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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	Registered agents and wholesale distribution of oils
Date this document prepared	9/25/19

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 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.

SB1719 requires the adoption of emergency regulations regarding the registration of agents for patients certified to receive cannabidiol or THC-A oil, so all sections that reference registered individuals are amended to include registered agents. The bill also provides for wholesale distribution of oils between processors, so section 251 is added to establish the requirements for such distribution.

The Board has also amended: 1) 18VAC110-60-130(G) to delete the prohibition on growing cannabis earlier than two weeks prior to an opening date for the processor; the amended regulation allow the processor to begin cultivation once the permit has been issued; and 2) 18VAC110-60-170 relating to employment of individuals with less than two years of experience for certain duties in the processor.

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.

SB1719 requires the adoption of emergency regulations regarding the registration of agents for patients certified to receive cannabidiol or THC-A oil and provides for wholesale distribution of oils between processors. The 2nd enactment clause on the legislation requires the Board to promulgate regulations to implement provisions of the act within 280 days of its enactment.

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:

1. To establish the qualifications for registration, certification, licensure or the issuance of a multistate licensure privilege in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.

2. *To examine or cause to be examined applicants for certification or licensure. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.*
3. *To register, certify, license or issue a multistate licensure privilege to qualified applicants as practitioners of the particular profession or professions regulated by such board.*
4. *To establish schedules for renewals of registration, certification, licensure, and the issuance of a multistate licensure privilege.*
5. *To levy and collect fees for application processing, examination, registration, certification or licensure or the issuance of a multistate licensure privilege and renewal that are sufficient to cover all expenses for the administration and operation of the Department of Health Professions, the Board of Health Professions and the health regulatory boards.*
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.).*
7. *To revoke, suspend, restrict, or refuse to issue or renew a registration, certificate, license, permit, or multistate licensure privilege which such board has authority to issue for causes enumerated in applicable law and regulations.*

The specific statutory authority for the Board to promulgate these regulations is found in the following sections:

§ 54.1-3408.3. Certification for use of cannabidiol oil or THC-A oil for treatment.

A. As used in this section:

"Cannabidiol oil" means any formulation of processed Cannabis plant extract that contains at least 15 percent cannabidiol but no more than five percent tetrahydrocannabinol, or a dilution of the resin of the Cannabis plant that contains at least five milligrams of cannabidiol per dose but not more than five percent tetrahydrocannabinol. "Cannabidiol oil" does not include industrial hemp, as defined in § [3.2-4112](#), that is grown, dealt, or processed in compliance with state or federal law.

"Practitioner" means a practitioner of medicine or osteopathy licensed by the Board of Medicine, a physician assistant licensed by the Board of Medicine, or a nurse practitioner jointly licensed by the Board of Medicine and the Board of Nursing.

"Registered agent" means an individual designated by a patient who has been issued a written certification, or, if such patient is a minor or an incapacitated adult as defined in § [18.2-369](#), designated by such patient's parent or legal guardian, and registered with the Board pursuant to subsection G.

"THC-A oil" means any formulation of processed Cannabis plant extract that contains at least 15 percent tetrahydrocannabinol acid but not more than five percent tetrahydrocannabinol, or a dilution of the resin of the Cannabis plant that contains at least five milligrams of tetrahydrocannabinol acid per dose but not more than five percent tetrahydrocannabinol.

B. A practitioner in the course of his professional practice may issue a written certification for the use of cannabidiol oil or THC-A oil for treatment or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use.

C. The written certification shall be on a form provided by the Office of the Executive Secretary of the Supreme Court developed in consultation with the Board of Medicine. Such written certification shall contain the name, address, and telephone number of the practitioner, the name and address of the patient issued the written certification, the date on which the written certification was made, and the signature of the practitioner. Such written certification issued pursuant to subsection B shall expire no later than one year after its issuance unless the practitioner provides in such written certification an earlier expiration.

D. No practitioner shall be prosecuted under § 18.2-248 or 18.2-248.1 for dispensing or distributing cannabidiol oil or THC-A oil for the treatment or to alleviate the symptoms of a patient's diagnosed condition or disease pursuant to a written certification issued pursuant to subsection B. Nothing in this section shall preclude the Board of Medicine from sanctioning a practitioner for failing to properly evaluate or treat a patient's medical condition or otherwise violating the applicable standard of care for evaluating or treating medical conditions.

E. A practitioner who issues a written certification to a patient pursuant to this section shall register with the Board. The Board shall, in consultation with the Board of Medicine, set a limit on the number of patients to whom a practitioner may issue a written certification.

