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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) Chapter citation(s)	18VAC110-60-10 et seq.
VAC Chapter title(s)	Regulations Governing Pharmaceutical Processors
Action title	Changes to implement provisions of SB976/cannabis dispensing facilities
Date this document prepared	9/16/20

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1VAC7-10), and the Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code.

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of the subject matter, intent, and goals of this this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

Amendments will: 1) include in regulation provisions for cannabis dispensing facilities; 2) provide for patients who are temporary residents to register; 3) allow for access to cultivation areas of the processor when a pharmacist is not present; 4) set out standards for laboratories that provide testing to obtain a controlled substance registration; 5) allow for sale of devices and inert sample products; 5) provide for wholesale distribution between processors and dispensing facilities; and 6) modify other provisions as applicable to changes in the Code of Virginia pursuant to SB976 of the 2020 General Assembly.

Acronyms and Definitions

Define all acronyms used in this form, and any technical terms that are not also defined in the "Definitions" section of the regulation.

N/A

Mandate and Impetus (Necessity for Emergency)

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

Adoption of amendments to regulations by emergency action is required to comply with the second enactment clause of Chapter 1278 of the 2020 Acts of the Assembly.

2. That the Board of Pharmacy shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment.

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts and Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Pharmacy the authority to promulgate regulations to administer the regulatory system:

§ 54.1-2400. General powers and duties of health regulatory boards.

The general powers and duties of health regulatory boards shall be:

…6. To promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) that are reasonable and necessary to administer effectively the regulatory system, which shall include provisions for the satisfaction of board-required continuing education for individuals registered, certified, licensed, or issued a multistate licensure privilege by a health regulatory board through delivery of health care services, without compensation, to low-income

individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those health services. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.).

The specific statutory provisions for changes to this regulation are found in Chapter 1278:

CHAPTER 1278

An Act to amend and reenact §§ 54.1-3408.3 and 54.1-3442.5 through 54.1-3442.8 of the Code of Virginia, relating to pharmaceutical processors; cannabis dispensing facilities.

[S 976]

Approved April 22, 2020

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3408.3 and 54.1-3442.5 through 54.1-3442.8 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-3408.3. Certification for use of cannabis 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.~~ *"Cannabis oil" means any formulation of processed Cannabis plant extract or a dilution of the resin of the Cannabis plant that contains at least five milligrams of cannabidiol (CBD) or tetrahydrocannabinolic acid (THC-A) and no more than 10 milligrams of tetrahydrocannabinol per dose. "Cannabis 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~~ *cannabis* oil for treatment or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use. *The practitioner shall use his professional judgement to*

determine the manner and frequency of patient care and evaluation and may employ the use of telemedicine consistent with federal requirements for the prescribing of Schedule II through V controlled substances.

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~~ *cannabis* 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~~ *cannabis* 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~~ *Committee* for Courts of Justice *and the Senate Committee on the Judiciary*, (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~~ *practitioners* 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 *or cannabis dispensing facility* 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.

§ 54.1-3442.5. Definitions.

As used in this article:

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

"Cannabis dispensing facility" means a facility that (i) has obtained a permit from the Board pursuant to § 54.1-3442.6; (ii) is owned, at least in part, by a pharmaceutical processor; and (iii) dispenses cannabis oil produced by a pharmaceutical processor 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.

"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~~ *cannabis* oil, produces ~~cannabidiol oil or THC-A~~ *cannabis* oil, and dispenses ~~cannabidiol oil or THC-A~~ *cannabis* 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 *or cannabis dispensing facility*.

A. No person shall operate a pharmaceutical processor *or a cannabis dispensing facility* 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 *or cannabis dispensing facility*. 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 *pharmaceutical processor and up to five cannabis dispensing facilities* 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 *and cannabis dispensing facility*.

C. The Board shall adopt regulations establishing health, safety, and security requirements for pharmaceutical processors *and cannabis dispensing facilities*. 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~~ *cannabis* 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~~ *cannabis oil* not exceed 10 milligrams of tetrahydrocannabinol; ~~and (xiii)~~ *(x)* a process for the wholesale distribution of and the transfer of ~~cannabidiol oil and THC-A~~ *cannabis* oil products between pharmaceutical processors *and between a pharmaceutical*

processor and a cannabis dispensing facility; (xi) an allowance for the sale of devices for administration of dispensed products; and (xii) an allowance for the use and distribution of inert product samples containing no cannabinoids for patient demonstration exclusively at the pharmaceutical processor or cannabis dispensing facility, and not for further distribution or sale, without the need for a written certification. The Board shall also adopt regulations for pharmaceutical processors that include requirements for (a) processes for safely and securely cultivating Cannabis plants intended for producing cannabis oil; (b) a maximum number of marijuana plants a pharmaceutical processor may possess at any one time; (c) the secure disposal of plant remains; and (d) a process for registering cannabis oil products.

