COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Second Floor
Henrico, Virginia 23233

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

August 30, 2016

10AM

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Call to Order: *Ryan Logan, Chairman*	
• Welcome & Introductions	1
• Approval of Agenda	
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Call for Public Comment	
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• Complete Review of Proposed Language for Draft Regulations, *Ryan Logan and Caroline Juran*	
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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

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATORY ADVISORY PANEL MEETING REGARDING CANNABIDIOL OIL AND THC-A OIL

July 26, 2016
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 10:10 am

PRESIDING: Ryan K. Logan, Chairman

MEMBERS PRESENT:
Cynthia Warriner, Board of Pharmacy
Jody H. Allen, Board of Pharmacy
Senator David W. Marsden (left at 3:05pm)
William L. Harp, MD, Board of Medicine
Alexander Pytlarz, Virginia Pharmacists Association
Ed McCann, former owner of cannabis facility
Regina Whitsett, Substance Abuse Free Environment, Inc.
Beth Collins, Americans for Safe Access (left at 3:30pm)
Baylor Rice, community compounding pharmacist
Jake Bergman, Surterra Holdings, Inc.
Julia Whiting, MD, concerned parent/physician
Chuck Morris, concerned family member
Paul Lyons, MD, child neurologist

MEMBERS ABSENT: Sridher Toor, MD, Board of Medicine/child neurologist

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Deputy Executive Director
David E. Brown, DHP Director
Elaine J. Yeatts, Senior Policy Analyst
Jim Rutkowski, Assistant Attorney General
Beth O'Halloran, Individual Licensing Manager

APPROVAL OF AGENDA: Agenda presented for review including presentations by Ms. Juran with reports on action items from the previous meeting of the panel and a review of the proposed language for draft regulations prepared by Board of Pharmacy staff.

APPROVAL OF MINUTES: A review of the draft minutes from the previous meeting of the panel identified areas needing correction. Item #15 with regard to dosing for the patient should read 20-30mg/kg/day and in Item #20 the panel decided to remove the term "agreed" and replace with "discussed" as the general consensus was that the panel did not come to an agreement on the number of patients to which prescribers should be limited.

MOTION:

The Panel voted unanimously to approve the minutes as amended for the Regulation Advisory Panel meeting held on July 1, 2016. (motion by Warriner, second by Whiting)

PUBLIC COMMENT:

Heather Davies, concerned parent and board member of the Unified Prevention Coalition of Fairfax County, spoke regarding concerns over diversion of the medical product by teenagers, the marketing of medical marijuana, and the impact it will have on youth and their perception with regard to its recreational use. Ms. Davies also spoke about her concerns regarding possible links between marijuana use and suicide. Other comments addressed by Ms. Davies included:

- Need for a definition of drug-resistant epilepsy;
- Compared to other state laws, SB701 allows the highest level of THC to be present in cannabidiol oil and THC-A oil;
- Descriptive statistics of target patient population needed to determine allowable facility size, production and inventory;
- Prescribing information should be submitted by applicants, consistent with FDA labeling regulations and approved by the Board of Pharmacy as part of permit;
- The Board of Pharmacy needs to survey Virginia physicians for interest in prescribing oils;
- Contraindications – prescribing to pregnant and lactating women
- Labeling and patient information clearly stating these products are not FDA approved;
- Dosing guidelines, a critical determinant of facility permit conditions;
- Adverse event reporting process needed, similar to FDA MedWatch;
- Documentation of patient response to treatment;
- Physician requirements – should be for neurologists only;
- Mandatory use of patient blood monitoring to determine beneficial dose, deter diversion;
- Photo identification for qualified patients and/or caregivers;
- Permitted administration methods – no vaping;
- Require physician training requirement;
- Emergency room guidelines for managing overdosing, adverse events;
- Consultation and approval of local jurisdictions for facility siting, location-specific conditions and zoning requirements;
- Standardized test protocols, lab accreditation;
- Shelf life, expiration determination;
- Drug-testing of all employees;
- Training standards – employees;
- Worker safety standards – personal protective equipment, indoor air quality;
- Absolutely no advertising;
- Penalties for violation of these regulations.

Marla Watson, legislative chair for the Community Coalitions of Virginia and Central Virginia Marijuana Prevention Task Force Coordinator, provided comment regarding concerns for the regulations to support SB701, emphasizing that use of marijuana remains illegal federally. Ms. Watson provided comment and a handout that explained participants in the marijuana industry should be thoroughly vetted including background checks, free of felony charges, no liens or judgements and have not been barred from any contracting processes. Ms. Watson also expressed concern over the one month supply and the lack of research on the dosage to calculate a one month supply. Ms. Watson commented that practitioners that issue a certification to patients should only do so as a last resort to traditional medications and that physicians should take a course on the use of marijuana oils as this subject is not taught in medical schools traditionally. Ms. Watson also stated that the state should create a board of doctors, health officials, addiction experts and law enforcement officials who are unaffiliated with the marijuana industry that will create the course based on scientific evidence.

Kevin Carroll, president of the Fraternal Order of Police of Virginia, provided comment on the ability to convert THC-A to THC when heated and the concern for where the plants are grown and possible diversion from the facilities. Mr. Carroll stated he has concerns over the security of the product and how it is going to be distributed.

REPORT ON ACTION ITEMS:

Information was shared and discussed regarding action items identified in the minutes from the July 1, 2016 meeting.

- Action Item-Basic Requirements for Temperature and Humidity

Mr. Bergman provided information regarding basic requirement for temperature and humidity. The following information was provided by Mr. Bergman:

	TEMPERATURE	HUMIDITY
"Mother" room	65-75 F	50-60 %
Nursery phase	77-85 F	65-75 %
Vegetation phase	77-85 F	55-65 %
Flower/Harvest phase	77-85 F	55-60 %
Drying/Extraction rooms	< 75 F	55-60 %

- Action Item – Whether SB701 allows a pharmaceutical processor to deliver dispensed oil to a patient's residence

Mr. Rutkowski informed the panel that while SB701 states delivery must be "in person" it does not state where the delivery should take place and therefore a delivery driver could be used to deliver the dispensed oil to the patient's residence. He indicated delivery could not be performed by a third party.

- Action Item – Maximum number of plants a pharmaceutical processor should be allowed to possess at any given time

Mr. Bergman stated that the number of plants depends on the dosing for the patient and how many plants are needed to treat that patient. Each plant will yield between 12-15grams of oil. It takes generally 4 months to grow a plant. If the maximum dose is 15 grams per month that would equal approximately 1 plant per month per patient. To address concerns

with the viability of plants, it was suggested that a 20% buffer for the cloning stage and a 5% buffer for the cultivating cycle should be considered, along with idea that patient may immediately not respond well to dispensed product and may need subsequent dispensing. Thus, Mr. Bergman recommended processors be allowed to possess 4-5 plants per patient at any given time. Additionally, time for testing the oil prior to dispensing should be considered. It was, also, suggested by a panel member that an amendment of the bill to limit the square footage for the growing area per patient rather than the number of plants may be a better approach. Ms. Juran stated that the National Alliance for Model State Drug Laws (NAMSDL) reports that states addressing the private production of low THC/cannabidiol (Virginia, Missouri, Texas, and Florida) do not generally address a number of plants that may be possessed, with the exception of Florida which appears to indicate the producer be capable of large-scale production. States with broader medical marijuana allowances do tend to address the number of plants a producer may possess.

