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Exempt Action: Final Regulation
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	Conforming to 2020 legislative changes
Final agency action date	6/16/20
Date this document prepared	6/16/20

Although a regulatory action may be exempt from executive branch review pursuant to § 2.2-4002 or § 2.2-4006 of the *Code of Virginia*, the agency is still encouraged to provide information to the public on the Regulatory Town Hall using this form. However, the agency may still be required to comply with the Virginia Register Act, 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 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. If applicable, generally describe the existing regulation.

To conform regulations in 18VAC110-60, amendments will: 1) change every reference from cannabidiol oil or THC-A oil to cannabis oil; 2) delete the requirement for an "in-person" examination by the prescriber certifying a patient to receive cannabis oil and allow for the use of telemedicine consistent with federal requirements; 3) allow the pharmacist-in-charge to authorize certain employee access to secured areas without a pharmacist on the premises; 4) allow a ratio of six pharmacy technicians per pharmacist working in the processor; and 5) allow a laboratory performing quality testing on products to determine a valid sample size to the testing with a minimum of sample size from each homogenized batch.

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, internal staff review, petition for rulemaking, periodic review, or board decision). "Mandate" is defined as "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

The mandate for the Board of Pharmacy is conform its regulations to changes made in the Code of Virginia by the 2020 General Assembly in order to eliminate conflicts between law and regulation.

HB1460 (Chapter 730 of the 2020 Acts of the Assembly):

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

A. As used in this section:

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

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

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

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

B. A practitioner in the course of his professional practice may issue a written certification for the use of cannabidiol oil or THC-A oil for treatment or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use. *The practitioner shall use his professional judgment 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 oil for the treatment or to alleviate the symptoms of a patient's diagnosed condition or disease pursuant to a written certification issued pursuant to subsection B. Nothing in this section shall preclude the Board of Medicine from sanctioning a practitioner for failing to properly evaluate or treat a patient's medical condition or otherwise violating the applicable standard of care for evaluating or treating medical conditions.

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

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

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

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

I. Information obtained under the registration process shall be confidential and shall not be subject to the disclosure provisions of the Virginia Freedom of Information Act (§ 2.2-3700 et seq.). However, reasonable access to registry information shall be provided to (i) the Chairmen of the House and Senate Committees for Courts of Justice, (ii) state and federal agencies or local law enforcement for the purpose of investigating or prosecuting a specific individual for a specific violation of law, (iii) licensed physicians or pharmacists for the purpose of providing patient care and drug therapy management and monitoring of drugs obtained by a registered patient, (iv) a pharmaceutical processor involved in the treatment of a registered patient, or (v) a registered patient, his registered agent, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, the patient's parent or legal guardian, but only with respect to information related to such registered patient.

SB976 (Chapter 1278 of the 2020 Acts of the Assembly):

§ 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.

Statement of Final Agency Action

Provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

On June 16, 2020, the Board of Pharmacy amended 18VAC110-60-10 et seq., Regulations Governing Pharmaceutical Processors to conform to actions of the 2020 General Assembly.