COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Second Floor **(804) 367-4456 (Tel)**
Henrico, Virginia 23233 **(804) 527-4472(Fax)**

Tentative Agenda of Regulation Advisory Panel Regarding Cannabidiol Oil and THC-A Oil

July 1, 2016

10AM

TOPIC	PAGES
Call to Order: *Ryan Logan, Chairman*	
• Welcome & Introductions	1
• Approval of Agenda	
Call for Public Comment	
Agenda Items	
• Presentations:	
○ Summary of SB701 and Charge of Regulatory Advisory Panel, *Caroline Juran, Executive Director*	2-6
○ General Overview of the Cannabis Plant, Methods for Extracting Cannabidiol Oil and THC-A Oil, Treating Intractable Epilepsy with Cannabidiol Oil and THC-A Oil, *Dr. Paul Lyons, Panelist*	
• Discussion Questions, *Ryan Logan*	7-8
• Review Part I of Draft Regulations, *Ryan Logan and Caroline Juran*	9-24
Adjourn	

******The Committee will have a working lunch at approximately 12pm. ******

Members of Regulatory Advisory Panel
Cannabidiol Oil and THC-A Oil
July 1, 2016

Board of Pharmacy members: Ryan Logan (Panel Chairman), Cindy Warriner, Jody Allen
Alternate: Ellen Shinaberry

Board of Medicine representation: Svinder Toor, MD, board member/child neurologist, Dr. Harp, executive director

Virginia Pharmacist Association: Alexander Pytlarz, compounding pharmacist

Ed McCann, former owner of cannabis facility

Substance Abuse Free Environment, Inc. (SAFE): Regina Whitsett

Americans for Safe Access: Beth Collins
Alternate: Tim Murphy

Baylor Rice, compounding pharmacist

Surterra Holdings - Jake Bergman

Julia Whiting, MD – concerned parent/physician

Chuck Moss- concerned family member

Paul Lyons, MD, child neurologist

Senator David W. Marsden
Alternate: Brent McKenzie, Legislative Assistant

VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact §§ 18.2-250.1 and 54.1-3408.3 of the Code of Virginia and to amend the Code of Virginia by adding in Chapter 34 of Title 54.1 an article numbered 4.2, consisting of sections numbered 54.1-3442.5 through 54.1-3442.8, relating to cannabidiol oil and THC-A oil; permitting of pharmaceutical processors to manufacture and provide.

[S 701]

Approved

Be it enacted by the General Assembly of Virginia:

1. That §§ 18.2-250.1 and 54.1-3408.3 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding in Chapter 34 of Title 54.1 an article numbered 4.2, consisting of sections numbered 54.1-3442.5 through 54.1-3442.8, as follows:

§ 18.2-250.1. Possession of marijuana unlawful.

A. It is unlawful for any person knowingly or intentionally to possess marijuana unless the substance was obtained directly from, or pursuant to, a valid prescription or order of a practitioner while acting in the course of his professional practice, or except as otherwise authorized by the Drug Control Act (§ 54.1-3400 et seq.).

Upon the prosecution of a person for violation of this section, ownership or occupancy of the premises or vehicle upon or in which marijuana was found shall not create a presumption that such person either knowingly or intentionally possessed such marijuana.

Any person who violates this section is guilty of a misdemeanor and shall be confined in jail not more than 30 days and fined not more than $500, either or both; any person, upon a second or subsequent conviction of a violation of this section, is guilty of a Class 1 misdemeanor.

B. The provisions of this section shall not apply to members of state, federal, county, city, or town law-enforcement agencies, jail officers, or correctional officers, as defined in § 53.1-1, certified as handlers of dogs trained in the detection of controlled substances when possession of marijuana is necessary for the performance of their duties.

C. In any prosecution under this section involving marijuana in the form of cannabidiol oil or THC-A oil as those terms are defined in § 54.1-3408.3, it shall be an affirmative defense that the individual possessed such oil pursuant to a valid written certification issued by a practitioner in the course of his professional practice pursuant to § 54.1-3408.3 for treatment or to alleviate the symptoms of (i) the individual's intractable epilepsy or (ii) if such individual is the parent or legal guardian of a minor *or of an incapacitated adult as defined in § 18.2-369*, such minor's *or incapacitated adult's* intractable epilepsy. If the individual files the valid written certification with the court at least 10 days prior to trial and causes a copy of such written certification to be delivered to the attorney for the Commonwealth, such written certification shall be prima facie evidence that such oil was possessed pursuant to a valid written certification.