D. The Board shall require that after processing and before dispensing cannabis oil, a pharmaceutical processor shall make a sample available from each homogenized batch of product for testing by an independent laboratory located in Virginia meeting Board requirements. A valid sample size for testing shall be determined by each laboratory and may vary due to sample matrix, analytical method, and laboratory-specific procedures. A minimum sample size of 0.5 percent of individual units for dispensing or distribution from each homogenized batch is required to achieve a representative sample for analysis.

E. A laboratory testing samples for a pharmaceutical processor shall obtain a controlled substances registration certificate pursuant to § 54.1-3423 and shall comply with quality standards established by the Board in regulation.

~~D.~~ *F.* Every pharmaceutical processor *or cannabis dispensing facility* shall be under the personal supervision of a licensed pharmacist on the premises of the pharmaceutical processor *or cannabis dispensing facility. A pharmacist in charge of a pharmaceutical processor may authorize certain employee access to secured areas designated for cultivation and other areas approved by the Board. No pharmacist shall be required to be on the premises during such authorized access. The pharmacist-in-charge shall ensure security measures are adequate to protect the cannabis from diversion at all times*.

~~E.~~ *G.* The Board shall require an applicant for a pharmaceutical processor *and cannabis dispensing facility* 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.~~ *H.* 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.

I. A pharmaceutical processor to whom a permit has been issued by the Board may establish up to five cannabis dispensing facilities for the dispensing of cannabis oil that has been cultivated and produced on the premises of a pharmaceutical processor permitted by the Board. Each cannabis dispensing facility shall be located within the same health service area as the pharmaceutical processor.

~~G.~~ *J.* 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 *or cannabis dispensing facility*.

~~H.~~ *K.* Every pharmaceutical processor *and cannabis dispensing facility* shall adopt policies for pre-employment drug screening and regular, ongoing, random drug screening of employees.

L. A pharmacist at the pharmaceutical processor and the cannabis dispensing facility shall determine the number of pharmacy interns, pharmacy technicians and pharmacy technician trainees who can be safely and competently supervised at one time; however, no pharmacist shall supervise more than six persons performing the duties of a pharmacy technician at one time.

M. Any person who proposes to use an automated process or procedure during the production of cannabis oil that is not otherwise authorized in law or regulation or at a time when a pharmacist will not be on-site may apply to the Board for approval to use such process or procedure pursuant to subsections B through E of § 54.1-3307.2.

§ 54.1-3442.7. Dispensing cannabis oil; report.

A. A pharmaceutical processor *or cannabis dispensing facility* shall dispense or deliver ~~cannabidiol oil or THC-A~~ *cannabis* oil only in person to (i) a patient who is a Virginia resident *or temporarily resides in Virginia as made evident to the Board*, 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 *or temporarily resides in Virginia as made evident to the Board* 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 *or cannabis dispensing facility* 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 *or cannabis dispensing facility* 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~~ *cannabis* 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 *or cannabis dispensing facility* shall dispense only ~~cannabidiol oil and THC-A~~ *cannabis* 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~~ *Committee* for Courts of Justice *and the Senate Committee on the Judiciary* on the operation of pharmaceutical processors *and cannabis dispensing facilities* 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~~ *cannabis* oil on site may be up to 10 percent greater than or less than the level of tetrahydrocannabinol measured for labeling. A pharmaceutical processor *and cannabis*

dispensing facility shall ensure that such concentration in any ~~THC-A onsite~~ *cannabis oil on site* is within such range ~~and~~. *A pharmaceutical processor producing cannabis oil* shall establish a stability testing schedule of ~~THC-A~~ *cannabis* oil.

§ 54.1-3442.8. Criminal liability; exceptions.

In any prosecution of an agent or employee of a pharmaceutical processor *or cannabis dispensing facility* under § 18.2-248, 18.2-248.1, 18.2-250, or 18.2-250.1 for possession or manufacture of marijuana or for possession, manufacture, or distribution of ~~cannabidiol oil or THC-A~~ *cannabis* oil, it shall be an affirmative defense that such agent or employee (i) possessed or manufactured such marijuana for the purposes of producing ~~cannabidiol oil or THC-A~~ *cannabis* oil in accordance with the provisions of this article and Board regulations or (ii) possessed, manufactured, or distributed such ~~cannabidiol oil or THC-A~~ *cannabis* oil in accordance with the provisions of this article and Board regulations. If such agent or employee files a copy of the permit issued to the pharmaceutical processor *or cannabis dispensing facility* pursuant to § 54.1-3442.6 with the court at least 10 days prior to trial and causes a copy of such permit to be delivered to the attorney for the Commonwealth, such permit shall be prima facie evidence that (a) such marijuana was possessed or manufactured for the purposes of producing ~~cannabidiol oil or THC-A~~ *cannabis* oil in accordance with the provisions of this article and Board regulations or (b) such ~~cannabidiol oil or THC-A~~ *cannabis* oil was possessed, manufactured, or distributed in accordance with the provisions of this article and Board regulations.

