townhall.virginia.gov

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	New chapter
Date this document prepared	9/26/16

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of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed.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.

Chapter 577 of the 2016 Acts of the Assembly requires the Board to promulgate regulations governing issuance of a permit for a pharmaceutical processor to manufacture and provide cannabidiol oil and THC-A oil to be used for the treatment of intractable epilepsy. Part I establishes definitions and fees to be charged to applicants, registrants, and permitted processors. As specified in the legislation, Part II of the regulations establishes requirements for issuance or

denial of registration for certifying physicians, patients, parents or legal guardians. Part III sets out the application and approval process for issuing a permit to a pharmaceutical processor, including the information that must be submitted, the requirements for issuing conditional and then final approval, the rules for notification to the Board of any changes or of closure of the processor, and the causes for action against a processor.

Part IV sets out the provisions for personnel at the pharmaceutical processor, including a requirement that a pharmacist with a current, unrestricted Virginia license provide personal supervision on the premises at all times during hours of operation or whenever the processor is accessed. It included requirements for employee training, supervision of pharmacy technicians, and the responsibilities of the pharmacist-in-charge. Part V sets out provisions for the operation of a pharmaceutical processor, including requirements for inventory, security, storage and handling, record-keeping, and reportable events.

Part VI establishes requirements for the cultivation, production, and dispensing of cannabidiol oil, including labeling, laboratory and testing standards, dispensing errors and quality assurance, and proper disposal.

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 577 (SB701) of the 2016 Acts of the Assembly contains a third enactment clause which states: That the Board of Pharmacy shall promulgate regulations to implement the provisions of the first enactment of this act within 280 days of its initial enactment. Such regulations shall not become effective unless the provisions of the first enactment of this act are reenacted by the 2017 Session of the General Assembly. Therefore, the Board has adopted emergency regulations in accordance with § 2.2-4011 of the Code of Virginia.

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 to treat intractable epilepsy.

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 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 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.

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 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.

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 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 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.

D. Every pharmaceutical processor shall be under the personal supervision of a licensed pharmacist on the premises of the pharmaceutical processor.

E. 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 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 dispensing, 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. No pharmaceutical processor shall dispense more than a 30-day supply for any patient during any 30-day period. The Board shall establish in regulation an amount of cannabidiol oil or THC-A oil that constitutes a 30-day supply to treat or alleviate the symptoms of a patient's intractable epilepsy.

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.

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 Chapter 577 of the Acts of the Assembly, which mandated adoption of regulations to implement the act. Regulations so

adopted will not become effective unless the provisions of the act are reenacted by the 2017 General Assembly. The goals of the new regulation are accessibility of cannabidiol or THC-A oil for patients with intractable epilepsy 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 sets limits on the number of permits that the Board may issue and requires that the Board adopt regulations establishing health, safety, and security requirements for permitted processors. It also provides that only a licensed practitioner of medicine or osteopathy who is a neurologist or who specializes in the treatment of epilepsy may issue a written certification to a patient for the use of cannabidiol oil or THC-A oil. It requires that a practitioner who issues a written certification for cannabidiol oil or THC-A oil, the patient issued such certification, and, if the patient is a minor or incapacitated, the patient's parent or legal guardian register with the Board. Further that a pharmaceutical processor shall not provide cannabidiol oil or THC-A oil to a patient or a patient's parent or legal guardian without first verifying that the patient, the patient's parent or legal guardian if the patient is a minor or incapacitated, and the practitioner who issued the written certification have registered with the Board.