- Action Item – to what standards should production of oils be held

Ms. Juran reported that per NAMSDL, states do not generally appear to reference a particular standard, e.g., USP, FDA cGMPs, but rather have identified individual requirements in regulation for cultivation and testing.

- Action Item – what constitutes a 30-day supply and how should the board interpret the requirement to define this element

Ms. Juran stated that NAMSDL reports that there are a few states that limit the actual dose of oil. Georgia limits a person to 20 fluid ounces of low THC oil, Iowa limits a person to 32 fluid ounces of oil, and Missouri restricts persons to 20 fluid ounces of hemp extract. It was discussed that the amount of active ingredient should be taken into consideration to ensure the amount of necessary carrier oil doesn't negatively impact the amount permissible to be dispensed. Ms. Collins stated that patients typically need fewer milligrams of THC-A oil for treatment than cannabidiol oil. Mr. Rutkowski simply advised that the board must have a reasonable explanation for the limit it sets.

- Action Item – number of patients that a practitioner may issue a written certification and how should the board interpret the requirement to define this element

Ms. Juran stated that NAMSDL reports that the other states limited to low THC/cannabidiol oil do not address this issue. Since the end of January 2015, when Iowa's law went into force, roughly 100 applications for cannabidiol registry cards have been received. Mr. Rice clarified that his suggestion of 600 patients during the last meeting was referencing allowances for medical concierge, but should not be the maximum number of patients a practitioner may issue a written certification.

- Action Item-how DHP could structure the registration process

Ms. Juran indicated she will be meeting with other DHP staff members later this week to discuss this issue and hopes to have more information to share at the next panel meeting.

- Review proposed language for draft regulations prepared by staff

The panel began a review of the draft regulations, pages 8 through 28 of the agenda packet, and offered comments and suggestions to the language. Comments/suggestions offered for consideration included:

- Add definition for intractable epilepsy; no single definition, tends to be based on a practitioner's clinical decision;
- Define what constitutes residency; staff to locate existing definitions in law; should address military transfers, and persons relocating who need continued cannabidiol therapy;
- Strike any reference to compounding;
- Proposed fees appear too low;
- Require in-person visits with practitioner for one year then may use telemedicine based on practitioner's professional judgement;
- Clarify record retention requirements;
- Require blood draws; unnecessary and overly burdensome for patients;
- Require training for practitioners;
- Background check for registration process for patient, parent, guardian should determine if convicted for possession as well;
- Review FDA standards for allowing compassionate use when convictions are present;
- When considering issuance of registration add great weight for consideration of the best interest of the child;
- Patient, parent, guardian should exercise reasonable precautions to prevent theft, loss, access by unauthorized persons;
- Don't require to carry written certification or registration, unless it's a wallet card;
- Application process for pharmaceutical processors should involve 3 phases, e.g., initial review of paperwork, initial approval to proceed with plan, and inspection
- Should not allow for monopolies;
- Consider a performance surety bond;
- Requirement for applicant to report actions taken in other states;
- Location restrictions should default to local zoning requirements;
- Impact of local ordinances preventing agriculture and retail on same lot; Right to Farm;
- Production process should allow for non-pharmacists and non-pharmacy technicians, e.g., chemists;
- Change required registration timeframe for eligible pharmacy technicians to two years, consider recognizing experience in other states;
- PIC should be required to perform criminal background checks on employees performing non-dispensing functions, decision to perform drug testing should be left to pharmacist-in-charge;
- Consideration for whether a pharmacist must be present at all times when in operation and if key and alarm code should be restricted to pharmacist(s);
- Consider restricting non-pharmacists to cultivation area based on design model with increased security, e.g., surveillance cameras, and requirement for drug testing;

- Add requirement to notify public if closing;
- Require processors to post pricing of oil on Internet website;
- If employed agent allowed to deliver oil need mechanism for verifying identify of patient, parent, guardian, as applicable;
- Surveillance videos should be required both inside and outside facility;
- Combine sections of regulation, as appropriate, for ease of reading.

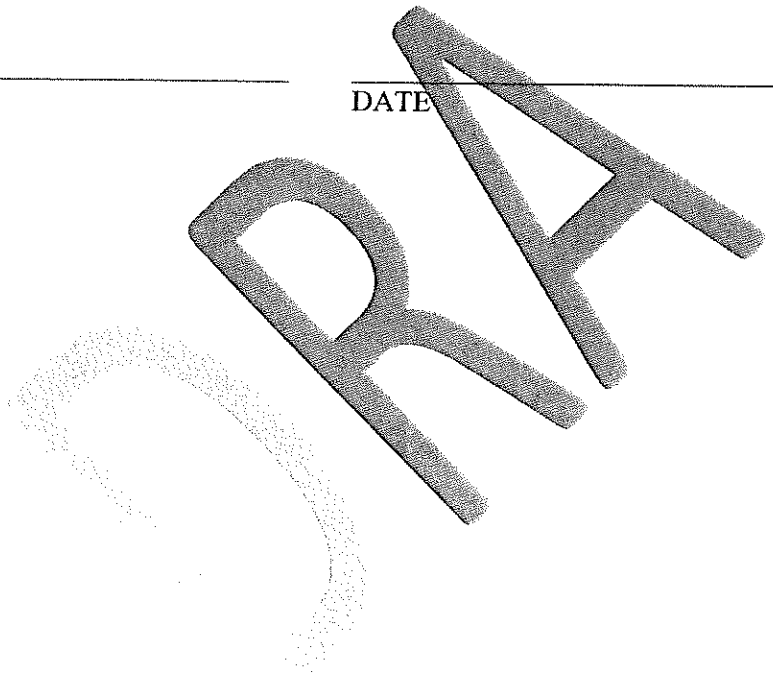
ADJOURN: With all business concluded, the meeting adjourned at approximately 4:00 pm.

Ryan K. Logan, Chairman

Caroline D. Juran, Executive Director

DATE

DATE



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

later than one year after its issuance unless the practitioner provides in such written certification an earlier expiration.

D. No practitioner shall be prosecuted under § 18.2-248 or 18.2-248.1 for dispensing or distributing cannabidiol oil or THC-A oil for the treatment or to alleviate the symptoms of a patient's intractable epilepsy pursuant to a written certification issued pursuant to subsection B. Nothing in this section shall preclude the Board of Medicine from sanctioning a practitioner for failing to properly evaluate or treat a patient's medical condition or otherwise violating the applicable standard of care for evaluating or treating medical conditions.

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

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

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

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

Article 4.2.

Permitting of Pharmaceutical Processors to Produce and Dispense Cannabidiol Oil and THC-A Oil.

§ 54.1-3442.5. Definitions.

As used in this article:

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

"Pharmaceutical processor" means a facility that (i) has obtained a permit from the Board pursuant to § 54.1-3408.3 and (ii) cultivates Cannabis plants intended only for the production of cannabidiol oil or THC-A oil, produces cannabidiol oil or THC-A oil, and dispenses cannabidiol oil or THC-A oil to a registered patient or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian for the treatment of intractable epilepsy.