2. That the Board of Pharmacy shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment.

Purpose

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

The purpose of the regulation is to establish the requirements for cannabis dispensing facilities and laboratories as necessary for the safety and integrity of cannabis oil products that patients will be consuming.

Substance

Briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of Changes" section below.

Amendments will: 1) include in regulation provisions for cannabis dispensing facilities; 2) provide for patients who are temporary residents to register; 3) allow for access to cultivation areas of the processor when a pharmacist is not present; 4) set out standards for laboratories that provide testing to obtain a controlled substance registration; 5) allow for sale of devices and inert sample products; 5) provide for wholesale distribution between processors and dispensing facilities; and 6) modify other provisions as applicable to changes in the Code of Virginia pursuant to SB976 of the 2020 General Assembly.

Issues

Identify the issues associated with the regulatory change, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, include a specific statement to that effect.

1) The advantage to the public will be additional facilities from which to obtain cannabis oil. There should be no disadvantages to the public; rules for dispensing facilities and laboratories that perform testing will safeguard the oils and ensure their quality.
2) There are no advantages or disadvantages to this agency or the Commonwealth.
3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. The Board is authorized under § 54.1-2400 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. 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.) This proposal is consistent with the agency's statutory responsibility to protect public health and safety and to protect the integrity and safety of prescription drugs in the Commonwealth.

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulatory change.

SB976 specifically requires regulations to be promulgated by the Board to implement provisions of the legislation. There are no viable alternatives.

Periodic Review and Small Business Impact Review Announcement

This NOIRA is not being used to announce a periodic review or a small business impact review.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below. In addition, as required by § 2.2-4007.02 of the Code of Virginia describe any other means that will be used to identify and notify interested parties and seek their input, such as regulatory advisory panels or general notices.

The Board of Pharmacy is providing an opportunity for comments on this regulatory proposal, including but not limited to (i) the costs and benefits of the regulatory proposal, (ii) any alternative approaches, and (iii) the potential impacts 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://townhall.virginia.gov. Comments may also be submitted by mail, email or fax to Elaine Yeatts, 9960 Mayland Drive, Suite 300, Richmond, VA 23233; phone (804) 367-4688; fax (804) 527-4434; Elaine.yeatts@dhp.virginia.gov. 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 this stage, and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (https://townhall.virginia.gov) and on the Commonwealth Calendar website (https://commonwealthcalendar.virginia.gov/). Both oral and written comments may be submitted at that time.

Detail of Changes

List all regulatory changes and the consequences of the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. For example, describe the intent of the language and the expected impact. Describe the difference between existing requirement(s) and/or agency practice(s) and what is being proposed in this regulatory change. Use all tables that apply, but delete inapplicable tables.

§ 54.1-3442.6 of the Code of Virginia requires a permit to operate a pharmaceutical processor *or a cannabis dispensing facility*. The Code requires the Board to establish an application fee for dispensing facilities and other general requirements for such application. It also limits the number of facilities to five, one for each health service area. Subsection C of the Code section specifies that the Board shall adopt regulations establishing health, safety, and security requirements for pharmaceutical processors *and cannabis dispensing facilities* and delineates those requirements that are applicable to both. Accordingly, amendments throughout Chapter 60 are promulgated to insert *cannabis dispensing facilities* into the current regulations for pharmaceutical processors where applicable to both. Since dispensing facilities will be dispensing cannabis oil products and not growing Cannabis and producing the products, some requirements are unique to that type of facility.

Wherever sections or subsections are amended just to insert the term "cannabis dispensing facility," they are not included in the detail of changes below.

