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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)	18VAC110-60-10 et seq.
Regulation title(s)	Regulations Governing Pharmaceutical Processors
Action title	2018 revisions
Date this document prepared	6/21/18

This form is used when an agency wishes to promulgate an emergency regulation (to be effective for up to eighteen months), as well as publish a Notice of Intended Regulatory Action (NOIRA) to begin the process of promulgating a permanent replacement regulation. This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

Chapters 246 and 567 of the 2018 Acts of the Assembly require the Board to amend its emergency regulations governing issuance of a permit for a pharmaceutical processor to manufacture and provide cannabidiol oil and THC-A oil. The amendments address the Code changes for patients who may receive a certification from a physician to possess the oil, the type of physician who may issue a certification, the change from a 30-day to a 90-day supply for

dispensing the oil and the number of plants allocated, criminal background checks for applicants, allowance for delivery of the oil after the initial dispensing, and requirements for registration and labeling of the product by brand name.

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

Emergency Authority

The APA (Code of Virginia § 2.2-4011) states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of subdivision A. 4. of § 2.2-4006. Please explain why this is an emergency situation as described above, and provide specific citations to the Code of Virginia or the Appropriation Act, if applicable.

Chapter 567 (SB330) of the 2018 Acts of the Assembly contains a third enactment clause which states: That the Board of Pharmacy shall promulgate regulations to implement the provisions of this act within 280 days of its enactment. Therefore, the Board has adopted emergency regulations in accordance with § 2.2-4011 of the Code of Virginia. Changes to conform regulations to changes in the Code, as required by Chapter 246 (HB1251) are included in this action.

Legal basis

Other than the emergency authority described above, please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and 2) the promulgating entity, i.e., agency, board, or person.

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. (Effective until January 1, 2017) To 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 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 a 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 ~~50~~ *five* milligrams of cannabidiol per milliliter but not more than five percent tetrahydrocannabinol.

"Practitioner" means a practitioner of medicine or osteopathy licensed by the Board of Medicine ~~who is a neurologist or who specializes in the treatment of epilepsy~~.

"THC-A oil" means a 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 ~~50~~ *five* milligrams of tetrahydrocannabinol acid per milliliter 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 ~~a patient's intractable epilepsy~~ *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 ~~intractable epilepsy~~ *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. 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, 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.

H. 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 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.

§ 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 or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian ~~for the treatment of intractable epilepsy~~.

"Practitioner" 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 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; ~~and~~ (x) the secure disposal of plant remains*; and (xi) a process for registering a cannabidiol oil and THC-A oil product*.

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. No person who has been convicted of a felony or of 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 shall be employed by or act as an agent of a pharmaceutical processor.

§ 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 or (ii) 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 ~~verify that the practitioner issuing the written certification, the patient, and, if such patient is a minor or an incapacitated adult, the patient's parent or legal guardian are registered with the Board~~ *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, parent, or legal guardian; and shall verify current board registration of the practitioner and the corresponding patient, 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, parent, or legal guardian; and the current board registration issued to the patient, parent, or legal guardian. No pharmaceutical processor shall dispense more than a ~~30-day~~ *90-day* supply for any patient during any ~~30-day~~ *90-day* period. The Board shall establish in regulation an amount of cannabidiol oil or THC-A oil that constitutes a ~~30-day~~ *90-day* supply to treat or alleviate the symptoms of a patient's ~~intractable epilepsy~~ *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 such pharmaceutical processor.

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, 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. A pharmaceutical processor shall ensure that the concentration of tetrahydrocannabinol in any THC-A oil on site is within 10 percent of the level of tetrahydrocannabinol measured for labeling and shall establish a stability testing schedule of THC-A oil.

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

The purpose of the regulatory action is compliance with Chapters 246 and 567 of the 2018 Acts of the Assembly, which mandated adoption of regulations to implement the act and which contained amendments inconsistent with the current emergency regulations. The goals of the new regulation are accessibility of cannabidiol or THC-A oil for patients with any disease or condition diagnosed by a physician licensed in the Commonwealth. Regulations for pharmaceutical processors and the oils that are produced and dispensed are promulgated in compliance with the conditions and restraints imposed by the statute and in consideration of the need for security of the facility and its contents and the integrity of the dispensed product.

Need

Please describe the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

The statute was amended to expand the access to cannabidiol oil and THC-A oil to any patient with a written certification from any licensed doctor of medicine or osteopathic medicine. The law specifically requires the Board to "adopt regulations establishing health, safety, and security requirements for pharmaceutical processors." (§ 54.1-3442.6 (C)) The safeguards put in place in

statute and regulations are essential to protect the health and safety of the general public and, in particular, the health of the patients to whom cannabidiol or THC-A oil is dispensed.

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 healthy, safety, or welfare of Virginians.