§ 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 ~~of medicine or osteopathy licensed by the Board of Medicine~~ 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

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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

118 *on the premises of the pharmaceutical processor.*
119 *E. No person who has been convicted of a felony or of any offense in violation of Article 1*
120 *(§ 18.2-247 et seq.) or Article 1.1 (§ 18.2-265.1) of Chapter 7 of Title 18.2 shall be employed by or act*
121 *as an agent of a pharmaceutical processor.*
122 ***§ 54.1-3442.7. Dispensing cannabidiol oil and THC-A oil; report.***
123 *A. A pharmaceutical processor shall dispense cannabidiol oil or THC-A oil only in person to (i) a*
124 *patient who is a Virginia resident, has been issued a valid written certification, and is registered with*
125 *the Board pursuant to § 54.1-3408.3 or (ii) if such patient is a minor or an incapacitated adult as*
126 *defined in § 18.2-369, such patient's parent or legal guardian who is a Virginia resident and is*
127 *registered with the Board pursuant to § 54.1-3408.3. Prior to dispensing, the pharmaceutical processor*
128 *shall verify that the practitioner issuing the written certification, the patient, and if such patient is a*
129 *minor or an incapacitated adult, the patient's parent or legal guardian are registered with the Board.*
130 *No pharmaceutical processor shall dispense more than a 30-day supply for any patient during any*
131 *30-day period. The Board shall establish in regulation an amount of cannabidiol oil or THC-A oil that*
132 *constitutes a 30-day supply to treat or alleviate the symptoms of a patient's intractable epilepsy.*
133 *B. A pharmaceutical processor shall dispense only cannabidiol oil and THC-A oil that has been*
134 *cultivated and produced on the premises of such pharmaceutical processor.*
135 *C. The Board shall report annually by December 1 to the Chairmen of the House and Senate*
136 *Committees for Courts of Justice on the operation of pharmaceutical processors issued a permit by the*
137 *Board, including the number of practitioners, patients, and parents or legal guardians of patients who*
138 *have registered with the Board and the number of written certifications issued pursuant to*
139 *§ 54.1-3408.3.*
140 ***§ 54.1-3442.8. Criminal liability; exceptions.***
141 *In any prosecution of an agent or employee of a pharmaceutical processor under § 18.2-248,*
142 *18.2-248.1, 18.2-250, or 18.2-250.1 for possession or manufacture of marijuana or for possession,*
143 *manufacture, or distribution of cannabidiol oil or THC-A oil, it shall be an affirmative defense that such*
144 *agent or employee (i) possessed or manufactured such marijuana for the purposes of producing*
145 *cannabidiol oil or THC-A oil in accordance with the provisions of this article and Board regulations or*
146 *(ii) possessed, manufactured, or distributed such cannabidiol oil or THC-A oil in accordance with the*
147 *provisions of this article and Board regulations. If such agent or employee files a copy of the permit*
148 *issued to the pharmaceutical processor pursuant to § 54.1-3442.6 with the court at least 10 days prior*
149 *to trial and causes a copy of such permit to be delivered to the attorney for the Commonwealth, such*
150 *permit shall be prima facie evidence that (a) such marijuana was possessed or manufactured for the*
151 *purposes of producing cannabidiol oil or THC-A oil in accordance with the provisions of this article*
152 *and Board regulations or (b) such cannabidiol oil or THC-A oil was possessed, manufactured, or*
153 *distributed in accordance with the provisions of this article and Board regulations.*
154 **2. That, except as provided in the third enactment of this act, the provisions of the first enactment**
155 **of this act shall not become effective unless reenacted by the 2017 Session of the General**
156 **Assembly.**
157 **3. That the Board of Pharmacy shall promulgate regulations to implement the provisions of the**
158 **first enactment of this act within 280 days of its initial enactment. Such regulations shall not**
159 **become effective unless the provisions of the first enactment of this act are reenacted by the 2017**
160 **Session of the General Assembly.**

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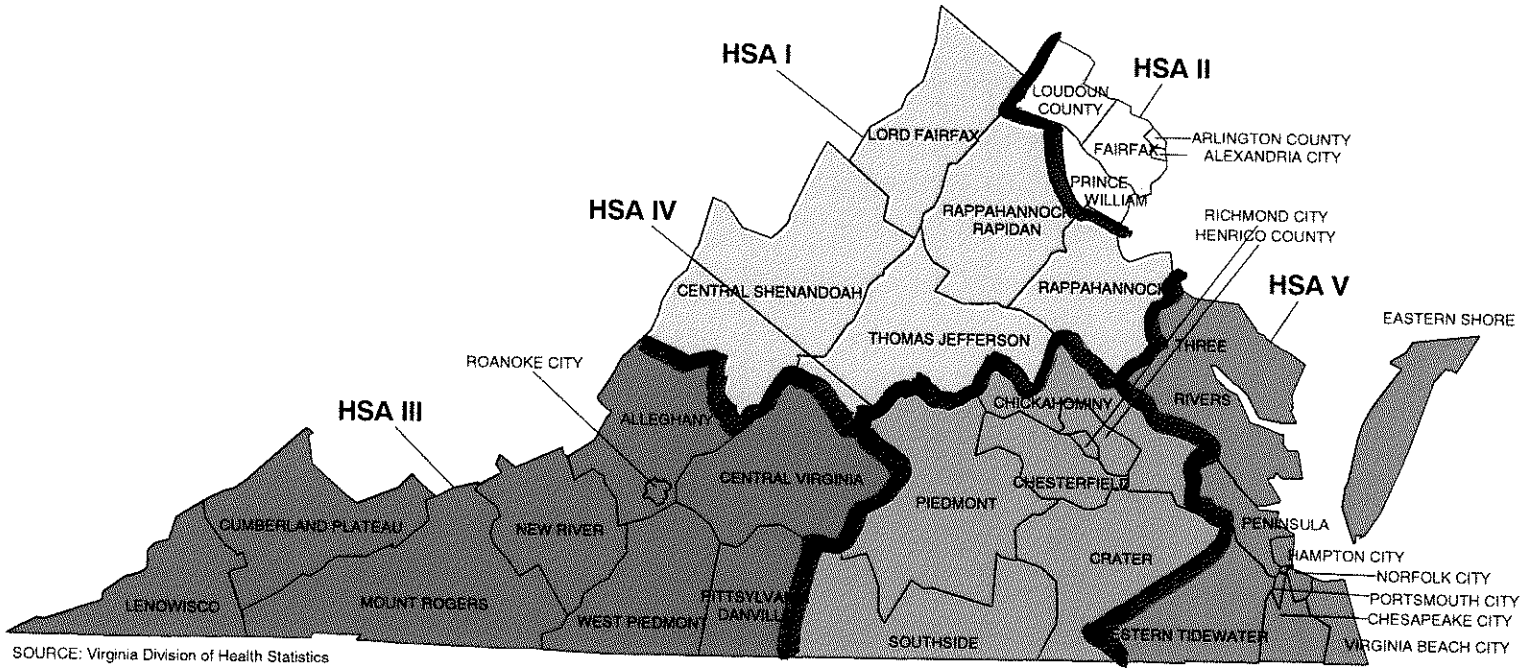
HEALTH DISTRICTS AND HEALTH SERVICE AREAS
COMMONWEALTH OF VIRGINIA