Current chapter section number	***New chapter-section number, if applicable***	***Current requirements in VAC***	**Change, intent, rationale, and likely impact of new requirements**
10		Sets out definitions for words and terms	*Definitions are added for:* *The acronyms ISO/IEC and ISO/IEC17025 because they are used in setting the requirements for*

		used in the chapter	*laboratories to obtain a controlled substance registration.* *The term "perpetual inventory" is defined because it is the term used in the requirement for inventory in cannabis dispensing facilities.* *The term "qualifying patient" is amended to include the allowance for a person temporarily residing in Virginia to be registered with the board to obtain cannabis oil. Likewise, the term "temporarily resides" is defined.* *The term "temperature and humidity" is revised to reflect a more flexible range, consistent those found in other states.*
20		Sets the fees for persons and facilities regulated in this chapter	Subsection E is added to set the fees for cannabis dispensing facilities. Except the fee for the initial permit and the annual renewal, the fees are identical to those for a processor. The application and initial permit fee for a pharmaceutical processor are set much higher because it is a competitive and multi-step process. *The fees for dispensing facilities are set to cover expenditures anticipated with the inspection, permitting, and regulation of such facilities. Fees for dispensing facilities will need to be sufficient to process an application, which includes criminal background checks, inspections, etc. The renewal fee of $1,500 is necessary to cover the cost of quarterly inspections, which are required by law. It is estimated that the Board will be assessed for approximately $185 per hour for an inspection, which could take 6-7 hours per facility.*
50		Establishes the requirements for a patient to register with the Board to obtain oil products	Subsection A is amended to specify the types of documentation that may be used as proof of temporary residency. *The intent of one amendment to SB976 was to allow a person who is not a resident of Virginia but residing here temporarily to be able to register (student, military assignment, etc.). Regulations offer examples of proof of temporary residency but also allow an attestation to suffice.*
60		Sets out the causes for which a person could be denied a registration	Lack of acceptable proof of temporary residency is added in subsection A as a cause for denial.
90		Sets out the causes for which a person's registration could be revoked or suspended	If a registrant is no longer residing in Virginia or is no longer temporarily residing in Virginia, the Board can revoke the registration because he/she no longer meets the statutory requirement for registration.
100		Sets out the requirement for publication of a notice for submission of applications	The title is amended to clarify that it is applicable only to the competitive process of awarding a permit for a pharmaceutical processor.

	135	Sets out the application process for granting a permit for a cannabis dispensing facility	The Code requires that each dispensing facility must be owned in whole or in part by the pharmaceutical processor in the health service area in which the facility is located and must only dispense cannabis oil that has been cultivated and produced by that processor. Subsection B includes the information that must be included with an application for a dispensing facility permit, including information about anyone with more than 5% ownership, since those persons are required to undergo a criminal background check. Other subsections in section 135 are similar to requirements for opening a new pharmacy or a processor, including inspections, restriction on persons with certain felony convictions, and a requirement for a pharmacist to be on site during hours of operation once the facility is in possession of cannabis oil.
	136	Sets out the causes for denial of a permit application for a cannabis dispensing facility	The grounds for denial include an incomplete, false, or misleading application; failure to pay fees; or failure to comply with requirements of Code and this chapter. If a facility's application is denied, the applicant has a right to a hearing pursuant to the Administrative Process Act.
140		Sets out requirements for notification of changes by a processor or facility	An amendment in subsection C adds industrial hemp extract because legislation in 2020 allows processors to acquire it from registered hemp dealers or processors.
150		Sets out requirements for the closing, going out of business, etc. for a processor	An amendment in subsection B adds industrial hemp extract because legislation in 2020 allows processors to acquire it from registered hemp dealers or processors. The Code also allows transfers to another cannabis dispensing facility if it is in the same health service area.
170		Sets the requirements for employees of processors or facilities	Subsection B is amended to recognize the allowance put in Code for authorized employees to be in the cultivation area when a pharmacist is not on duty. Other language currently found in subsections G and H are incorporated into this subsection.
190		Sets out the rules for pharmacy technicians	Subsection A is amended to reflect the change in the Code by SB976 (subsection L), which changed the allowable ratio of pharmacist to technician from 4:1 to 6:1.
200		Sets out the requirements for a pharmacist-in-charge (PIC)	Subsection A is amended to specify that the person who is PIC of a processor cannot be PIC of any other facility, but a person could serve as PIC for two cannabis dispensing facilities located within the same health service area. *The regulation is consistent with requirements for pharmacies, in which one pharmacist is allowed to be the PIC of two pharmacies. The operation of a dispensing facility is similar to that of a pharmacy in function, whereas the operation of a pharmaceutical processor is considerably more complex because there are growing and production functions in*