"Practitioner" has the same meaning as specified in § 54.1-3408.3.

"THC-A oil" has the same meaning as specified in § 54.1-3408.3.

§ 54.1-3442.6. Permit to operate pharmaceutical processor.

A. No person shall operate a pharmaceutical processor without first obtaining a permit from the Board. The application for such permit shall be made on a form provided by the Board and signed by a pharmacist who will be in full and actual charge of the pharmaceutical processor. The Board shall establish an application fee and other general requirements for such application.

B. Each permit shall expire annually on a date determined by the Board in regulation. The number of permits that the Board may issue or renew in any year is limited to one for each health service area established by the Board of Health. Permits shall be displayed in a conspicuous place on the premises of the pharmaceutical processor.

C. The Board shall adopt regulations establishing health, safety, and security requirements for pharmaceutical processors. Such regulations shall include requirements for (i) physical standards; (ii) location restrictions; (iii) security systems and controls; (iv) minimum equipment and resources; (v) recordkeeping; (vi) labeling and packaging; (vii) quarterly inspections; (viii) processes for safely and securely cultivating Cannabis plants intended for producing cannabidiol oil and THC-A oil, producing cannabidiol oil and THC-A oil, and dispensing cannabidiol oil and THC-A oil to a registered patient or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian; (ix) a maximum number of marijuana plants a pharmaceutical processor may possess at any one time; and (x) the secure disposal of plant remains.

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

on the premises of the pharmaceutical processor.

E. No person who has been convicted of a felony or of any offense in violation of Article 1 (§ 18.2-247 et seq.) or Article 1.1 (§ 18.2-265.1) of Chapter 7 of Title 18.2 shall be employed by or act as an agent of a pharmaceutical processor.

§ 54.1-3442.7. Dispensing cannabidiol oil and THC-A oil; report.

A. A pharmaceutical processor shall dispense cannabidiol oil or THC-A oil only in person to (i) a patient who is a Virginia resident, has been issued a valid written certification, and is registered with the Board pursuant to § 54.1-3408.3 or (ii) if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian who is a Virginia resident and is registered with the Board pursuant to § 54.1-3408.3. Prior to dispensing, the pharmaceutical processor shall verify that the practitioner issuing the written certification, the patient, and if such patient is a minor or an incapacitated adult, the patient's parent or legal guardian are registered with the Board. No pharmaceutical processor shall dispense more than a 30-day supply for any patient during any 30-day period. The Board shall establish in regulation an amount of cannabidiol oil or THC-A oil that constitutes a 30-day supply to treat or alleviate the symptoms of a patient's intractable epilepsy.

B. A pharmaceutical processor shall dispense only cannabidiol oil and THC-A oil that has been cultivated and produced on the premises of such pharmaceutical processor.

C. The Board shall report annually by December 1 to the Chairmen of the House and Senate Committees for Courts of Justice on the operation of pharmaceutical processors issued a permit by the Board, including the number of practitioners, patients, and parents or legal guardians of patients who have registered with the Board and the number of written certifications issued pursuant to § 54.1-3408.3.

§ 54.1-3442.8. Criminal liability; exceptions.

In any prosecution of an agent or employee of a pharmaceutical processor 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 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 oil in accordance with the provisions of this article and Board regulations or (ii) possessed, manufactured, or distributed such cannabidiol oil or THC-A 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 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 oil in accordance with the provisions of this article and Board regulations or (b) such cannabidiol oil or THC-A oil was possessed, manufactured, or distributed in accordance with the provisions of this article and Board regulations.

2. That, except as provided in the third enactment of this act, the provisions of the first enactment of this act shall not become effective unless reenacted by the 2017 Session of the General Assembly.

3. That the Board of Pharmacy shall promulgate regulations to implement the provisions of the first enactment of this act within 280 days of its initial enactment. Such regulations shall not become effective unless the provisions of the first enactment of this act are reenacted by the 2017 Session of the General Assembly.

Information provided by Regina Whitsett:

Video files -
https://www.dropbox.com/sh/4zq2w5hk5szq5s4/AACbrcHmXAWUYZp7YrgXm0Lca?dl=0

Preamble; Warning; Consultation Suggested

A. Marijuana is classified as a Schedule I controlled substance by the U.S. Department of Justice, Drug Enforcement Administration.

1. As provided by the federal Controlled Substances Act, the procurement, possession, prescribing, distribution, dispensing, or administering of any Schedule I controlled substance, including marijuana, is a violation of federal law.

2. Neither Virginia law nor the board's rules can preempt federal law. Therefore, the provisions of this Subchapter notwithstanding, persons engaged in the activities described herein remain subject to the full force of federal law enforcement, including arrest and prosecution of criminal charges, the assessment of civil fines and forfeitures, as well as administrative consequences such as forfeiture of federal controlled substance registrations and exclusion from Medicare and other federal payer programs.

B. For the foregoing reasons, pharmacists and other persons credentialed by the board may wish to consult with their own legal counsel as well as any health care facility, private or governmental payor with which they are affiliated, professional malpractice insurers, and financial institutions with which they maintain depository relationships before engaging in the activities described herein.

HEADQUARTERS NEWS

August 11, 2016
Contact: DEA Public Affairs
(202) 307-7977

DEA Announces Actions Related to Marijuana and Industrial Hemp

AUG 11 (WASHINGTON) - The Drug Enforcement Administration (DEA) announced several marijuana- related actions, including actions regarding scientific research and scheduling of marijuana, as well as principles on the cultivation of industrial hemp under the Agricultural Act of 2014.

DEA Publishes Responses to Two Pending Petitions to Reschedule Marijuana
DEA has denied two petitions to reschedule marijuana under the Controlled Substances Act (CSA). In response to the petitions, DEA requested a scientific and medical evaluation and scheduling recommendation from the Department of Health and Human Services (HHS), which was conducted by the U.S. Food and Drug Administration (FDA) in consultation with the National Institute on Drug Abuse (NIDA). Based on the legal standards in the CSA, marijuana remains a schedule I controlled substance because it does not meet the criteria for currently accepted medical use in treatment in the United States, there is a lack of accepted safety for its use under medical supervision, and it has a high potential for abuse.

In his letter to the petitioners, DEA Acting Administrator Chuck Rosenberg offered a detailed response outlining the factual and legal basis for the denial of the petitions.

The full responses to the petitions can be found in the Federal Register. Response 1 AND Response 2

The DEA and the FDA continue to believe that scientifically valid and well-controlled clinical trials conducted under investigational new drug (IND) applications are the most appropriate way to conduct research on the medicinal uses of marijuana. Furthermore, DEA and FDA believe that the drug approval process is the most appropriate way to assess whether a product derived from marijuana or its constituents is safe and effective and has an accepted medical use. This pathway allows the FDA the important ability to determine whether a product meets the FDA criteria for safety and effectiveness for approval.