SOURCE: Virginia Division of Health Statistics

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18VAC110-11-70. Appointment of Regulatory Advisory Panel.

A. The agency may appoint a regulatory advisory panel (RAP) to provide professional specialization or technical assistance when the agency determines that such expertise is necessary to address a specific regulatory issue or action or when individuals indicate an interest in working with the agency on a specific regulatory issue or action.

B. Any person may request the appointment of a RAP and request to participate in its activities. The agency shall determine when a RAP shall be appointed and the composition of the RAP.

C. A RAP may be dissolved by the agency if:

1. The proposed text of the regulation is posted on the Town Hall, published in the Virginia Register, or such other time as the agency determines is appropriate; or

2. The agency determines that the regulatory action is either exempt or excluded from the requirements of the Administrative Process Act.

Statutory Authority

§§ 2.2-4007.02 and 54.1-2400 of the Code of Virginia.

Historical Notes

Derived from Volume 25, Issue 02, eff. October 29, 2008.

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Discussion Questions:

1. What standards in cultivating marijuana should be taken into consideration and/or regulated to ensure consistency in quality, potency, and mitigation of diversion? (Lighting, temperature and humidity control, nutrients, use of pesticides, size of canopy, root zone, room size, division of room for various phases of growth, number of plants?)
2. What other physical standards must the pharmaceutical processor meet, e.g., room size, separate rooms or space for various functions, etc.?
3. What security requirements are appropriate to mitigate diversion, e.g., motion sensors throughout, video surveillance with 24 hour tape, etc.?
4. What location restrictions should apply to pharmaceutical processors?
5. What is the maximum number of plants that a pharmaceutical processor should be allowed to possess at any given time?
6. What minimum equipment and resources are necessary, e.g., sink, refrigerator, acceptable reference sources, etc.?
7. What recordkeeping should be required for the cultivation, e.g., grow diary with marijuana strains, growing characteristics, nutrients, grow room environment, harvest weight, and harvest quality?
8. How and at what frequency is an inventory recordkeeping best performed to prevent or identify theft of loss of product?
9. What are the recommended methods for disposing of plant remains?
10. Are there certain strains known to be better for producing cannabidiol oil or THC-A oil for the treatment of intractable epilepsy?
11. How is cannabidiol oil and THC-A oil produced? What part of the plant is used? Comparison of the methods, pros and cons? Should certain methods be permitted and others not due to a concern with safety or quality?
12. To what standards should the production of oils be held, e.g., USP standards for non-sterile compounding or FDA good manufacturing practices for dietary supplements?
13. How is cannabidiol oil and THC-A administered? Any paraphernalia involved?
14. Are there public locations where it would be inappropriate for the oils to be administered?
15. What are appropriate dosages of the cannabidiol oil and THC-A oil in treating epilepsy, i.e., what constitutes a 30-day supply?
16. Should there be any minimal age restrictions for who may be administered the oils?
17. How should one test for quality and potency, e.g., methods, in–house testing, outside laboratory, acceptable levels, etc.?
18. If outside labs are used, do they maintain a particular accreditation? Are there labs in Virginia that could perform the appropriate testing?

19. Are there population groups that should not be eligible for the oils, e.g., inmates within the Department of Corrections?
20. What is the maximum number of patients that a practitioner should be allowed to issue a written certification?
21. Is it reasonable that all persons working in a pharmaceutical processor should be registered with the board? Should they all be required to be a pharmacist or pharmacy technician?
22. CT is built on model of physician submitting written certification to board, patient registers with board and is issued a registration certificate with photo. VA law requires patient to maintain written certification as an affirmative defense. Is it appropriate to require either the physician or the patient to submit a copy of the written certification to board, issue the patient a registration card with or without photo, and require the patient, parent, or guardian to carry the registration and original written certification when in possession of the oil?

