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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) citation(s)	18VAC110-60
Regulation title(s)	Regulations Governing Pharmaceutical Processors
Action title	Prohibition on products containing Vitamin E acetate
Date this document prepared	12/9/19

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 VAC 7-10), 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 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.

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

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.

N/A

Mandate and Impetus (Necessity for Emergency)

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

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 cannabidiol or THC-A 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 will be reviewed by the Office of the Attorney General. The proposal has been sent to the Governor's office for approval.

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:

§ 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.).

Authority for promulgation of an emergency regulation is found in:

§ 2.2-4011. Emergency regulations; publication; exceptions.
A. Regulations that an agency finds are necessitated by an emergency situation may be adopted by an agency upon consultation with the Attorney General, which approval shall be granted only after the agency has submitted a request stating in writing the nature of the emergency, and the necessity for such action shall be at the sole discretion of the Governor.

Purpose

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

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 cannabidiol or THC-A 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

Please describe any changes that are proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate. Set forth the specific reasons the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of Virginians.

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.*

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) The advantage to the public is some assurance of the safety and integrity of the products dispensed containing cannabidiol or THC-A oils; there are no disadvantages to the public.
2) There are no specific advantages or disadvantages to the agency.
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 and in a situation in which marijuana remains an illegal substance on the federal level.

The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. The proposed regulation promulgated by the Board does not represent any restraint on that competition. 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.*"

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.

As noted in the substance section, Massachusetts has banned all vaporizer products produced from marijuana. The Virginia Board considered a general ban on products from pharmaceutical producers that are intended for vaping. Instead, the Board took a more narrow approach and followed the specific recommendation from the CDC about elimination of vitamin E acetate in any product intended for vaping or inhalation.

Public Participation

Please indicate how the public should contact the agency to submit comments on this regulation, including ideas to assist the agency in the development of the regulation and the costs and benefits of the alternatives stated in this notice or other alternatives.

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.