Increasing the Number of Authorized Marijuana Manufacturers Supplying Researchers

DEA announced a policy change designed to foster research by expanding the number of DEA- registered marijuana manufacturers. This change should provide researchers with a more varied and robust supply of marijuana. At present, there is only one entity authorized to produce marijuana to supply researchers in the United States: the University of Mississippi, operating under a contract with NIDA. Consistent with the CSA and U.S. treaty obligations, DEA's new policy will allow additional entities to apply to become registered with DEA so that they may grow and distribute marijuana for FDA-authorized research purposes.

This change illustrates DEA's commitment to working together with the FDA and NIDA to facilitate research concerning marijuana and its components. DEA currently has 350 individuals registered to conduct research on marijuana and its components. Notably, DEA has approved
every application for registration submitted by researchers seeking to use NIDA-supplied marijuana to conduct research that HHS determined to be scientifically meritorious.

Statement of Principles Concerning Industrial Hemp and the Agricultural Act of 2014

The U.S. Department of Agriculture (USDA), in consultation with DEA and the FDA, also released a statement of principles concerning provisions of the Agricultural Act of 2014 relating to the cultivation of industrial hemp. Industrial hemp is a low-concentration THC variety of the cannabis plant intended to be used for industrial purposes (e.g., fiber and seed). This statement of principles is intended to inform the public, including institutions of higher education and State departments of agriculture, how Federal law applies to activities associated with industrial hemp that is grown and cultivated in accordance with Section 7606 of the Agricultural Act of 2014.

This statement of principles outlines the legalized growing and cultivating of industrial hemp for research purposes under certain conditions, such as in states where growth and cultivation are legal under state law. The 2014 Act did not remove industrial hemp from the list of controlled substances and, with certain limited exceptions, the requirements of the Federal Food, Drug, and Cosmetic Act and the CSA continue to apply to industrial hemp-related activities. The statement of principles addresses questions including the extent to which private parties may grow industrial hemp as part of an agricultural pilot program, the circumstances under which the sale of hemp products is permitted, and other related topics.

©In Defense of Our Brains

Bertha K Madras, PhD
Professor, Psychobiology
Department of Psychiatry
McLean Hospital

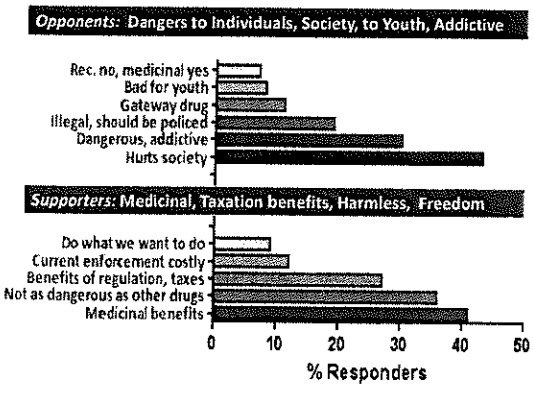
Our Nation's Challenges

- Marijuana
- Opioids, overdose deaths
- New Psychoactive Drugs
- Hallucinogens As Medicines

Next...

All Drugs Legal?

Opponents, Supporters: Marijuana Legalization "Hurts society" vs "It's a medicine"



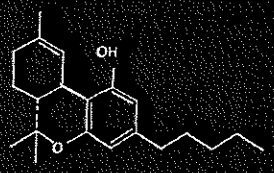
Adapted by BK Madras from: PEW RESEARCH CENTER Survey conducted March 25-29, 2015.
Open-ended question. Total exceeds 100% because of multiple responses

How Does Marijuana Act?

Marijuana Chemistry

Cannabis sativa contains ~ 750 chemicals

Δ^9-TetraHydroCannabinol (THC) highest

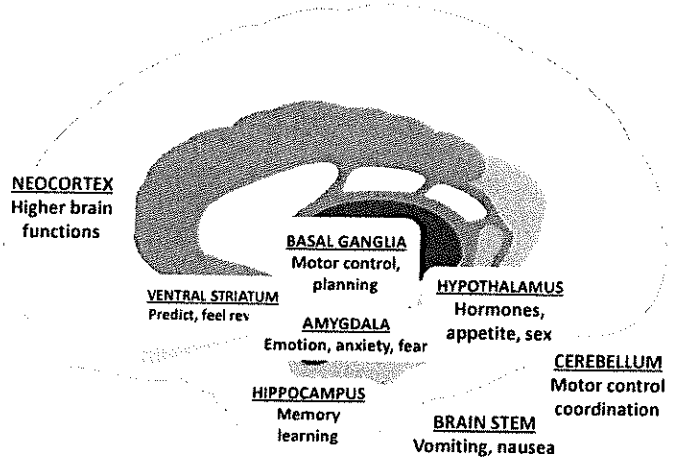


- ~104 *Phyto*cannabinoids, 200-300 terpenoids
- *Synthetic* cannabinoids: 1,000's made by chemists
- *Endo*cannabinoids: Made by brain, body

Endocannabinoids: Brain, Organs, Blood Cells

CB1 receptors	CB2 receptors
BRAIN	BLOOD CELLS
Heart	IMMUNE CELLS
Pancreas	Brain
Muscle	Heart
Testis, ovaries	Adrenal
Uterus	Intestinal tract
Prostate	Pancreas
Vascular tissue	Bone
Immune cells	Smooth muscle
	Reproductive organs

Marijuana Affects Cannabinoid Signals in Brain



Is Marijuana Safe?

- Can overdose cause death?
- Cognitive degradation
- Cannabis (Marijuana) Use Disorder
- Motivation
- Psychosis
- Marijuana and other drugs:
  - Alcohol or marijuana?
  - "Opioid priming"?
- Social problems
  - Educational
  - Workplace
  - Parenting

Does Marijuana Kill?

Heroin Overdose Deaths Are Common, not Marijuana... Why?

Marijuana unlikely to produce an overdose death

- Marijuana targets (cannabinoid receptors) *scant* in brain stem region that regulates heart rate and breathing.
- Heroin targets (mu opioid receptors) *abundant* in brain stem.

Intoxication can lead to injuries; injuries can be fatal

- Marijuana can affect judgment, perception, coordination:
  - driving
  - extreme anxiety with high doses (panic attacks)
  - psychosis in vulnerable people (loss of reality, paranoid)

Cognitive Degradation

Marijuana Intoxication Can Impair Higher Brain Function

- Impairs learning, working memory
- Reduces attention span and concentration
- Reduces ability to plan
- Reduces organizational skills
- Reduces problem solving
- Reduces decision making
- Reduces perception of facts
- Reduces emotional control
- Reduces behavioral control
- Impairs motor coordination
- Increases impulsivity
- Increases hunger
- Distorts perception of time, distance, sounds
- Promotes euphoria, relaxation, sedation

Cognitive Degradation Associated with Short or Long term Marijuana Use

Impairs learning and memory (short and long term)
- Verbal IQ, Memory
- Word associations
- Processing speed
- Perseveration

Impairs decision making
- Risky sexual behavior
- Driving
- Executive function
- Psychosis

Impairs motor function
- Balance, coordination in
  - sports
  - driving
  - aviation
  - workplace

Addiction Medicine 2011;5:1-8; Pope HG Jr, et al. Early-onset cannabis use and cognitive deficits: what is the nature of the association? Drug Alcohol Depend. 2003 Apr 1;69(3):303-10; Pope and Yurgelun-Todd 1996; Solowij et al. 2002, Fletcher et al., 1996; McHale and Hunt,2008; Porter, & Frampton, 2007 et al., 2002; Harvey et al. 2007; Solowij & Pesa 2010 ; Novaes et al. 2008; Battisti et al., 2010;

Cognitive Degradation:

Early, Persistent Marijuana Use Associated with Reduced I.Q.