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
10	Creates definitions for words and terms used in this chapter	§§ 54.1-3408.3 and 54.1-3442.7, as amended in Chapter 246	The definition of certification is amended to include any diagnosed condition or disease, as opposed to the previous requirement of a diagnosis of intractable epilepsy. There are amendments throughout the regulation to delete "intractable epilepsy" and insert "any diagnosed condition or disease." The definition of "one-month supply" is deleted and replaced by a definition for a "90-day supply" with the amount allowed to be dispensed changed from 20 fluid ounces to 60 fluid ounces. In sections 10, 90 and in any other sections in which there is a reference to a one-month supply, the regulation is amended to read "90-day supply."
20	Sets fees to be charged for registration of	§§ 54.1-2400 (5) and 54.1-3442.6 C, as amended by Chapters 246 and 567	*Chapter 567 adds a new requirement for registration of a cannabidiol oil and THC-A oil product. A $25 fee is added to the fee schedule to cover costs related to the registration process by the Board.*
30	Sets out requirements for practitioners issuing a certification for cannabidiol or THC-A oil for treatment of intractable epilepsy.	§§ 54.1-2519, 54.1-2521,54.1-2522.1, as amended by Chapter 567	Chapter 567 amended law relating to the Prescription Monitoring Program to include cannabidiol oil and THC-A oil as covered substances with dispensing reportable to the PMP. There is also a new requirement in statute for a practitioner issuing a written certification for the use of the oils to request information from the PMP to determine what covered substances a patient may be receiving. Therefore, subsection B (9) is amended in regulation to

			include such a requirement for a practitioner.
110	The process for permits is set out in this section, beginning with the initial application, followed by awarding of conditional approval, and granting of a full permit.	§§ 54.1-3307 and 54.1-3442.6 as amended by Chapter 567	In the current emergency regulation, there is a requirement for information necessary for the Board to conduct a criminal background check on owners and other person employed by the processors. The amended Code specifies a criminal background check by the Board on an "applicant." The regulation is amended accordingly.
220	Establishes prohibitions for practice by a processor, including requirements that: 1) the facility be closed and secured if there is no pharmacist on premises; 2) no other products are sold; 3) there is no marketing or advertising except basic information on a website; 4) proper identification be worn and access to the facility limited; and 5) no oils be sold, dispensed or distributed by delivery.	§§ 54.1-3307, 54.1-3442.6 and 54.1-3442.7, ad amended by Chapter 567	Subsection D currently prohibits the marketing or advertising of the oils. However, a processor must give the products a brand name and may provide other pertinent information of a website, which could be considered a form of marketing. Therefore, the rule is amended to delete the word "market" to allow the processor to market the products but continue to prohibit advertisements. Subsection H is amended because a change in the law will allow delivery of the product after the initial dispensing, as specified in section 310. An amendment to subsection I corrects a cite.
240	Sets out the requirements for security of the processor to include: 1) a limitation on the number of plants; 2) locking and protection from entry to the areas; 3) a security system capable of remaining operational during a power outage and in accordance with industry standards; and 4) security of the perimeter with video recording of all access points and on-site surveillance.	§§ 54.1-3307, 54.1-3442.6 and 54.1-3442.7, as amended by Chapter 246	Since the Code was amended to allow the processor to dispense a 90-day, rather than a one-month supply, all limitations were adjusted accordingly. A processor may cultivate only the number of plants necessary to produce the amount of oil needed for the first nine months of operation (rather than three months). The processor is not allowed to maintain more than 23 plants per patient (rather than four plants) based on dispensing data from the previous 90 days (rather than 30 days).
285 NEW SECTION	Sets out requirements for registration of the oil products	§§ 54.1-3307 and 54.1-3442.6, as amended by Chapter 567	The registration requirements for the product are separated from the labeling of a batch of cannabidiol oil or THC-A product, as currently found in subsection B of section 290. Subsections A, B, and C in the new section 285 are almost identical to the deleted language in subsections B, C, and D in section 290.
290	Establishes the requirements for labeling of	§§ 54.1-3307 and 54.1-3442.6 as	The labeling and name of batched products is important for the purpose

	batches of oil, including results of batch testing by a laboratory.	amended by Chapter 567	of sample testing of active ingredients. If the sample batch is small, the label for dispensing the oil product may be affixed to the named batch.
295 NEW SECTION	Sets out the requirements for labeling of the dispensed cannabidiol or THC-A oil	§§ 54.1-3307 and 54.1-3442.6 as amended by Chapter 567	The provisions of section 295 are almost identical to provision in subsections E and F in section 290, which now only addresses labeling of batches of oil. The additional labeling are requirements (name of patient, physician, directions for use, name and address of processor) are identical to requirements for medications dispensed by a pharmacy.
310	Sets out the requirements for dispensing of oils, including presentation of the registration of the patient, the written certification, and photo ID. The dispensing is limited to a 90-day supply.	§§ 54.1-3307, 54.1-3408.3, 54.1-3442.6 and 54.1-3442.7 as amended by Chapters 246 and 567	The Code was amended to allow for delivery of the oil after the initial dispensing. Provisions in subsection A are amended to specify the identification required at the time of initial dispensing at the processor, for retention of certification documentation, and for identification required prior to any subsequent dispensing.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

Initial emergency regulations for the permitting of pharmaceutical processors and registration of physicians, patients, and parents were developed using the expertise and recommendations of a Regulatory Advisory Panel. Revisions to those regulations in this action have been adopted to reflect changes in the Code through passage of HB1251 and SB330. There are no alternatives to the adoption of regulations, which is mandated by Chapter 567 of the 2018 Acts of the Assembly.

Public participation

Please indicate whether the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public meeting is to be held to receive comments. Please also indicate whether a Regulatory Advisory Panel or a Negotiated Rulemaking Panel has been used in the development of the emergency regulation and whether it will also be used in the development of the permanent regulation.

The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation.

The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**) or by mail to Elaine Yeatts, 9960 Mayland Drive, Suite 300, Henrico, VA 23233; by email to elaine.yeatts@dhp.virginia.gov; by fax to (804) 527-4434. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight 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.

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

To the extent the cannabidiol oil and THC-A oil is available and effective for patients with various diseases and conditions, these regulations could have an impact on the institution and stability of the family.