific requirements for pharmacist break periods. The pharmacy may close during a pharmacist's break period based on the professional judgment of the pharmacist on duty as long as the pharmacy has complied with public notice requirements contained in Va. Code § 54.1-3434 and 18VAC110-20-135. If the pharmacy does not close during a pharmacist's break, the pharmacist must ensure security of drugs in the pharmacy by remaining in the pharmacy department or on the premises. Additionally, the pharmacist must determine if pharmacy technicians or pharmacy interns on staff may continue to perform duties while the pharmacist is on break. Subsection (B)(5)(c) contains responsibilities regarding patient counseling required by Va. Code § 54.1-3319 is provided immediately following the pharmacist's break. The rationale behind these amendments is to provide options and minimum requirements for pharmacist break periods, including options for the pharmacy closing or remaining open during the pharmacist break period. Subsection C states that a permit holder shall not override the control of the pharmacist on duty regarding all aspects of the practice of pharmacy. Although this is implied in other provisions of regulation and statute, this provision is meant to state the obvious and specifically prohibit encroaching on a

			pharmacist's professional responsibilities. Subsection D provides a mechanism for internally reporting and recording staffing issues and resolving reported issues. Subsection D further prohibits workplace discipline against pharmacists or other pharmacy staff for good faith reporting of staffing concerns. The intent behind these provisions is to provide requirements for internal reports of staffing concerns and documentation of those concerns. The amendments additionally intend to require that a permit holder provide any staffing concern forms provided by staff to the permit holder to Board inspectors.