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 54.1-3442.5	To provide clarity for use of terms such as dispensing error, one-month supply, resident, qualifying patient, temperature and humidity.
20	Sets fees to be charged for registration of	§§ 54.1-2400 (5) and 54.1-3442.6	Fees are proposed with the intent of covering the expenditures to be incurred by the Board and Department for registration of individuals, renewal of registration,

			processing of applications for a pharmaceutical processor, a permit fee, renewal of permits, and any changes that require a re-inspection of the facility. *Since this is a new activity for the Board, there was no precedence to follow in setting fees. Fees in other states were reviewed for some guidance. For example, in Maryland, the application fee for a combination grower/processor is $11,000 and the annual renewal fee is $165,000. In Connecticut, the annual fee for a producer is $25,000 and for a dispensary, it is $75,000. (In Virginia, the growing, producing, and dispensing are all housed in a single pharmaceutical processor.) The Board based its fees on estimates of additional staffing for licensing, investigations, and inspections (which are required by law to be conducted quarterly.) Specialized training and personnel will be required to conduct the regulatory and disciplinary functions relating to growing, processing and dispensing of these oils.*
30	Sets out requirements for practitioners issuing a certification for cannabidiol or THC-A oil for treatment of intractable epilepsy.	§ 54.1-3408.3	The requirements are intended to fulfill the statutory mandate for registration of a practitioner who issues certification for the use of cannabidiol oil or THC-A oil. The practitioner must be personally responsible for his/her diagnosis, availability, and certification and for instruction about the use of the oils.
40	Lists the practices that are prohibited for a practitioner registered to issue certifications, including benefitting from such certification, providing samples or discounts, or certifying for self or family	§§ 54.1-3316 and 54.1-3408.3	The Board has statutory authority to refuse to issue or discipline a registration. The prohibitions listed in section 40 are unique to the registration of a certifying physician and are intended to protect the integrity of the process and discourage certifying irresponsibly.
50	Sets out requirements for registration of a patient, parent or legal guardian. Regulations list the information that must be submitted on a registration application. Applicants must give permission for a criminal background check and cannot be issued more	§ 54.1-3408.3	The requirements for registration are consistent with the statute and are intended to ensure the identity of the person(s) being registered and their suitability for possession of the oils. The limitation of one certification during any given time frame is specified in the law.

	than one certification at any one time.		
60	Sets out the causes for denial of registration for a patient or parent or legal guardian	§§ 54.1-3316 and 54.1-3408.3	The Board has statutory authority to refuse to issue or discipline a registration. The causes listed in section 60 are unique to the registration of a qualifying patient, his parent or legal guardian and are intended to protect the integrity of the process and appropriate dispensing.
70	Lists the reporting requirements for registered entities as necessary to ensure current information is available and eligibility for certifying and use of the oils is maintained.	§ 54.1-3408.3	The statute requires regulations to establish "a process for ensuring that any changes in the information are reported in an appropriate timeframe." That is the intent of section 70. If, for any reason, the registrant is no longer eligible or the registration is lost or stolen, the Board must be notified within 5 business days and the initial registration must be deactivated.
80	Establishes the rules for proper storage and disposal of the oils by patients or parents or guardians	§ 54.1-3307	Disposal of unused oil is intended to prevent theft, loss or access by unauthorized persons. The methods of disposal are similar to advised methods for prescription drugs.
90	Sets out causes for revocation, suspension of a patient, parent or guardian registration	§§ 54.1-3316 and 54.1-3408.3	The Board has statutory authority to discipline a registrant. The causes listed in section 90 are unique to the specific requirements for a qualifying patient, his parent or legal guardian and for the product being dispensed.
100	Establishes the rules for publication of a notice for submission of an application	§§ 54.1-3307 and 54.1-3442.6	The application and approval of a processor is intended to be a three-part process, initiated with the publication of a notice that the board is receiving applications.
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	The initial application is intended to provide the Board with sufficient information to determine the financial status of the applicant, the proposed location of the facility, authorization to conduct a processing/dispensing business in the locality, graphic and blueprints of the facility, and information about expertise in agriculture and other production techniques required to produce the oils. At the initial application phase, the Board will review paper submissions to determine the viability and suitability of an applicant.
120	Requirements for conditional approval are established to include the criteria by which the Board	§§ 54.1-3307 and 54.1-3442.6	At this 2nd phase, an applicant will be given conditional approval to operate, which will allow construction or remodeling of a facility and