IQ drop associated: with age of onset of use and length of time addicted

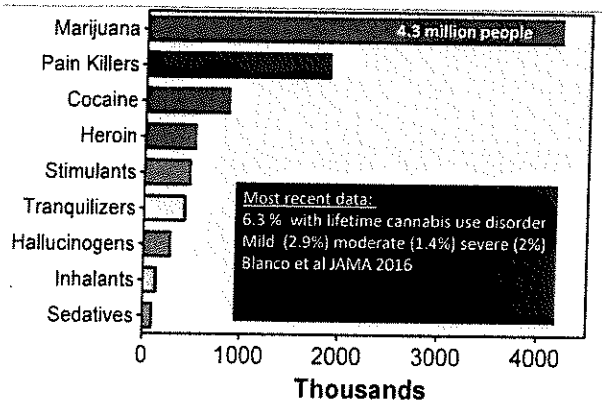
IQ drop most: if use before age 18, continue, and addicted at 38

IQ reduced: if did not quit use at age 38

IQ still reduced: if use before 18 and then quit later

Meier et al, Persistent cannabis users show neuropsychological decline from childhood to midlife. Proc. Natl. Acad. Sci *USA*, 2012 Oct 2;109(40):E2657-64.

Cannabis Use Disorder



SAMHSA, *Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings, NSDUH Series H-48, HHS* Publication No. (SMA) 14-4863. Rockville, MD: SAMHSA, 2014. Hasin et al., Prevalence of Marijuana Use Disorders in the United States Between 2001-2002 and 2012-2013. JAMA Psychiatry. 2015 Dec 1;72(12):1235-42.

Prevalence of Addiction to Marijuana is Higher Among Early Users

5-6 Times Higher if Teenager Starts Using at Age 14 or Less

Addiction Higher to Drugs

Nicotine
Alcohol
Marijuana
Inhalants
Stimulants
Cocaine
Opioids
Hallucinogens
Anxiolytics

Cannabis Use Disorder

User	Ratio	%
All	~1 in 10	10% 30.5% (recent)
Mid-teen	1 in 6	16.6%
Daily use	1 in 2-3	25-50%

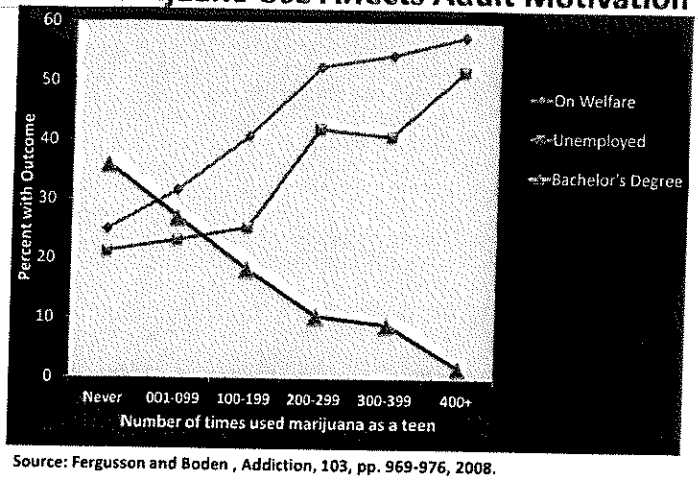
SAMHSA, *Results from the 2013 National Survey on Drug Use and Health: Summary of National Findings, NSDUH Series H-48, HHS* Publication No. (SMA) 14-4863. Rockville, MD: SAMHSA, 2014. Hasin et al., Prevalence of Marijuana Use Disorders in the United States Between 2001-2002 and 2012-2013. JAMA Psychiatry. 2015 Dec 1;72(12):1235-42.

Cannabis Use Disorder and Public Policy

- Cannabis use associated: increased prevalence of drug/alcohol use disorders (nicotine)
- Smoking and alcohol: 1st and 3rd leading causes of preventable death
- Illicit drug use associated: ~ $200 billion/year costs health care, lost productivity, incarceration, drug enforcement
- Caution in implementing legalization of cannabis for recreational use,
- Legalization may lead to:
  - more marijuana availability
  - more acceptance
  - reduced perception of risk
  - increased risk of adverse mental health outcomes.
- Public education on consequences of cannabis use may limit expansion of recreational use and inform ongoing debates on legalization.

Motivation

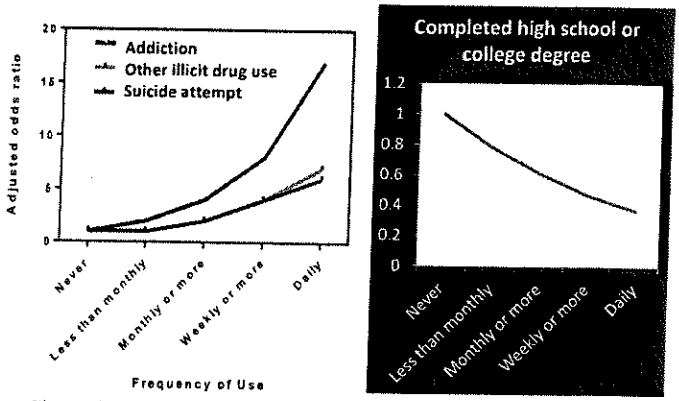
Teen Marijuana Use Affects Adult Motivation



Source: Fergusson and Boden , Addiction, 103, pp. 969-976, 2008.

Motivation

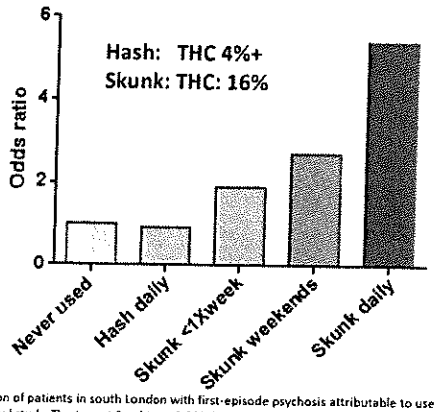
More Marijuana Use, Worse Outcomes



Silins et al, Lancet Psychiatry 1: 286–93, 2014; n= 2537-3765; 13-30 years

Psychosis

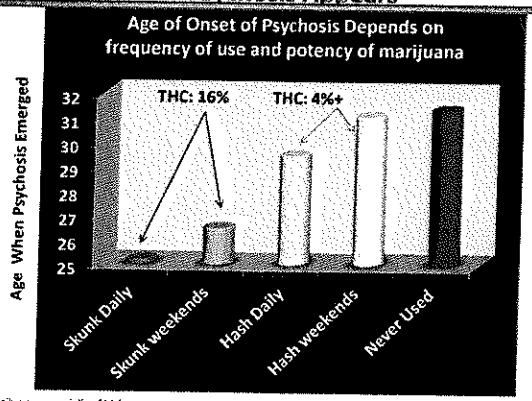
Strength, Frequency of Marijuana Use Increases Risk



Di Forti et al Proportion of patients in south London with first-episode psychosis attributable to use of high potency cannabis: a case-control study. The Lancet Psychiatry 2:233-238, 2015

Psychosis

Strength, Frequency of Marijuana Use Lowers Age When Psychosis Appears



Di Forti et al. Daily use, especially of high-potency cannabis, drives the earlier onset of psychosis in cannabis users. Schizophr Bull. 2014 Nov;40(6):1509-17; Kelley ME, et al, Marijuana use in the immediate 5-year premorbid period is associated with increased risk of onset of schizophrenia and related psychotic disorders. Schizophr Res. 2016 Jan 16. [Epub ahead of print]

Is Marijuana Safe for Children? Adversity Associated With Marijuana Use Higher for Adolescent Initiates...

