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Proposed Regulation
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) Chapter citation(s)	18VAC110-60
VAC Chapter title(s)	Regulations Governing Pharmaceutical Processors
Action title	Prohibition on products containing Vitamin E acetate
Date this document prepared	December 10, 2020

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 (1VAC7-10), 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 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 280 on cultivation and production of cannabis oil is amended to prohibit the production of an oil intended to be vaporized or inhaled from containing vitamin E acetate.

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

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, or board decision). 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the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

Due to the outbreak of e-cigarette or vaping product use-associated lung injury, the Board evaluated whether there should be a prohibition on products containing cannabidiol or THC-A oil in formations intended for vaping or inhalation. As of November 13, 2019, the Centers for Disease Control (CDC) reported 2,172 cases of lung disease associated with e-cigarette or vaping product use in 49 states (including Virginia) and 42 deaths in 24 states. The CDC advised against vaping any products that contain THC, especially if obtained from informal or unregulated source. In a consumer alert issued on October 4, 2019, the Food and Drug Administration also warned the public not to use vaping products containing THC.

The CDC has specifically identified vitamin E acetate as a chemical of concern among people with lung injury associated with e-cigarettes or vaping and advised that vitamin E acetate should not be added to e-cigarettes or vaping products.

The Board has regulatory authority only over products from pharmaceutical processors producing cannabis oil. It considered a ban of any products intended for vaping or inhalation. Instead, it has adopted a more narrow prohibition on production of any such products containing vitamin E acetate, consistent with the most recent findings of the CDC.

The need for emergency action was approved by the Office of the Attorney General and the Governor's office. The impetus is replacement of the emergency regulation currently in effect.

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 and Acts of 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 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:

§ 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.).*

Statutory provisions specific to regulation of pharmaceutical processors are found in:

§ 54.1-3442.6. Permit to operate pharmaceutical processor.
A. No person shall operate a pharmaceutical processor without first obtaining a permit from the Board. The application for such permit shall be made on a form provided by the Board and signed by a pharmacist who will be in full and actual charge of the pharmaceutical processor. The Board shall establish an application fee and other general requirements for such application.
B. Each permit shall expire annually on a date determined by the Board in regulation. The number of permits that the Board may issue or renew in any year is limited to one for each health service area established by the Board of Health. Permits shall be displayed in a conspicuous place on the premises of the pharmaceutical processor.
C. The Board shall adopt regulations establishing health, safety, and security requirements for pharmaceutical processors. Such regulations shall include requirements for (i) physical standards; (ii) location restrictions; (iii) security systems and controls; (iv) minimum equipment and resources; (v) recordkeeping; (vi) labeling and packaging; (vii) quarterly inspections; (viii) processes for safely and securely cultivating Cannabis plants intended for producing cannabidiol oil and THC-A oil, producing cannabidiol oil and THC-A oil, and dispensing and delivering in person cannabidiol oil and THC-A oil to a registered patient, his registered agent, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian; (ix) a maximum number of marijuana plants a pharmaceutical processor may possess at any one time; (x) the secure disposal of plant remains; (xi) a process for registering a cannabidiol oil and THC-A oil product; (xii) dosage limitations, which shall provide that each dispensed dose of cannabidiol oil or THC-A not exceed 10 milligrams of tetrahydrocannabinol; and (xiii) a process for the wholesale distribution of and the transfer of cannabidiol oil and THC-A oil products between pharmaceutical processors.
D. Every pharmaceutical processor shall be under the personal supervision of a licensed pharmacist on the premises of the pharmaceutical processor.
E. The Board shall require an applicant for a pharmaceutical processor permit to submit to fingerprinting and provide personal descriptive information to be forwarded along with his fingerprints through the Central Criminal Records Exchange to the Federal Bureau of Investigation for the purpose of obtaining criminal history record information regarding the applicant. The cost of fingerprinting and the criminal history record search shall be paid by the applicant. The Central Criminal Records Exchange shall forward the results of the criminal history background check to the Board or its designee, which shall be a governmental entity.
F. In addition to other employees authorized by the Board, a pharmaceutical processor may employ individuals who may have less than two years of experience (i) to perform cultivation related duties under the supervision of an individual who has received a degree in horticulture

or a certification recognized by the Board or who has at least two years of experience cultivating plants and (ii) to perform extraction-related duties under the supervision of an individual who has a degree in chemistry or pharmacology or at least two years of experience extracting chemicals from plants.
G. No person who has been convicted of (i) a felony under the laws of the Commonwealth or another jurisdiction or (ii) within the last five years, any offense in violation of Article 1 (§ 18.2-247 et seq.) or Article 1.1 (§ 18.2-265.1 et seq.) of Chapter 7 of Title 18.2 or a substantially similar offense under the laws of another jurisdiction shall be employed by or act as an agent of a pharmaceutical processor.
H. Every pharmaceutical processor shall adopt policies for pre-employment drug screening and regular, ongoing, random drug screening of employees.