PART I - DRAFT REGULATIONS
FOR CANNABIDIOL OIL AND
THC-A OIL

Definitions

"Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of cannabidiol oil or THC-A oil;

"Cultivation"

"Pharmaceutical processor employee" means a dispensary, dispensary technician, pharmaceutical processor staff and all other persons employed by a pharmaceutical processor or who otherwise have access to the pharmaceutical processor, including independent contractors who are routinely on the facility premises;

"Dispensing error" means an act or omission relating to the dispensing of cannabidiol oil or THC-A oil that results in, or may reasonably be expected to result in, injury to or death of a qualifying patient or results in any detrimental change to the medical treatment for the patient;

"Disqualifying conviction" means a conviction for the violation of any statute or regulation pertaining to the illegal manufacture, sale or distribution of a controlled substance or controlled substance analog unless the violation resulting in the conviction occurred when the person held a valid permit or registration certificate from the board and the violation was of a federal statute or regulation related to the possession, purchase or sale of cannabidiol oil or THC-A oil that is authorized under the Act and sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies;

"Electronic data intermediary" means an entity that provides the infrastructure that connects the computer systems or other electronic devices utilized by dispensaries with those used by practitioners or the board in order to facilitate the secure transmission of qualifying patient or parent or legal guardian information;

"Label" means a display of written, printed or graphic matter upon the immediate container of any product containing cannabidiol oil or

Comment [d1]: This document is based on CT's regulations. Throughout document, the following terms were changed to conform to VA's law: "physician" to "practitioner"; "department" to "board"; "marijuana" to "cannabidiol oil and THC-A oil"' "primary caregiver" to "parent or legal guardian"

Comment [d2]: Necessary? Should everyone be licensed or registered by the board?

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THC-A oil;
"Laboratory" -?
"Marijuana" -?
"Produce"
"Cannabidiol oil or THC-A oil" - ?
"One-month supply" means the amount of cannabidiol oil or THC-A oil reasonably necessary to ensure an uninterrupted availability of supply for a thirty-day period for qualifying patients, which amounts shall be determined by the board on the basis of practical administration of the Act, available research and recommendations from the Board of Practitioners;
"Pesticide chemical" has the same meaning as provided in section 21a-92 of the Connecticut General Statutes;
"Pharmaceutical grade cannabidiol oil or THC-A oil" means cannabidiol oil or THC-A oil or cannabidiol oil or THC-A oil products that are not adulterated and are:

(A) processed, packaged and labeled according to the Food and Drug Administration's "Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements," 21 CFR 111;

(B) labeled with the results of an active ingredient analysis, a microbiological contaminants analysis, a mycotoxin analysis, a heavy metal analysis and a pesticide chemical residue analysis which have been completed on a batch basis by a laboratory;
and

(C) where each step of the production, cultivating, trimming, curing, manufacturing, processing and packaging method has been documented by using established standard operation procedures approved by the board;

"Pharmaceutical Processor"
"PIC"
"Practitioner" has the same meaning as provided in 54.1-3408.3.
"Production" or "produce" means the manufacture, planting, preparation, cultivation, growing, harvesting, propagation, compounding, conversion

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or processing of marijuana, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation or compounding of marijuana by a patient or parent or legal guardian for the patient's use;

"Production facility" means a secure, indoor facility where the production of marijuana occurs and that is operated by a person to whom the board has issued a producer permit under the Act and sections 21a-408-20 of the Regulations of Connecticut State Agencies;

"Production facility employee" means any person employed by a producer or who otherwise has access to the production facility, including independent contractors who are routinely on the production facility premises;

"Registration certificate" means an identification card or other document issued by the board that identifies a person as a registered qualifying patient or parent or legal guardian;

"Written certification" means a written or electronically submitted statement issued by a practitioner to the board certifying a patient for cannabidiol oil or THC-A oil, which shall be submitted on a form and in a manner prescribed by the board.

Requirements for Practitioner Issuing Written Certification

Comment [d3]: In CT physician submits the written certification to the agency. In VA, practitioner would issue the written cert to the patient as an affirmative defense.

A. Prior to issuing a written certification for cannabidiol oil or THC-A oil pursuant to 54.1-3408.3 for the treatment or to alleviate symptoms of intractable epilepsy, the practitioner shall first register with the board and satisfy the following conditions:
   (1) Maintain a current active medical permit with the Board of Medicine;
   (2) Practice as a neurologist or specialize in the treatment of epilepsy; and,
   (2) Is registered with, and able to access, the Prescription Monitoring Program.