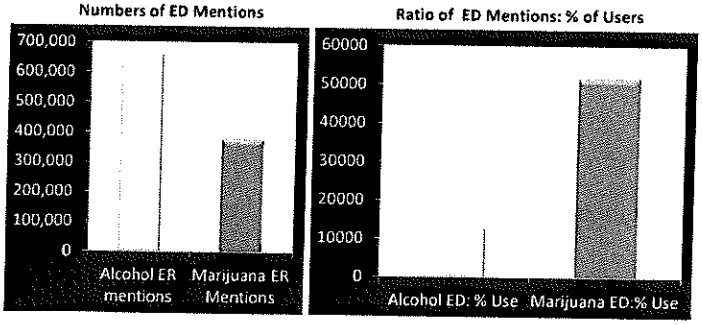
- Addiction; addiction to other drugs
- Marijuana poisoning
- Brain changes
- IQ loss; cognitive impairment
- Poor grades at school (drop-out)
- Psychosis

Marijuana Compared with Alcohol
Health, developmental outcomes may differ

ISSUE	MARIJUANA	ALCOHOL
Parent, teacher, supervisor relationships	Worse	Better
Education	Worse (direct link)	Better (No direct link)
Energy	Worse	Better
Interest in activities	Worse	Better
Work, school	Worse	Better
Adverse psychological	Worse	Better
Burden of disease	Better	Worse
Adverse psychosocial	Better	Worse

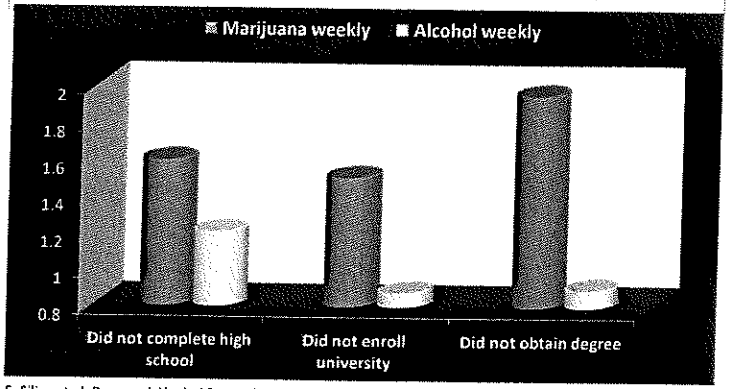
Palamar et al Am J Drug Alcohol Abuse, 2014; 40(6): 438–446

Marijuana Compared with Alcohol
Emergency Department Mentions: Higher Proportion of Marijuana Users Compared with Alcohol users



Marijuana Compared with Alcohol
Use Before Age 17 and Academic Achievement

N=2,179-3,678; longitudinal study between 13-25 years



E. Silins et al. Drug and Alcohol Dependence 156 (2015) 90–96; previous research (Esch et al., 2014; Macleod et al., 2004; Maggs et al., 2015; Silins et al., Lancet Psychiatry, 2014; Townsend et al., 2007).

Marijuana Compared with Alcohol
Marijuana Effects Persist

MARIJUANA

- THC dissolves in fat; cleared slowly
- IMMEDIATE EFFECTS: up to 6 hours
- SUB-ACUTE EFFECTS: can last 6 - 20 days
- LONG-TERM EFFECTS: more than 20 days
- Even if not using now, learning ability may be compromised for several days

ALCOHOL

- Alcohol dissolves in water: quickly cleared
- IMMEDIATE EFFECTS: no effects or intoxication depends on amount consumed
- One drink clears the body within ~3 hours
- SUB-ACUTE EFFECTS: do not persist longer than 24 h
- LONG-TERM EFFECTS: depends on how much, how frequently used

Sources: Hall W & Degenhard L (2009). Adverse health effects of non-medical cannabis use. *Lancet, 374:1383-1391.* Jager and Ramsey, 2008

Marijuana and Opioids

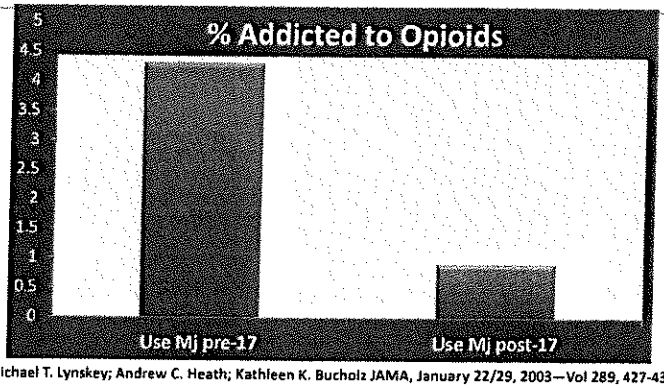
Cannabinoid and Opioid Signaling Systems Co-exist in Brain

Befort K, Frontiers in Pharmacology, Neuropharmacology 6: Feb 2015 –epub; Fattore et al, 2005; Vigano et al, 2005; Robledo et al, 2008; Trigo et al, 2010; Lötsch J, Schneider G, Reker D, Parnham MJ, Schneider P, Geisslinger G, Doehring A. Common non-epigenetic drugs as epigenetic modulators. Trends Mol Med.2013 Dec;19(12):742-53.

Marijuana Use Primes Brain to "Like" Opioids: Children at Risk

- Marijuana use during adolescence: *human and rodent research*)
- Marijuana use during pregnancy: human research on marijuana consequences (not opioids) and *rodent research*
- Marijuana use before conception: *rodent research*

Humans: Adolescent Marijuana Use and Opioid Addiction...
Twin A started marijuana before age 17
Co-Twin B after age 17: Twin A is 4x risk for opioid addiction



Michael T. Lynskey; Andrew C. Heath; Kathleen K. Bucholz JAMA, January 22/29, 2003—Vol 289, 427-433

Marijuana Exposure During Human Pregnancy:
Association with Developmental Problems (causation? Or co-factor?)

In utero:
- Infertility
- Placental problems
- Low birth weight

< week- 1 month
- Increased tremor, startle

9 months
- impaired mental development

3 – 6 years
- inattention, impulsivity hyperactivity, impaired memory, behavioral problems

14-21 years
- increased risk of smoking, marijuana

19-21 years
- altered brain function during memory task
- increased incidence of schizophrenia, addiction

Morris CV, DiNieri JA, Szutorisz H, Hurd YL. Molecular mechanisms of maternal cannabis and cigarette use on human neurodevelopment. Eur J Neurosci. 2011 Nov;34(10):1574-83.

