



[townhall.virginia.gov](http://townhall.virginia.gov)

## Fast-Track Regulation Agency Background Document

<b>Agency name</b>	Board of Pharmacy, Department of Health Professions
<b>Virginia Administrative Code (VAC) citation(s)</b>	18VAC110-20-10 et seq.
<b>Regulation title(s)</b>	Regulations Governing the Practice of Pharmacy
<b>Action title</b>	Definition of "cold" temperature
<b>Date this document prepared</b>	12/19/18

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 10 is amended to conform the definition of "cold" to include revised the temperature range for drug storage in a freezer in accordance with recent guidance from the United States Pharmacopeia.

### 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.*

USP = *United States Pharmacopeia*

### Statement of Final Agency Action

Please provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

On December 18, 2018, the Board of Pharmacy adopted an amendment to 18VAC110-20-10 et seq., Regulations Governing the Practice of Pharmacy.

### 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."

As required by Virginia Code § 2.2-4012.1, please also explain why this rulemaking is expected to be noncontroversial and therefore appropriate for the fast-track process.

The impetus for this action is conforming to a national standard for drug safety and purity and should not be controversial, so a fast-track process is appropriate.

### 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 Pharmacy the authority to promulgate regulations to administer the regulatory system and a specific mandate of Chapter 82 of the 2016 General Assembly:

**§ 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 (§ 2.2-4000 et seq.) that are reasonable and necessary to administer effectively the regulatory system, which shall include provisions for the satisfaction of board-required continuing education for individuals registered, certified, licensed, or issued a multistate licensure privilege by a health regulatory board through delivery of health care services, without compensation, to low-income*

*individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those health services. 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.).*

The statutory authority for the Board to promulgate regulations to regulate the security and integrity of drugs and devices is found in:

**§ 54.1-3307. Specific powers and duties of Board.**

*A. The Board shall regulate the practice of pharmacy and the manufacturing, dispensing, selling, distributing, processing, compounding, or disposal of drugs and devices. The Board shall also control the character and standard of all drugs, cosmetics and devices within the Commonwealth, investigate all complaints as to the quality and strength of all drugs, cosmetics, and devices and take such action as may be necessary to prevent the manufacturing, dispensing, selling, distributing, processing, compounding and disposal of such drugs, cosmetics and devices that do not conform to the requirements of law.*

*The Board's regulations shall include criteria for:*

- 1. Maintenance of the quality, quantity, integrity, safety and efficacy of drugs or devices distributed, dispensed or administered.*
- 2. Compliance with the prescriber's instructions regarding the drug, its quantity, quality and directions for use.*
- 3. Controls and safeguards against diversion of drugs or devices.*
- 4. Maintenance of the integrity of, and public confidence in, the profession and improving the delivery of quality pharmaceutical services to the citizens of Virginia.*
- 5. Maintenance of complete records of the nature, quantity or quality of drugs or substances distributed or dispensed, and of all transactions involving controlled substances or drugs or devices so as to provide adequate information to the patient, the practitioner or the Board.*
- 6. Control of factors contributing to abuse of legitimately obtained drugs, devices, or controlled substances.*
- 7. Promotion of scientific or technical advances in the practice of pharmacy and the manufacture and distribution of controlled drugs, devices or substances.*
- 8. Impact on costs to the public and within the health care industry through the modification of mandatory practices and procedures not essential to meeting the criteria set out in subdivisions 1 through 7 of this section.*
- 9. Such other factors as may be relevant to, and consistent with, the public health and safety and the cost of rendering pharmacy services.*

## 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 the amended regulation is maintain state regulations for consistency with the national standards for temperature and storage of drugs found in Chapter 659 of USP. The *United States Pharmacopeia (USP)* is a pharmacopeia (compendium of drug information) for the United States. The *USP* is published in a combined volume with the *National Formulary* (a formulary) as the *USP-NF*. *USP-NF* standards have a role in U.S. federal law; a drug or drug ingredient with a name recognized in *USP-NF* is considered adulterated if it does not satisfy compendial standards for strength, quality or purity. USP has no role in enforcing its standards; enforcement is the responsibility of Food and Drug Administration (FDA) and other government authorities in the U.S. and elsewhere. Therefore, consistency of state regulations with USP standards protects the public health and safety in matters relating to drug storage and integrity.

## 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 10 is amended to conform the definition of "cold" to include revised the temperature range for drug storage in a freezer in accordance with recent guidance from the United States Pharmacopeia.

## 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 real advantages or disadvantages to the public
- 2) There are no advantages or disadvantages to this agency or the Commonwealth.
- 3) 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 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. 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.) This proposal is consistent with the agency's statutory responsibility to protect public health and safety and to protect the integrity and safety of prescription drugs in the Commonwealth.

### 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 – Any state agency that has a pharmacy that stores drugs in a freezer would have a less restrictive regulation (wider temperature range allowed).

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

<p><i>For your agency:</i> 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</p>	<p>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.</p>
<p><i>For other state agencies:</i> projected costs, savings, fees or revenues resulting from the regulatory change, including a delineation of one-time versus on-going expenditures.</p>	<p>No costs</p>

<i>For all agencies:</i> Benefits the regulatory change is designed to produce.	Any state agency that has a pharmacy that stores drugs in a freezer would have a less restrictive regulation (wider temperature range allowed).
---	---

**Impact on Localities**

Projected costs, savings, fees or revenues resulting from the regulatory change.	None
Benefits the regulatory change is designed to produce.	None

**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.	Pharmacies that store certain drugs in a freezer
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.	There are 1813 permitted pharmacies in Virginia; there is no estimate of the number that may be a small business, since most retail pharmacies are now owned by large national chains.
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.	No costs; no need for new equipment, etc.
Benefits the regulatory change is designed to produce.	It is a somewhat less restrictive rule, so compliance may be easier with a wider range of temperature for a freezer.

**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 that will achieve the purpose of this regulatory action.

## 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 is no alternative to the adoption of amendments to regulations to accomplish the intent of this action.

## Public Participation

*If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register; and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.*

## 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.*

*If the regulatory change will be a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory change. Delete inapplicable tables.*

*If the regulatory change is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below. Please include citations to the specific section(s) of the regulation that are changing.*

Current section number	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
10	Sets out definitions for words and terms used in the Chapter	Within the definition of “cold,” there is a definition of a freezer. It currently says a freezer is a cold place in which the temperature is maintained thermostatically between -20° and -10°C (-4° and 14°F). The revised definition says a freezer is <u>controlled between -25° and -10° C (-13° and 14° F). In those instances in which articles may have a recommended storage condition below -20° C (-4° F), the temperature</u>

		<p><u>of the storage location should be controlled to +/-10°.</u> <i>The revision is consistent with a revised bulletin for USP Chapter 659 for Temperature and Storage Definitions. The revised definition offers a wider range of temperature allowance and is thereby less restrictive than the current definition.</i></p>
--	--	--