B. A practitioner issuing a written certification shall:

(1) Have a bona fide practitioner-patient relationship with the qualifying patient;

(2) Conduct an assessment and evaluation of the patient in order to develop a

treatment plan for the patient, which shall include an examination of the patient and the patient's medical history, prescription history and current medical condition, including an in-person physical examination;

(3) Diagnose the patient as having intractable epilepsy;

(4) Be of the opinion that the potential benefits of cannabidiol oil or THC-A oil would likely outweigh the health risks of such use to the qualifying patient;

(5) Have prescribed, or have had a reasonable basis for determining that it is not in the best interest of the patient to prescribe, prescription drugs to address the symptoms or effects of the intractable epilepsy;

(6) Be reasonably available to provide follow-up care and treatment to the qualifying patient including, but not limited to, physical examinations, to determine the efficacy of cannabidiol oil or THC-A oil for treating the intractable epilepsy;

(7) Comply with generally accepted standards of medical practice except to the extent such standards would counsel against certifying a qualifying patient for cannabidiol oil or THC-A oil; and

(8) Explain the potential risks and benefits of the cannabidiol oil or THC-A oil to the qualifying patient and, if the qualifying patient lacks legal capacity, to a parent or legal guardian, prior to issuing the written certification.

C. A practitioner shall not delegate the responsibility of diagnosing a patient or determining whether a patient should be issued a written certification. Employees under the direct supervision of the practitioner may assist with preparing a written certification so long as the final written certification is reviewed and approved by the practitioner before it is submitted to the board.

D. If a practitioner provides instructions for the use of cannabidiol oil or

THC-A oil to the patient, or includes instructions as part of the written certification, the practitioner shall also securely transmit such instructions to the qualifying patient's designated pharmaceutical processor.

Comment [d4]: Needs review. It would seem directions must be provided somehow to the pharmaceutical processor for dispensing and labeling purposes.

Practitioner requirements for maintaining patient medical records

A. A practitioner shall maintain medical records for all patients for whom the practitioner has issued a written certification.

Comment [d5]: Is there a BOM law or regulation to cite? "pursuant to...."

B. A practitioner shall make a copy of such medical records reasonably available to an agent of the Boards of Medicine and Pharmacy, other state agencies and to state and local law enforcement agencies for the purpose of enabling the board or other agency to ensure compliance with the law and regulations or investigate a possible violation.

Practitioner prohibitions

A practitioner that has issued or intends to issue a written certification shall not:

(1) Directly or indirectly accept, solicit, or receive anything of value from any person associated with a pharmaceutical processor or provider of paraphernalia.

(2) Offer a discount or any other thing of value to a qualifying patient based on the patient's agreement or decision to use a particular parent or legal guardian or pharmaceutical processor or cannabidiol oil or THC-A oil product;

(3) Examine a qualifying patient for purposes of diagnosing intractable epilepsy at a location where cannabidiol oil or THC-A oil is dispensed or produced; or

(4) Directly or indirectly benefit from a patient obtaining a written certification. Such prohibition shall not prohibit a practitioner from charging an appropriate fee for the patient visit.

(b) A practitioner that issues written certifications, and such practitioner's co-worker, employee, spouse, parent or child, shall not have a direct or indirect financial interest in a pharmaceutical processor, provider of paraphernalia, or any other entity that may benefit from a qualifying patient's acquisition, purchase or use of cannabidiol oil or THC-

A oil, including any formal or informal agreement whereby a pharmaceutical processor or other person provides compensation if the practitioner issues a written certification for a qualifying patient or steers a qualifying patient to a specific pharmaceutical processor, paraphernalia provider, or cannabidiol oil or THC-A oil product.

(c) A practitioner shall not issue a written certification for such practitioner or for the practitioner's family members, employees or co-workers.

(d) A practitioner shall not provide product samples containing cannabidiol oil or THC-A oil other than those approved by the United States Food and Drug Administration.

Enforcement actions against practitioners

Comment [d6]: Is this section necessary? Seems law would already allow for BOM or BOP to take action or restrict ability to issue certs, if necessary. May need to add certain actions to "unprofessional conduct" for either or both boards.

(a) Pursuant to 54.1-3316, the board may issue an order to revoke or suspend a practitioner's registration or to restrict a practitioner's registration so as to prohibit the practitioner from issuing written certifications if the practitioner has:

(1) Failed to comply with any provision of the law or regulations; or

(2) Intentionally or negligently permitted another person to issue written certifications under the practitioner's name.

(b) If the board has reason to believe that the public health, safety or welfare imperatively requires emergency action, the board may issue an order restricting the practitioner's registration to summarily prohibit the practitioner from issuing written certifications pending a hearing. Such hearing shall be conducted pursuant to the Uniform Administrative Procedure Act, sections 4-166 to 4-189, inclusive, of the Connecticut General Statutes.

(c) The board may enter into an agreement with a practitioner placing conditions on the practitioner's registration that prohibit or restrict the issuing of written certifications.

(d) In addition to any other action permitted in this section, the board may refer any case involving an alleged violation by a practitioner of the law or regulations, to the Board of Medicine or to a state or local

law enforcement agency.