THC Exposure in Adolescent Rodents
Primes Brain to Seek More Heroin During Adulthood

- Male rats received THC (1.5 mg/kg, i.p.) or vehicle every third day for 21 days.
- Heroin self-administration studied in young adults 10 days after last THC dose until 53 days later

THC-pretreated animals showed:
- Upward shift during heroin self-administration acquisition.
- Heightened opiate sensitivity manifest by higher heroin consumption.
- Changed endogenous opioid system in brain of adults after adolescent exposure

Findings support gateway hypothesis:
- adolescence THC exposure had an enduring impact in adults
- enhanced opiate intake, possibly a consequence of changed opioid neurons in brain.

Ellgren M, Spano SM, Hurd YL. Adolescent cannabis exposure alters opiate intake and opioid limbic neuronal populations in adult rats. Neuropsychopharmacology. 2007 Mar;32(3):607-15.

THC Exposure Prenatally in Rodents
Primes Brain to Greater Response to Heroin in Adulthood

If rodents are exposed to THC daily in utero, adult rodents are more vulnerable to heroin:

- **Shorter time to the first active heroin seeking**
- **Respond more to lower doses of heroin**
- **Seek heroin more after a mild stress**
- **Seek heroin more if heroin not available**
- **Brain opioid system in adults is different than brains of adults never exposed to THC**

Spano MS, Ellgren M, Wang X, Hurd YL. Prenatal cannabis exposure increases heroin seeking with allostatic changes in limbic enkephalin systems in adulthood. Biol Psychiatry. 2007 Feb 15;61(4):554-63.

THC Exposure in Rodents Prior to Conception
Primes Offspring for Heroin

Step 1: Adolescent males, females given THC, 1X/every three days, for 3 weeks

Step 2. At 3 weeks, THC stopped

Step 3. Adolescents mature to adults (no THC)

Step 4. Adults mate (no THC in brain or blood)

Step 5. Rate of pregnancy reduced 40% in THC-exposed females

Step 6. Offspring (no THC exposure ever) **mature to adults**

Szutorisz H et al., . Parental THC Exposure Leads to Compulsive Heroin-Seeking and Altered Striatal Synaptic Plasticity in the Subsequent Generation. Neuropsychopharmacology. 2014 May;39(6):1315-23

Adolescent Rodents THC Exposure Long Before Conception Primes Offspring for Heroin

What happens to adult rats, never exposed to THC, whose parents were exposed to THC during adolescence?

Compared with offspring whose parents were never exposed to THC, adult offspring of parents exposed to THC during adolescence:

- **Seek heroin more compulsively**
- **Show greater heroin withdrawal symptoms**
- **Show changed behavior**
- **Show brain changes (abnormal receptors) in reward region**

Szutorisz H et al., . Parental THC Exposure Leads to Compulsive Heroin-Seeking and Altered Striatal Synaptic Plasticity in the Subsequent Generation. Neuropsychopharmacology. 2014 May;39(6):1315-23

Implications

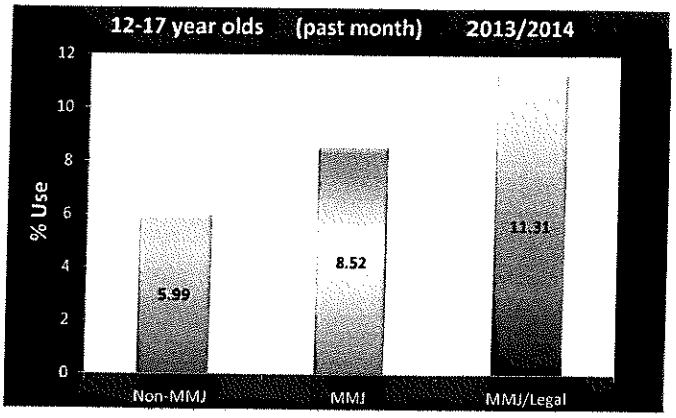
- **Some brain changes in offspring may remain dormant**
  - *But may interact with environment to change vulnerability to addiction, to psychiatric illness*
- **Increased marijuana use among young people who may bear children**
  - *Highlights possible impact of drugs not only on the user but also on their future generations.*

Legalization? Colorado 1 year change: 2013-2014

Traffic deaths	increased
Driving under the influence	increased
Marijuana-related emergency room visits	increased
Marijuana-related hospitalizations	increased
Marijuana-only related poison exposures	increased (800% increase in 5 years, younger than 12)
THC production lab explosions	increased

The Legalization of Marijuana in Colorado: The Impact Vol. 3/September 2015 Executive Summary P a g e | 2; AA. Monte; RD. Zane. K J. Heard, The Implications of Marijuana Legalization in Colorado *JAMA.* 2015;313(3):241-242.

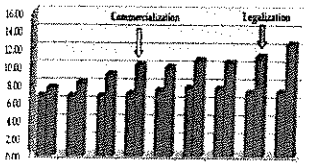
Marijuana Status and Youth Marijuana Use in U.S.



Source: NSDUH, 2014, Issued 2015

Marijuana Status in Colorado and Youth Marijuana Use in CO and in U.S.

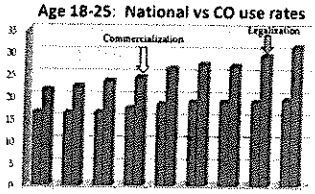
Age 12-17: National vs CO use rates



National Colorado

Age 18-25: National vs CO use rates

National Colorado



Source: NSDUH, 2014, Issued 2015

Predictions of Legalization? Mental Health Care

Impact of non-medical marijuana use on health	Improve, no change or worsen?	Evidence strength
Psychosis, psychotic symptoms	Worse	Very strong
Brain function	Worse	Strong
Psychosocial function	Worse	Strong
Addiction	Worse	Very Strong
Addiction other drugs	Worse	Strong
Schizophrenia	Worse	Fair
Anxiety	Worse	Fair-weak
Depression	Worse	Fair-weak

Health Impact Assessment: Marijuana Regulation in Vermont; Vermont Dept. of Health 2016 HealthVermont.gov; BK Madras edits

Predictions of Legalization? General Health Care

Impact of non-medical marijuana use on health	Improve, no change or worsen?	Evidence strength
Motor vehicle accidents	Worse	Very strong
Child poisoning	Worse	Fair [strong]
Bronchitis	Worse	Strong
Pregnancy	Worse	Strong
Stroke, heart attack	Worse	Fair
Cancer	?	Limited

Health Impact Assessment: Marijuana Regulation in Vermont; Vermont Dept of Health 2016 HealthVermont.gov; BK Madras

Predictions of Legalization? Society and Welfare

Impact of non-medical marijuana use on health	Does condition improve, no change or worsen?	Evidence strength
Academic performance	Worse	Strong
Welfare	Worse	Strong
Life Satisfaction	Worse	Good
Employment, economic	Worse	Good
Workplace	Worse	Limited

Health Impact Assessment: Marijuana Regulation in Vermont; Vermont Dept of Health 2016 HealthVermont.gov; BK Madras

The Present and Future

SCIENTIFIC EVIDENCE WILL PREVAIL

FULL ACCESS	RESTRICT
• Only a plant	• Plants produce toxins
• SAFE	• UNSAFE
• Pleasure	• Cognitive degradation
• No addiction	• Addiction, Amotivation
• Civil right	• Greater good
• Beneficial	• Psychiatric, behavioral
• Alcohol worse	• Marijuana vs alcohol
• Victimless	• Adolescents, children at risk
• MMJ: Patients suffering	• Public health, safety
• MMJ: FDA cumbersome	• MMJ: No accountability
• MMJ: Difficult to patent	• MMJ: NOFDA approval
• MMJ: Cheap alternative	• MMJ: Circumvents FDA

This is not a war on drugs
It is a Defense of our brains

The brain is the repository of our humanity, wisdom, our ability to love, learn, create, compute, compose, contemplate, think, to remember, to feel empathy for others, to administer justice and compassion. How precious, unique and fortunate we are to be the bearer of unclouded minds. We are united in a passionate desire to defend the minds of our most vulnerable – our youth.