F. A patient who has been issued a written certification shall register with the Board or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, a patient's parent or legal guardian shall register and shall register such patient with the Board.

G. A patient, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian, may designate an individual to act as his registered agent for the purposes of receiving cannabidiol oil or THC-A oil pursuant to a valid written certification. Such designated individual shall register with the Board. The Board may set a limit on the number patients for whom any individual is authorized to act as a registered agent.

H. The Board shall promulgate regulations to implement the registration process. Such regulations shall include (i) a mechanism for sufficiently identifying the practitioner issuing the written certification, the patient being treated by the practitioner, his registered agent, and, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, the patient's parent or legal guardian; (ii) a process for ensuring that any changes in the information are reported in an appropriate timeframe; and (iii) a prohibition for the patient to be issued a written certification by more than one practitioner during any given time period.

I. Information obtained under the registration process shall be confidential and shall not be subject to the disclosure provisions of the Virginia Freedom of Information Act (§ 2.2-3700 et seq.). However, reasonable access to registry information shall be provided to (i) the Chairmen of the House and Senate Committees for Courts of Justice, (ii) state and federal agencies or local law enforcement for the purpose of investigating or prosecuting a specific individual for a specific violation of law, (iii) licensed physicians or pharmacists for the purpose of providing patient care and drug therapy management and monitoring of drugs obtained by a registered patient, (iv) a pharmaceutical processor involved in the treatment of a registered patient, or (v) a

registered patient, his registered agent, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, the patient's parent or legal guardian, but only with respect to information related to such registered patient.

Article 4.2. Permitting of Pharmaceutical Processors to Produce and Dispense Cannabidiol Oil and THC-A Oil.

§ 54.1-3442.5. Definitions.

As used in this article:

"Cannabidiol oil" has the same meaning as specified in § 54.1-3408.3.

"Pharmaceutical processor" means a facility that (i) has obtained a permit from the Board pursuant to § 54.1-3408.3 and (ii) cultivates Cannabis plants intended only for the production of cannabidiol oil or THC-A oil, produces cannabidiol oil or THC-A oil, and dispenses cannabidiol oil or 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.

"Practitioner" has the same meaning as specified in § 54.1-3408.3.

"Registered agent" has the same meaning as specified in § 54.1-3408.3.

"THC-A oil" has the same meaning as specified in § 54.1-3408.3.

§ 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.

§ 54.1-3442.7. Dispensing cannabidiol oil and THC-A oil; report.

A. A pharmaceutical processor shall dispense or deliver cannabidiol oil or THC-A oil only in person to (i) a patient who is a Virginia resident, has been issued a valid written certification, and is registered with the Board pursuant to § [54.1-3408.3](#), (ii) such patient's registered agent, or (iii) if such patient is a minor or an incapacitated adult as defined in § [18.2-369](#), such patient's parent or legal guardian who is a Virginia resident and is registered with the Board pursuant to § [54.1-3408.3](#). Prior to the initial dispensing of each written certification, the pharmacist or pharmacy technician at the location of the pharmaceutical processor shall make and maintain for two years a paper or electronic copy of the written certification that provides an exact image of the document that is clearly legible; shall view a current photo identification of the patient, registered agent, parent, or legal guardian; and shall verify current board registration of the practitioner and the corresponding patient, registered agent, parent, or legal guardian. Prior to any subsequent dispensing of each written certification, the pharmacist, pharmacy technician, or delivery agent shall view the current written certification; a current photo identification of the patient, registered agent, parent, or legal guardian; and the current board registration issued to the patient, registered agent, parent, or legal guardian. No pharmaceutical processor shall dispense more than a 90-day supply for any patient during any 90-day period. The Board shall establish in regulation an amount of cannabidiol oil or THC-A oil that constitutes a 90-day supply to treat or alleviate the symptoms of a patient's diagnosed condition or disease.

B. A pharmaceutical processor shall dispense only cannabidiol oil and THC-A oil that has been cultivated and produced on the premises of a pharmaceutical processor permitted by the Board. A pharmaceutical processor may begin cultivation upon being issued a permit by the Board.

C. The Board shall report annually by December 1 to the Chairmen of the House and Senate Committees for Courts of Justice on the operation of pharmaceutical processors issued a permit by the Board, including the number of practitioners, patients, registered agents, and parents or

legal guardians of patients who have registered with the Board and the number of written certifications issued pursuant to § 54.1-3408.3.

D. The concentration of tetrahydrocannabinol in any THC-A oil on site may be up to 10 percent greater than or less than the level of tetrahydrocannabinol measured for labeling. A pharmaceutical processor shall ensure that such concentration in any THC-A onsite is within such range and shall establish a stability testing schedule of THC-A oil.