Patient and parent or legal guardian registration

(a) A qualifying patient for whom a practitioner has issued a written certification, and the qualifying patient's parent or legal guardian where applicable shall register with the board on forms, and in a manner, prescribed by the board. For a registration application to be considered complete, the following items shall be submitted:

(1) A copy of the written certification issued by a qualifying practitioner;

(2) Proof of residency of the qualifying patient acceptable to the board;

(3) Proof of identity of the qualifying patient acceptable to the board;

~~(4) Proof of the qualifying patient's age acceptable to the board;~~

(5) A photograph of the qualifying patient meeting the following requirements: (A) A current, digital, passport-size image, taken no more than thirty calendar days before the submission of the application;

(B) Taken against a plain white or off-white background or backdrop; (C) At least two inches by two inches in size;

(D) In natural color;

(E) Provides a front, unobstructed view of the full face;

(F) Has between one and one and three-eighths inches from the bottom of the chin to the top of the head; and

(G) Is in "jpeg" format or such other format as the board may authorize; (6) A parent or legal guardian form, if applicable;

(7) Proof of identity of the parent or legal guardian, if patient is a minor or an incapacitated adult, in a manner acceptable to the board;

(8) Proof of the parent or legal guardian's age acceptable to the board;

(9) A photograph of the parent or legal guardian meeting the requirements set forth in subsection (a)(5) of this section;

Comment [d7]: Should there be any minimal age requirements?

Comment [d8]: Is photo necessary or would we simply issue a paper registration without photo as we do with other registrations?

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(10) Permission for the board to determine whether the patient is an inmate confined in a correctional institution or facility under the supervision of the Department of Correction;

(11) Permission for the board to conduct a background check of the parent or legal guardian for the purpose of determining if such applicant has been convicted of a violation of any law pertaining to the illegal manufacture, sale or distribution of a controlled substance;

(12) Payment of the appropriate fees;

(13) The name, address and telephone number of the pharmaceutical processor from which the qualifying patient or the patient's parent or legal guardian will purchase cannabidiol oil or THC-A oil;
and

(14) Such other information as the board may reasonably require to determine the applicant's suitability for registration or to protect public health and safety.

(d) A qualifying patient shall only designate, and the board shall only register, one parent or legal guardian for the patient at any given time.

(e) Absent permission from the board or executive director for good cause shown, a qualifying patient may only change parent or legal guardians once per year at the time of renewal. A qualifying patient may change parent or legal guardians at the time of their registration renewal by requesting a different parent or legal guardian, who shall meet the requirements of this section, and be approved by the board or the executive director prior to the patient's registration certificate being renewed. If the qualifying patient requests permission to change parent or legal guardian prior to renewal, the qualifying patient shall submit a change of parent or legal guardian request form to the board, which shall set forth the reasons the qualifying patient seeks to change parent or legal guardians. If the board approves such change of parent or legal guardian request, the new parent or legal guardian shall register with the board and shall submit the non-refundable parent or legal guardian application fee required by section 21a-408-28 of the Regulations of Connecticut State Agencies. The board shall approve a new parent or

Comment [d9]: Would need ability to recoup cost within the application fee.

Comment [d10]: Is it appropriate to designate the patient to obtain oil from only one pharmaceutical processor? If there is need to use a different pharmaceutical processor, does patient need to inform board first?

Comment [d11]: This applies to a "caregiver" in CT. Should only one parent/guardian be allowed to register for the patient at any given time? Would it be problematic to allow a patient to have two parents/guardians registered for the one patient in the same time period? Is this section necessary?

legal guardian only if such person meets the requirements of the Act and this section.

Denial of a qualifying patient or parent or legal guardian registration application

(a) The board may deny an application or renewal of a qualifying patient's registration if the applicant:

(1) Does not meet the requirements set forth in law or regulation;

(2) Fails to properly complete the application form;

(3) Does not provide acceptable proof of identity, residency or age to the board;

(4) Provides false, misleading or incorrect information to the board;

(5) Fails to provide a photograph;

(6) Has had a qualifying patient's registration denied, suspended or revoked by the board in the previous six months;

(7) Has not paid all applicable fees;

(8) Has a written certification issued by a practitioner who is not authorized to certify patients for cannabidiol oil or THC-A oil; or

(9) Needs a parent or legal guardian to also register and:

(A) The applicant has not designated a parent or legal guardian; or

(B) The board has denied the application of the parent or legal guardian designated by the qualifying patient.

(b) The board may deny an application or the renewal of a parent or legal guardian's registration if the qualifying patient is not a minor or incapacitated or if the parent or legal guardian applicant:

(1) Does not meet the qualifications set forth law and regulation;

~~(2) Has a disqualifying conviction;~~

(3) Fails to properly complete the parent or legal guardian application form;

(4) Does not provide acceptable proof of identity or age to the board;

(5) Fails to provide a photograph;

(6) Has not paid all applicable fees as required;;

(7) Provides false, misleading or incorrect information to the board;

(8) Has had a parent or legal guardian registration denied,

Comment [d12]: Note to staff: Per bill, need ability to prohibit patient from being issued a written cert from more than one practitioner during any time period; identify on application if patient is a minor or incapacitated which would necessitate registration from parent/guardian.

Comment [d13]: Law does not appear to prohibit patient, parent, or guardian with conviction from obtaining oil.