Purpose

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 is to address the public health concern from a significant number of cases of lung disease associated with vaping or e-cigarettes. Since testing by the CDC has shown that vitamin E acetate is a chemical of concern, the Board has adopted a prohibition against production of cannabis oil containing vitamin E acetate in products intended for vaping or inhalation. The amended regulation is intended to protect the health and safety of consumers who will have access to the oils in the coming months.

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 280 on cultivation and production of cannabis oil is amended to prohibit the production of an oil intended to be vaporized or inhaled from containing vitamin E acetate.

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 advantages to the public include greater assurance of the safety and integrity of the vaping products dispensed; there are no disadvantages to the public;
2) There are no advantages or disadvantages to the agency; and
3) This is a significant new program for the Board of Pharmacy and the Department of Health

Professions in an evolving environment of medical marijuana with wide variance in the policies and models adopted across the United States.
The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. Regulations for processors are a foreseeable result of the statute requiring the Board to protect the health and safety of patients in the Commonwealth. The Board is authorized under § 54.1-2400 to "*promulgate regulations in accordance with the Administrative Process Act which are reasonable and necessary to administer effectively the regulatory system*" and has acted in accordance with a statutory mandate in § 54.1-3442.6 to "*adopt regulations establishing health, safety, and security requirements for pharmaceutical processors."*

Requirements More Restrictive than Federal

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

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, 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. 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.	No impact
For all agencies: Benefits the regulatory change is designed to produce.	No benefits

Impact on Localities

Projected costs, savings, fees or revenues resulting from the regulatory change.	No impact
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.	Pharmaceutical processors There are 4 processors that have been issued permits.
Agency's best estimate of the number of such entities that will be affected. 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 should be no processors affected because the prohibition has been in effect by emergency action.
All projected costs for affected individuals, businesses, or other entities resulting from the regulatory change. 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.
Benefits the regulatory change is designed to produce.	Protection for the public consuming vaping products dispensing by pharmaceutical processors

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 are no alternatives that meet the essential purpose of public protection.

Regulatory Flexibility Analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, 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; the prohibition is not enforceable unless it is stated in regulation.

Periodic Review and Small Business Impact Review Report of Findings

If you are using this form to report the result of a periodic review/small business impact review that is being conducted as part of this regulatory action, and was announced during the NOIRA stage, indicate whether the regulatory change meets the criteria set out in Executive Order 14 (as amended, July 16, 2018), e.g., is necessary for the protection of public health, safety, and welfare; minimizes the economic impact on small businesses consistent with the stated objectives of applicable law; and is clearly written and easily understandable.

In addition, as required by § 2.2-4007.1 E and F of the Code of Virginia, discuss the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation; (3) the complexity of the regulation; (4) the extent to the which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, discuss why the agency's decision, consistent with applicable law, will minimize the economic impact of regulations on small businesses.

This action is not being used for a periodic review.

Public Comment

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

There was a comment period on the NOIRA from August 31, 2020 to September 30, 2020. No comment was received.

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.

The Board of Pharmacy is seeking comments on this regulation, including but not limited to: ideas to be considered in the development of this regulation, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation. Also, the agency/board is also 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) the probable effect of the regulation on affected small businesses; and 3) the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

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 Elaine Yeatts, Senior Policy Analyst, 9960 Mayland Drive, Suite 300, Henrico, VA 23233; email: Elaine.yeatts@dhp.virginia.gov FAX- 804-527-4434. 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 (https://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.

A regulatory advisory panel will not be used.

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.

Current section number	Current requirement	Change, intent, rationale, and likely impact of new requirements
280	Provides rules for cultivation and production of cannabidiol oil or THC-A oil	Subsection D is amended to prohibit production of an oil intended to be vaporized or inhaled from containing Vitamin E acetate. *The intent of the action is to proactively protect consumers who want to purchase products from pharmaceutical processors in formulations that may be vaped or inhaled. In Massachusetts, the Cannabis Control Commission issued a quarantine on and order for cessation of sales of all vaporizer products for marijuana establishments and treatment centers based on the determination that these products pose an immediate or serious threat to public health, safety or welfare.* *The Board decided not to impose a general ban on vaped products from pharmaceutical processors but to adopt a prohibition on products containing vitamin E acetate, based on findings from the CDC.*