	will evaluate the initial applications, the causes for disqualification of an applicant, and the time limitation of one year for completion of all requirements necessary to operate.		employment of personnel. Since there is a statutory limitation of one processor perm health service area (5 in Virginia), it is important to grant conditional approval only to those applicants that have been deemed suitable and viable to conduct business.
130	Sets out the process and requirements for granting a full permit as a pharmaceutical processor, including designation of a pharmacist-in-charge, criminal background checks for all employees, utilization of an electronic tracking system for all plants from seed to finished oils, and a satisfactory inspection.	§§ 54.1-3307 and 54.1-3442.6	An applicant that has not commenced operation with 180 days of granting a permit may have the permit withdrawn. Again, there can only be one per health district, so a permit holder that is not operational is denying access to the oils to patients and preventing the Board from issuing another permit in that area. Regulations restrict the growing or holding of cannabis more than 2 weeks prior to the approved opening date, which is a requirement intended to limit access to the marijuana used to produce the oils.
140	Lists the requirements for notification to the board of any changes by processors from the information provided in the initial application. The pharmacist-in-charge is responsible for maintenance of current information, and the permit holder cannot make changes to the location, structure, or security of the processor without a new inspection and payment of a fee.	§§ 54.1-3307 and 54.1-3442.6	The statute requires regulations to include requirements for physical standards, location restrictions, security systems, etc, Any substantive changes in such requirements necessitates a new inspection to ensure that safety and security continue to be met.
150	Sets out requirements for the closing, going out of business or change in ownership of a processor. The board must be informed about the disposition and the public must be properly notified to mitigate the effect of a loss of access to the oils.	§§ 54.1-3434.01 and 54.1-3442.6	There are specific steps that must be followed to ensure the security and proper disposition of the contents of a processor, including the plants, dispensing records, and patient information records. The requirements are similar to those for all pharmacies in the Drug Control Act and are intended to provide for continuity of services to the extent possible.
160	Sets out the causes for disciplinary action against a pharmaceutical processor	§§ 54.1-2400 and 54.1-3316	The Board has statutory authority to take disciplinary against a permit holder. The causes listed in section 160 are unique to the specific requirements for a pharmaceutical processor.
170	Establishes the rules for	§§ 54.1-3307, 54.1-	While other states require all

	employee licenses and registrations, including a requirement to have a pharmacist-in-charge and a pharmacist personally supervising in the facility whenever it is being accessed. The duties that may be performed by a pharmacy technician are specified. The qualifications of other employees, who are not pharmacists or pharmacy technicians are also set out in this section	3320 and 54.1-3442.6	employees to be registered with the Board, there is no such authorization in the Virginia law. However, the law does grant general authority to establish requirements as may be necessary to ensure the quality and security of the dispensed product.
180	Requires training for employees, to include proper security measures, state and federal law about patient confidentiality, and procedures for responding to an emergency. The pharmacist-in-charge must assure on-the-job training as necessary and the continuing competence of all employees	§§ 54.1-3307 and 54.1-3442.6	The intent of this section is assurance that all employees are properly trained to ensure the security of the facility and its contents and efficacy of the dispensed product.
190	Specifies the ratio of pharmacy technicians and the responsibility for supervision	§§ 54.1-3321, 54.1-3320 and 54.1-3442.6 18VAC110-20-111. Pharmacy Technicians 18VAC110-20-270. Dispensing of Prescriptions; Certification of Completed Prescriptions; Supervision of Pharmacy Technicians.	The requirement for registration of technicians and for work under supervision of a licensed pharmacist is set in Code in Chapter 33 of Title 54.1. The ratio is the same for processors as for pharmacy practice in general. The limitations on the practice of pharmacy technicians are necessary to ensure that they do not exceed their scope of practice.
200	Sets out the responsibilities of the pharmacist-in-charge, including a requirement that he/she: 1) only be PIC for one processor at a time and work full-time (at least 35 hours a week); 2) is in full and actual control of all aspects of the practice; 3) is responsible for compliance with all requirements for employees, security, etc. There are provisions for a transition to a new	§§ 54.1-3307, 54.1-3432 and 54.1-3442.6 18VAC110-20-110. Pharmacy Permits Generally.	The Code specifies that the processor must have a pharmacist in full and actual charge. Regulations set forth in section 200 are similar to the requirements for a pharmacist-in-charge in Chapter 20 for all pharmacies.