Comment [d14]: Photo necessary?

suspended or revoked in the previous six months;

(10) Is designated as a parent or legal guardian for a qualifying patient whose application is denied by the board or whose qualifying patient registration has been suspended or revoked.

(c) If the board denies an application or renewal of a qualifying patient applicant or parent or legal guardian applicant, the board shall provide the applicant with notice of the grounds for the denial and shall inform the applicant of the right to request a hearing.

Revocation or suspension of a qualifying patient or parent or legal guardian registration

(a) The board may revoke or suspend the registration certificate of a qualifying patient under the following circumstances:

(1) The qualifying patient becomes an inmate confined in a correctional institution or facility under the supervision of the Department of Corrections;

Comment [d15]: does this cover all correctional institutions? Juvenile justice?

(2) The qualifying patient's practitioner notifies the board that the practitioner is withdrawing the written certification submitted on behalf of the qualifying patient and, thirty days after the practitioner's withdrawal of the written certification, the patient has not obtained a valid written certification from a different practitioner;

(3) The qualifying patient or parent or legal guardian provided false, misleading or incorrect information to the board;

(4) The qualifying patient is no longer a resident of Virginia;

(5) The qualifying patient, together with the qualifying patient's parent or legal guardian where applicable, obtains more than a one-month supply of cannabidiol oil or THC-A oil in a one-month period;

(6) The qualifying patient provides or sells cannabidiol oil or THC-A oil to any person, including another registered qualifying patient or parent or legal guardian;

(7) The qualifying patient uses cannabidiol oil or THC-A oil in a place or manner not permitted by the law or regulations;

Comment [d16]: Should there be restrictions on where the oils may be administered?

(8) The qualifying patient uses cannabidiol oil or THC-A oil in a

manner that puts others at risk or fails to take reasonable precautions to avoid putting others at risk;

(9) The qualifying patient permits another person to use the qualifying patient's registration certificate;

(10) The qualifying patient tampers, falsifies, alters, modifies or allows another person to tamper, falsify, alter or modify, the qualifying patient's registration certificate;

(11) The qualifying patient's practitioner is no longer available to provide care to the patient and, after thirty days from the practitioner notifying the board of the practitioner's unavailability, the patient has not established a bona-fide relationship with a different practitioner;

(12) The qualifying patient's registration is lost, stolen or destroyed and the patient or the patient's parent or legal guardian fails to notify the board or notifies the board of such incident more than five business days after becoming aware that
the registration was lost, stolen or destroyed;

(13) The qualifying patient fails to notify the board of a change in registration information or notifies the board of such change more than five business days after the change; or

(14) The qualifying patient has violated any section of the law or regulation.

(b) The board may revoke or suspend the registration of a parent or legal guardian under the following circumstances:

(1) The registration certification of the qualifying patient has been revoked or suspended;

(2) The qualifying patient or parent or legal guardian provided false, misleading or incorrect information to the board;

(3) The parent or legal guardian obtains more than a one-month supply of cannabidiol oil or THC-A oil in a one-month period on behalf of a single qualifying patient;

(4) The parent or legal guardian obtains cannabidiol oil or THC-A oil for, or provides or sells cannabidiol oil or THC-A oil to, any person other than the qualifying patient of the parent or legal guardian, including a different qualifying patient or parent or legal guardian;

(5) The parent or legal guardian permits another person to use the

parent or legal guardian's registration certificate;

(6) The parent or legal guardian has tampered, altered, modified, falsified, or allowed any person to tamper, alter, modify or falsify, the parent or legal guardian's registration certificate or the registration certificate of the qualifying patient;

(7) The parent or legal guardian has permitted the use of cannabidiol oil or THC-A oil that endangers the health or well-being of a person other than the qualifying patient or parent or legal guardian;

~~(8) The parent or legal guardian has a disqualifying conviction;~~

(9) The parent or legal guardian's registration is lost, stolen or destroyed and the parent or legal guardian fails to notify the board or notifies the board of such incident more than five business days after becoming aware that the registration certificate was lost, stolen or destroyed;

(10) The parent or legal guardian fails to notify the board of a change in registration information or notifies the board of such change more than five business days after the change; or

(11) The parent or legal guardian has violated any section of the law or regulations.

Reporting requirements for practitioners, patients and parent or legal guardians

(a) A practitioner shall report to the board, in a manner prescribed by the board, the death of a qualifying patient or change in status of the intractable epilepsy involving a qualifying patient for whom the practitioner has issued a written certification if such change may affect the patient's continued eligibility to use cannabidiol oil or THC-A oil. A practitioner shall report such death or change of status not more than five business days after the practitioner becomes aware of such fact.

(b) A qualifying patient or parent or legal guardian, who has been issued a registration, shall notify the board of any change in the information provided to the board not later than five business days after such change. A qualifying patient or parent or legal guardian shall report

changes that include, but are not limited to, a change in the qualifying patient's name, address, contact information, medical status, or status with the Department of Corrections. A qualifying patient or parent or legal guardian shall report such changes on a form, and in a manner, prescribed by the board.

