townhall.virginia.gov

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	Requirements for use of central fill pharmacy and remote database access
Date this document prepared	June 25, 2024

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.

Pursuant to a directive from the 2024 General Assembly, the Board of Pharmacy has adopted emergency regulations to allow the use of central fill pharmacies and remote database access. Both actions are permitted on a case-by-case basis as part of pilot programs approved by the Board. The terms of those pilot programs have been incorporated into the emergency regulations.

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.

Chapter 407 of the 2024 Acts of Assembly requires the Board to promulgate regulations to implement the provisions of the act. These emergency regulations are therefore promulgated pursuant to Va. Code § 2.2-4011(B). The Board did not determine the necessity for this regulatory change. That determination was made by the General Assembly.

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."

Additionally, Chapter 407 of the 2024 Acts of Assembly requires the Board to promulgate regulations regarding central fill pharmacies and remote database access.

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 Board has not made this determination; the determination was made by the General Assembly.

As the regulation develops, the Board may need to amend regulations at the proposed or final stage to appropriately account for descriptions of operations at central fill pharmacies to ensure the regulatory language covers all necessary scenarios.

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 276 is amended to ensure pharmacy technicians and pharmacy interns performing the duties of pharmacy technicians are able to access remote databases of the pharmacy employer to perform functions listed in 18VAC110-20-276(A).

Section 277 is added to Chapter 20 to provide a framework for use of central fill pharmacies. The section addresses requirements for operation and dispensing at a central fill pharmacy, among other topics specified in the chart below.

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 faster refilling of prescriptions that may be outsourced to a central fill pharmacy or for which tasks may be completed remotely prior to dispensing the prescription. 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.

There is no alternative to regulation. The Board was directed by the General Assembly to promulgate regulations regarding central fill pharmacies and remote database access. The draft changes closely mirror existing pilot programs currently in operation and which the stakeholder and business community requested.

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
20-112		Provides requirements for supervision of pharmacy technicians	Subsection A is amended to exempt the stated pharmacist to pharmacy technician ratio from application in sections 276 and 277.
20-276		Provides requirements for centralized or remote processing of prescriptions	F currently states that nothing in the section shall prohibit an employee that is a pharmacist from accessing the employer's pharmacy database from a remote location to perform functions listed in 20-276 A. The phrase "or registered as a pharmacy technician or pharmacy intern performing the duties of a pharmacy technician" is added to F to include pharmacy technicians and pharmacy interns performing pharmacy technician functions in the exception. This will allow pharmacy technicians and pharmacy interns to access the employer pharmacy's remote database to perform functions listed in 20-276 A.
	20-277	Provides requirements for operation of a central fill pharmacy	Subsection A provides the general allowance for a pharmacy in the Commonwealth or out-of-state to outsource certain tasks to a central fill pharmacy. Subsection B provides three specific requirements to operate as a central fill pharmacy. Those are that sufficient automation is employed to safely support the practice of pharmacy and limit distractions for pharmacy personnel, that the central fill pharmacy does not accept prescriptions or communications directly from patients or providers, and that dispensing is limited to Schedule VI drugs. These requirements currently exist in pilot programs approved by the Board and are listed as requirements in the legislation. Subsection C provides a list of non-dispensing functions that may be performed by unlicensed or unregistered personnel in the central fill pharmacy. Those include certain movement of sealed manufacturer bottles, manually bagging certain prescriptions, loading an automated robotic dispenser in certain

			situations, and performing monthly cycle counts of sealed manufacturer-packaged products in certain situations. This list currently exists in pilot programs approved by the Board and is intended to allow safe participation by unlicensed or unregistered personnel in the operation of the central fill pharmacy for greater efficiency. Subsection D provides an allowance for a pharmacist to supervise up to 12 licensed or registered persons at a central fill pharmacy. This supervisory limit is consistent with existing pilot programs. Additionally, an allowance is provided for a pharmacist to supervise up to 12 unlicensed persons performing the functions listed in subsection C. The current pilot program does not provide a supervisory limit for unlicensed personnel, but HB1068 requires the Board to provide such a supervisory limit. The subsection also states that the pharmacist shall determine the number of persons that the pharmacist can safely and competently supervise at one time. This will allow a supervising pharmacist to determine that a lower number than 12 can be safely and competently supervised. Subsection E allows the pharmacist verification of a canister of medication after it is filled and sealed but prior to being loaded into a barcoded automated robotic dispenser to serve as the final product verification of a prescription. Certain requirements related to accuracy checks, record maintenance, and packaging and labeling apply as described in the subsection. The final statement of the subsection clarifies that the pharmacist is still required to verify the accuracy of data entry of the prescription. These provisions are part of existing pilot programs and reflect current practices of pharmacies using central fill pharmacies. Subsection F contains a requirement for central fill pharmacies to notify customers by signage or in writing of the dispensing and delivery process by the central fill pharmacy to the recipient pharmacy. The subsection exempts central fill

			pharmacies from the requirement contained in 18VAC110-20-275 B 2 h, which would require the recipient pharmacy to obtain consent from patients for central fill dispensed medications and delivery and for the recipient pharmacy to maintain a manual which describes the process for obtaining such consent. Subsection G requires the central fill pharmacy to maintain written policies and procedures that include, at a minimum, the seven requirements in the subsection. The requirements include the following topics: • packaging and repackaging of drugs in the robotic pharmacy system; • stocking and restocking of the robotic pharmacy system; • removal of expired drugs; • handling of drugs dropped by the robotic pharmacy system; • routine maintenance of the robotic pharmacy system; • investigation, identification, and correction of discrepancies or errors associated with the robotic pharmacy system; and • quality assurance reports. These are current requirements in approved pilot programs. Subsection H requires manual picks for dispensing at a central fill pharmacy be verified for accuracy by a pharmacist. This is a current requirement in approved pilot programs. Subsection I describes what steps must be taken in the event the robot at a central fill pharmacy selected an incorrect medication. These steps include identification and correction of the source of the discrepancy, an investigation of the cause of the event, corrective action, and documentation. This is a current requirement in approved pilot programs. Subsection J sets forth requirements for a quarterly audit by a pharmacist of one prescription per automated dispensing

			device. Quality assurance records generated from these quarterly audits must be maintained for two years from the date the audit is performed. This is a current requirement in approved pilot programs. Subsection K allows the central fill pharmacy to deliver the dispensed drug to the patient's residence or the originating pharmacy. This is a current allowance in approved pilot programs. Subsection L allows out-of-state recipient pharmacies to return prescriptions that were not picked up by the patient to the central fill pharmacy without obtaining a registration as a nonresident pharmacy. This will allow for drugs to be returned to the central fill pharmacy without unduly burdening the recipient pharmacies. Subsection M states that a transfer of the prescription between the originating pharmacy and the central fill pharmacy shall not be required if the two share a common electronic file or have technology that allows information necessary for dispensing of the prescription to be shared. This exemption is contained in the legislation.