	pharmacist-in-charge and for an absence of more than 30 days.		
210	Sets out the general provisions for operation of a pharmaceutical processor to include prohibitions in practice, requirement for dispensing, restrictions on access, requirements for identification of employees and hours of operation, notification of a closure, informational materials, and work place policies.	§§ 54.1-3307 and 54.1-3442.6	Provisions for operation of a processor are intended to ensure a secure environment that offers appropriate access and information to patients. Since there will be a very limited number of processors, there is a virtual monopoly for provision of the oils to patients in a geographic area. Therefore, processors have an obligation of accessibility and notification of any limitations. Regulations adopted for operation are very similar to those in other states.
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	The intent of prohibitions is to follow the statutory mandate to adopt regulations establishing health, safety, and security requirements, including personal supervision by a pharmacist on premises. The prohibition on delivery of the product was discussed by the Panel, but the statute is clear in requiring dispensing of the oils “only in person” to someone with a valid physician’s certification and a registration issued by the board.
230	Sets out requirement for a comprehensive inventory at the processor, including all plants, seeds, extracts and oils to allow the facility to detect diversion, theft or loss. When the business is operational, there must be a weekly inventory to account for all contents and dispensing, and records must be maintained for 3 years.	§§ 54.1-3307 and 54.1-3442.6	Inventory control is one of the primary methods for maintaining the processor in a security manner. Processors use an electronic tracking system by which every part of the plant and the oils produced thereof can be traced. Without such a system, it would be possible for diversion to occur without detection.
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	§§ 54.1-3307 and 54.1-3442.6	The Code specifies requires a limitation on the number of plants that a processor may possess at any time. Likewise, the law requires regulations for security systems and controls. Requirements adopted are similar to other states, primarily Connecticut.

	recording of all access points and on-site surveillance.		
250	Sets out requirements for storage and handling of plants and oils to include a quarantined area for outdated, damaged or adulterated products or plant parts and compartmentalized areas based on function with restricted access between compartments. The policy and procedures for the processor must include handling recalls, crisis management, and destruction of damaged, deteriorated, etc. items.	§§ 54.1-3307 and 54.1-3442.6	Since the pharmaceutical processor in Virginia will be engaged in the activities of cultivation, production, and dispensed, rules for all of those facilities in other states were incorporated into this chapter.
260	Recordkeeping requirements are listed to include an electronic system for storage and retrieval of patient information and records related to cultivating, producing and dispensing of the oils. All records, including inventories, laboratory results, and dispensing must be maintained for 3 years.	§§ 54.1-3307 and 54.1-3442.6	Recordkeeping is essential to accountability for processors and the persons who might seek access to the plants and/or the oils.
270	Sets out requirements for reporting to the board any discrepancies, diversion, theft, loss, unauthorized entry, or alteration of records.	§§ 54.1-3307 and 54.1-3442.6	The reporting requirements are consistent with the statutory mandate for regulations for the health, safety and security of processors.
280	Sets out the requirements for cultivation and production of the oils.	§§ 54.1-3307 and 54.1-3442.6	The rules for cultivation are intended to produce oils from cannabis plants that are safe for very vulnerable patients.
290	Establishes the requirements for labeling of batches of oil, including results of batch testing by a laboratory. No two oil products can have the same name unless the laboratory identifies them with the same level of active ingredients within a range of 97% to 103%. There are restricts of the name that may be given and	§§ 54.1-3307 and 54.1-3442.6	The labeling and name of batched products is important for the purpose 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.