(c) A qualifying patient or parent or legal guardian may change the patient's designated pharmaceutical processor no more than four times per year without good cause shown and prior approval by the executive director of the board. A qualifying patient or parent or legal guardian shall report the change on a form and in a manner prescribed by the board. A change in the designated pharmaceutical processor shall not be effective until five business days after the qualifying patient or parent or legal guardian notifies the board of such change. A qualifying patient or parent or legal guardian shall only purchase cannabidiol oil or THC-A oil from the pharmaceutical processor currently designated by the patient or parent or legal guardian with the board.

Comment [d17]: Is this necessary given only one pharmaceutical processor per health service area?

(d) If a qualifying patient's or parent or legal guardian's appearance has substantially changed such that the photograph submitted to the board does not accurately resemble such qualifying patient or parent or legal guardian, such person shall submit, in a timely manner, an updated photograph that meets the requirements.

(e) If a qualifying patient has a parent or legal guardian, that parent or legal guardian may notify the board of any changes on behalf of the qualifying patient using the same forms and process prescribed for qualifying patients.

(f) If a qualifying patient or parent or legal guardian notifies the board of any change that results in information on the registration certificate being inaccurate or the photograph needing to be replaced, the qualifying patient or parent or legal guardian shall submit the fee for a replacement registration certificate. The board shall thereafter issue the qualifying patient or parent or legal guardian a new registration certificate provided the applicant continues to satisfy the requirements of the law and regulations. Upon receipt of a new registration certificate, the qualifying patient or parent or legal guardian shall destroy in a non-

recoverable manner the registration certificate that was replaced.

(g) If a qualifying patient or parent or legal guardian becomes aware of the loss, theft or destruction of the registration certificate of such qualifying patient or parent or legal guardian, the qualifying patient or parent or legal guardian shall notify the board, on a form and in a manner prescribed by the commissioner, not later than five business days of becoming aware of the loss, theft or destruction, and submit the fee for a replacement registration. The board shall inactivate the initial registration upon receiving such notice and issue a replacement registration upon receiving the applicable fee provided the applicant continues to satisfy the requirements of law and regulation.

Precautions for preventing the loss, theft or misuse of cannabidiol oil or THC-A oil by patients and parent or legal guardians

(a) A qualifying patient and parent or legal guardian shall store cannabidiol oil or THC-A oil in a secure location to prevent theft, loss or access by unauthorized persons.

(b) Qualifying patients and parent or legal guardians shall carry their registration and original written certification with them whenever they are in possession of cannabidiol oil or THC-A oil.

Proper disposal of cannabidiol oil or THC-A oil by patients or parents or legal guardians

A patient or parent or legal guardian shall dispose of all usable cannabidiol oil or THC-A oil in the patient or parent or legal guardian's possession no later than ten calendar days after the expiration of the patient's registration certificate, if such certificate is not renewed, or sooner should the patient no longer wish to possess cannabidiol oil or THC-A oil. A patient or parent or legal guardian shall complete such disposal by one of the following methods:

(1) By rendering the cannabidiol oil or THC-A oil non-recoverable in accordance with the board's proper disposal instructions, which are available on the board's Internet web site at ~~www.ct.gov/dcp/drugdisposal;~~

(2) By depositing it in a law enforcement medication drop-box; or

(3) By disposing of the cannabidiol oil or THC-A oil at a government-recognized drug take-back program located in Virginia.

DRAFT

Qualifying Patient & Primary Caregiver Registration Certificates

CONNECTICUT REGISTRATION CERTIFICATE

Patient ID: CT987600076523456714

JANE A DOE
DOB:01/15/1970
Issued Date:10/01/12
Expiration Date:10/01/13
Authorized Amount: 2.5 Ounces

PATIENT

To verify: www.ctpmp.com

MMP

Marijuana may impair an individual's ability to drive a motor vehicle or operate heavy machinery and may interact with other medications you may be taking.

This registration does not permit the use of marijuana (i) in a motor bus or a school bus or in any other moving vehicle; (ii) in the workplace; (iii) on any school grounds or any public or private school, dormitory, college or university property; (iv) in any public place; (v) in the presence of a person under the age of eighteen; or (vi) in any other way that endangers the health or well-being of a person other than the qualifying patient or the primary caregiver.

For more information, please contact the Medical Marijuana Program at (860) 713-6066 or email us at: dcp.mmp@ct.gov.

Website: www.ct.gov/dcp/mmp

CONNECTICUT REGISTRATION CERTIFICATE

Caregiver ID: CT123000087635419832

DOE B JANE
DOB:01/15/1970
Issued Date:10/01/12
Expiration Date:10/01/13
Authorized Amount: 2.5 Ounces

CAREGIVER

Patient Name: JANE A DOE
To verify: www.ctpmp.com

MMP

Marijuana may impair an individual's ability to drive a motor vehicle or operate heavy machinery and may interact with other medications you may be taking.

This registration does not permit the use of marijuana (i) in a motor bus or a school bus or in any other moving vehicle; (ii) in the workplace; (iii) on any school grounds or any public or private school, dormitory, college or university property; (iv) in any public place; (v) in the presence of a person under the age of eighteen; or (vi) in any other way that endangers the health or well-being of a person other than the qualifying patient or the primary caregiver.

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MMP