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.

Amendments are adopted to allow a patient to designate an agent who is registered with the Board to act on the patient’s behalf in the receipt of cannabidiol or THC-A oil. Persons registered as agents must provide qualifying information and abide by rules governing patients, parents, or legal guardians for obtaining and protecting the oils. Additionally, amended regulations will allow for wholesale distribution of the oils between processors. Rules for such distribution require that all testing has been completed to ensure that the products are safe for dispensing and that security and record-keeping is adequate to protect public health and safety.

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	New section number, if applicable	Current requirement	Change, intent, rationale, and likely impact of new requirements
All through Chapter 60		Current regulations refer to a registered patient, parent or legal guardian	<p>The emergency regulation has added reference to a patient’s agent or registered agent in 65 places throughout the chapter. The agent must be registered with the Board in order to have the same authority as a patient, parent or guardian to possess the oils and for the processor to be able to dispense the oils. Fees for initial registration and renewal of registration are the same as those for a parent or legal guardian (\$25).</p> <p>In sections that include a registered patient, parent or guardian, a registered agent has been added.</p> <p>Subsection B of section 50 is added to specify the allowance of a patient to</p>

			<p>name an agent to act on his behalf and to set a limit of two patients per agent. In that subsection are also the requirements for information that must be provided in order for a person to register as an agent for a particular patient.</p> <p><i>Subsection G of 54.1-3408.3 authorizes the Board to set a limit on the number of patients for whom an individual may serve as a registered agent. The expressed intent for a registered agent is to allow someone close to a patient (child, caregiver, etc.) who does not qualify as a parent or guardian to be able to obtain the oils on behalf of a patient. It was not intended to become a business venture for unconnected persons to serve as agents for patients. Therefore, the Board set a limitation of 2:1 with the intent of maintaining the security of the products.</i></p> <p><i>Since the only authority for a person to possess oils intended for a specific patient is through registration as an agent for that patient, subsection C is added to section 70 to specify that a registered agent must notify the Board within 15 days if there is a change in the patient for who he is serving as an agent.</i></p>
130		Sets out the rules for granting a pharmaceutical processor permit	<p>For consistency with subsection B of § 54.1-3442.7 (as amended by SB1719 of the 2019 General Assembly), the Board has amended 18VAC110-60-130(G) to delete the prohibition on growing cannabis earlier than two weeks prior to an opening date for the processor; the amended regulation allow the processor to begin cultivation once the permit has been issued.</p>
170		Sets out the requirements for employees of pharmaceutical processors	<p>For consistency with new subsection F of § 54.1-3442.6 (as amended by SB1719 of the 2019 General Assembly), the Board has amended 18VAC110-60-170 relating to employment of individuals with less than two years of experience for certain duties in the processor.</p>
220		Sets out prohibitions for pharmaceutical processors	<p>Subsections A and H are amended to make an exception for the prohibition on selling, delivering, transporting, or distributing Cannabis, including the oils to any other facility for the wholesale distribution of oil products.</p> <p><i>Since amendments to the Code through SB1719 will permit wholesale</i></p>

			<i>distribution, the exception to the current prohibition was necessary.</i>
251	Sets out the requirements for wholesale distribution of cannabidiol and THC-A oil products		<p>Subsection A specifies that oil products that have passed all required testing and have been labeled for sale may be wholesale distributed between processors.</p> <p>Subsection B sets out the records required for the transaction and distribution and the requirements for maintaining records for three years (consistent with other record-keeping requirements)</p> <p>Subsection C sets requirements for storage, handling, and maintaining policies and procedures that will ensure any recalls are safely executed.</p> <p>Subsection D specifies that any electronic system for records comply with requirements of section 260 of this chapter.</p> <p><i>All requirements of section 251 are consistent with other provisions in regulation for wholesale distribution and consistent with the need for public safety in the handling and distribution of these products.</i></p>

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 advantages to the public include assurance of the safety and integrity of the products dispensed and security for the Cannabis and oils; there are no disadvantages to the public;
- 2) The advantage to the agency is clarity in the rules and consistency with the law; there are no 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 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 limited number of pharmaceutical processors (one in each of the five health planning districts) as specified in statute created competition for permits, but the regulations promulgated by the Board do 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.

There are no alternatives to the adoption of regulations; it is mandated by action of the General Assembly.

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.

Also, indicate whether a public hearing is to be held to receive comments. Please include one of the following choices: 1) a panel will be appointed and the agency’s contact if you’re interested in serving on the panel is _____; 2) a panel will not be used; or 3) public comment is invited as to whether to use a panel to assist in the development of this regulation.

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.