	requirements for the content of the label on the oils that are sold.		
300	Sets out requirement for laboratories that are testing the batches of cannabis for microbiological contaminants, mycotoxins, heavy metals, and pesticide chemical residue for an analysis of the active ingredients.	§§ 54.1-3307 and 54.1-3442.6	The standards for testing of cannabis batches were taken from regulations in other states (primarily CT). Since the production of oils is similar to a manufacturing process, it is necessary to set standards for content of substances that may be potentially harmful to very vulnerable patients. If a sample of a batch does not pass the tests, the entire batch of cannabis must be disposed. If it does pass the required tests, the entire batch can be released for immediate manufacturing, packaging and labeling for sale. Rules are also adopted to ensure independence of the laboratory and the qualification of the person or persons conducting the tests.
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 one-month supply. Rules set out the content of a label on the oils and the requirement that the dispensing record be maintained for 3 years. The pharmacy must document the patient's self-assessment of the effects of the oils.	§§ 54.1-3307, 54.1-3408.3, 54.1-3442.6 and 54.1-3442.7	The Code mandates: 1) dispensing occur in person (as opposed to delivery to the patient); 2) verification of registrants by the pharmacist; 30 limit of a 30-day supply. Labeling requirements are consistent with those in other states and with the Board's mandate to promulgate regulations for maintenance of the quality, quantity, integrity, safety and efficacy of drugs dispensed in the Commonwealth.
320	Requires reporting of dispensing errors and establishment of a quality assurance program	§§ 54.1-3307 and 54.1-3442.6 18VAC110-20-418. Continuous Quality Improvement Programs.	All pharmacies are required to maintain a continuous quality improvement program in which there are written policies and procedures for detecting and preventing dispensing errors. Since pharmaceutical processors will be dispensaries of oils, similar rules are adopted for them.
330	Sets out the requirements for disposal of cannabidiol oil or THC-A oil	§ 54.1-3442.6 (C)	The rules for disposal are intended to mitigate the risk of diversion of the plants, seeds, extracts, or oils by requiring disposal in a manner to render them non-recoverable and in the presence of an authorized representative of the board. The record of disposal includes information about the method and

			witnesses and must be retained for 3 years for date of disposal.

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.

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. The Panel was comprised of a broad range of interested parties with relevant experience and information. In addition to Senator David Marsden, Panel member and patron of the 2016 legislation (SB701), the Panel included:

Ryan Logan, Board of Pharmacy and Chair
Cynthia Warriner, Board of Pharmacy
Jody H. Allen, Board of Pharmacy
Svinder Toor, MD, Board of Medicine/ child neurologist
William L. Harp, MD, Board of Medicine, Executive Director
Alexander Pytlarz, Virginia Pharmacists Association
Ed McCann, former owner of cannabis facility
Regina Whitsett, Substance Abuse Free Environment, Inc. (SAFE)
Beth Collins, Americans for Safe Access
Baylor Rice, community compounding pharmacist
Jake Bergman, Surterra Holdings
Julia Whiting, MD, concerned parent/physician
Chuck Moss, concerned family member
Paul Lyons, MD, child neurologist

The Panel held three lengthy meetings, on July 1, 2016, July 26, 2016, and August 30, 3016, to receive public comment from law enforcement, advocates for accessibility of medical marijuana, opponents of expanded access, health system pharmacists, and others. The Panel had a presentation on medical literature on intractable epilepsy, reviewed information from other states with similar regulatory schemes, responded to discussion questions, and considered draft regulatory language. After much deliberation, the Panel recommended draft regulations which were presented and adopted with only minor revisions by the Board at its meeting in September.

There are no alternatives to the adoption of regulations, which is mandated by Chapter 577 of the 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 intractable epilepsy, these regulations could have an impact on the institution and stability of the family.