			addition to dispensing. Therefore, there is a restriction on a pharmacist serving as PIC for any other facility other than a pharmaceutical processor.
220		Establishes the prohibitions for a processor or a dispensing facility	Subsection B is added to specify the prohibitions for a dispensing facility. They include a prohibition against dispensing cannabis oil in any place other than the permitted facility, selling or distributing oil to any facility other than back to the processor from which it came, and providing cannabis oil samples. *The prohibitions for facilities are identical to those for processors in subsection A as applicable.* Subsection D is amended to allow a processor or dispensing facility to sell devices for administration of dispensed products (same as change made in SB976).
230		Establishes requirements for inventories	A pharmaceutical process is required to have an inventory system that tracks everything from the Cannabis seeds to the cannabis oil in stock. A dispensing facility does not need a tracking system but does need to maintain a perpetual inventory of the amount of cannabis oil coming into the facility and the amount being dispensed. An inventory would also need to account from any disposal or transfer of oil. A perpetual inventory is the requirement for a pharmacy that dispenses Schedule II drugs, so it is a process familiar to pharmacists.
240		Sets out the security requirements	Subsection B is added to limit the amount of cannabis oil a dispensing facility can maintain to an amount needed for normal, efficient operation. *Such a requirement would be part of a quarterly inspection of a facility in which a board inspector would review stock on hand against dispensing records for a recent period of time.* Subsection C is amended to distinguish between the items that must be secured in a processor and the cannabis oil that a dispenser must secure. Amendments to #5 allow exceptions for access to secured areas designated for cultivation when no pharmacist is present (consistent with provision in SB976). Subsection D 5 is amended to authorize employee access to certain secured areas but to also specify that it is the pharmacist-in-charge who is responsible for ensuring that security measures are adequate to protect cannabis oil from diversion at all times.
250		Sets out requirements for the storage and handling of Cannabis or cannabis oil	Subsection C of 54.1-3442.6 requires the Board to promulgate regulations for processes for safely and securely dispensing and delivering cannabis oil. Subsection C is added to section 250 to require a cannabis dispensing facility to have policies and procedures for secure and proper dispensing of cannabis oil. *The policies and procedures for a dispensing facility will need to be similar to but different from a processor, since there is no Cannabis being grown.* Subsection F is added to require safe storage of cannabis oil at a facility and to limit the number of employees who have access to the oil only to those

			essential for efficient operation. All oil must be returned to a secure location after dispensing or at the end of a business day.
251		Sets out requirements for wholesale distribution of cannabis oil products	Subsections A, B, D and E are identical to the emergency regulation in Action 5398 that is currently in effect. Because section 251 is not yet in the VAC, it had to be added to this action. Subsection C of 54.1-3442.6 requires regulations to prescribe a process for the wholesale distribution of and the transfer of cannabis oil products between pharmaceutical processors and between a pharmaceutical processor and a cannabis dispensing facility. *Subsection C of section 251 is new language in this action; it requires a copy of the lab results or electronic access to information to be provided to the other processor or facility so it can be shared upon request by a patient, practitioner, etc.*
300		Sets out the requirements for testing and laboratory testing	Subsection E of 54.1-3442.6 requires a laboratory that will be testing samples for a pharmaceutical processor to obtain a controlled substances registration certificate pursuant to § 54.1-3423 and to comply with quality standards established by the Board in regulation. Subsection E 4 sets out the quality standards for those laboratories that will be testing for quality assurance. The standard in the industry is ISO/IEC 17025 accreditation. *Since the laboratory must be located in Virginia, the Board has consulted with laboratories and they agree that the ISO/IEC accreditation is the appropriate standard. However, it will take time for these labs to achieve accreditation, so regulations allow for them to obtain a controlled substance registration if they have applied for accreditation. Such accreditation must be achieved within two years, but they may be given additional time for good cause shown.* Subsection E 5 requires the lab to comply with a transportation protocol to ensure the safety and integrity of the cannabis oil.
	321		Establishes the requirements for the sale of devices and inert product samples. New requirements are necessary because an amendment Code in SB976 makes an "allowance for the use and distribution of inert product samples containing no cannabinoids for patient demonstration exclusively at the pharmaceutical processor or cannabis dispensing facility, and not for further distribution or sale, without the need for a written certification."
330		Sets out the requirements for disposal of cannabis oil	Amendments to this section will: 1) Eliminate the need for a processor or facility to submit a plan for board approval for disposition of disposal or destruction of green waste. The amendment to subsection A requires green waste (Cannabis plants, seeds and parts of plants) to be rendered unrecognizable. 2) An amendment to subsection B allows destruction or disposal to be witnessed by a pharmacist and at least

			one other employee of the processor or facility instead of the current requirement that specifies witnessing by the pharmacist-in-charge and an agent of the board or another pharmacist not employed by the processor. *The amendment will facilitate the disposal and destruction within a processor or facility.*