World Health Organization Report

http://www.who.int/medicines/access/controlled-substances/6_2_cannabis_update.pdf

Update of Cannabis

and its medical use

Bertha K. Madras
Professor of Psychobiology
Department of Psychiatry
Harvard Medical School

This update of cannabis and its medical use was commissioned by the Secretariat of the Expert Committee on Drug Dependence, Department of Essential Medicines and Health Products, World Health Organization. This document is not a comprehensive review of the literature on cannabis, but a summary of the current status of the field and a framework to incorporate new information as it arises.

Information provided by Theodore Adams, McGuireWoods

- Draft language for delivery of the product
- Draft language for a Virginia quality control unit

Delivery of the Product – Draft provided by Theodore Adams, McGuireWoods

Requiring patients to travel to a Pharmaceutical Processor to receive their prescription for Cannabidiol Oil or THC-A Oil presents a potential risk to public safety and may be unduly burdensome to patients. First, cannabis cultivation facilities are usually located in rural areas that are less exposed to the public and cheaper to operate. In some states, the locations of these facilities are kept confidential as a precautionary security measure. By requiring patients to travel to the pharmaceutical processor, the location and profile of this facility will become public knowledge. Furthermore, many cultivation facilities have exterior security features that limit access to the property to only pre-approved vehicles or visitors. By placing the dispensing function in the same facility as the cultivation and production facility, this exterior security measure will be more difficult to implement.

Second, the limited number of pharmaceutical processors will likely result in patients having to travel long distances to fill their prescriptions. Since the patients may only receive a one-month supply, this trip will have to be repeated every 30 days. Moreover, since the market is highly regulated, a pharmaceutical processor may have limited or back-ordered supply of a particular formulation, thus requiring the patient to travel to a more distant pharmaceutical processor.

To reconcile the complicated regulatory landscape of dispensing Cannabidiol Oil, public safety, and the needs of patients, we support the proposal to allow home-delivery to patients. We believe that pharmaceutical processors can deliver Cannabidiol Oil to patients in a more secure and efficient manner than individual patients traveling to the pharmaceutical processor. Delivery operations should be designed around stringent security procedures, high-tech security measures like real-time GPS tracking and emergency communication channels, and coordination with local law enforcement.

Before Cannabidiol Oil is secured in a vehicle for delivery, a licensed pharmacist should confirm the label and patient information is correct, verify the patient is qualified to receive the shipment, coordinate the delivery time with the patient, and record the delivery in the delivery manifest (which can be made available to local police, as needed). Upon delivery of the Cannabidiol Oil to the patient, a lab technician should confirm that the label matches the patient's information, verify that the person receiving the package is the patient, and document the patient's receipt of the delivery. Furthermore, the lab technician shall give the patient a toll-free phone number where he or she may contact a licensed pharmacist for a free consultation or to report any problems with the product.

Existing Guidance that may be relevant:

1. Virginia Board of Pharmacy. Mobile Units for Dispensing for the Indigent or Underserved Population. Guidance Document 110-10 (Adopted Mar. 2006, revised April 2006).
2. Virginia Board of Pharmacy. Alternate Delivery of Prescriptions in Virginia, pharmacy to physician or pharmacy to controlled substance registration type of delivery. Guidance Document 110-3 (Adopted Dec. 8, 2005, revised Sept. 9, 2014).

Delivery Regulations

A. A Pharmaceutical Processor may deliver Cannabidiol Oil or THC-A Oil to Qualified Patients if:
   1. The Qualified Patient has previously filled a prescription for Cannabidiol Oil or THC-A Oil at the Pharmaceutical Processor's facility; and
   2. The Qualified Patient voluntarily agrees to receive his or her prescription via delivery.

B. The Quality Control Unit shall develop, enforce, and continuously improve Standard Operating Procedures for all delivery operations, including:
   1. Coordinating the delivery of product to qualified patients, including verification that the patient is eligible to receive the delivery and ensuring that the patient doesn't "double-fill"
   2. Creating a delivery manifest to record the: delivery date, employee IDs of the delivery team, pharmacist's pre-transport verification that the label is correct, unique product ID, verification of patient's identity upon delivery, time-stamped documentation that the patient received the delivery, and any other information that the Board requires.
   3. Planning delivery routes to limit transit time and avoid any undue risk
   4. Procedure to investigate any deviation from the planned route or any unexpected stop
   5. Routinely reviewing delivery manifest information to ensure compliance with all SOPs

C. Cannabidiol Oil or THC-A Oil shall be delivered in a nondescript SUV that is outfitted, at a minimum, with the following:
   1. real-time GPS tracking;
   2. secure lock-box for storing product;
   3. camera with live feed to the Pharmaceutical Processor Security Center; and
   4. multiple communication devices that can be used in case of an emergency

D. A vehicle used for delivery shall be operated by two employees with the following roles:
   1. a driver, who shall stay in the car at all times, unless compelled to exit by imminent danger;

2. a pharmacy technician, who will be responsible for properly delivering the product to the qualified patient

E. The Pharmacist-In-Charge must notify the Board or local police in the following instances:
   1. any actual or suspected diversion or theft of product;
   2. any emergency or unexpected delay during delivery (e.g. flat tire, vehicle malfunction)
   3. failure to complete delivery
   4. any suspected or security threat to the Pharmaceutical Processor, either on premises or in delivery operation

Virginia quality control unit – Draft provided by Theodore Adams, McGuireWoods

This proposal addresses the Board of Pharmacy's requirement that a licensed pharmacist be on the premises at all times during hours of operation. This requirement could be overly burdensome if literally applied to the cultivation process. Having a pharmacist on premises while plants are growing will unnecessarily increase the cost of production, which will ultimately be passed on to patients. Our proposed solution is an attempt to delegate operational responsibility to a body (which we have called the Quality Control Unit) that will be directly supervised by the Pharmacist in Charge (PIC). The goal is to avoid a burdensome or unworkable provision while respecting the Board's concerns, principally risk of diversion and administrative feasibility.

The Quality Control Unit would be responsible for creating and enforcing all Pharmaceutical Processor operations, detailed in Standard Operating Procedures (SOPs). The PIC would be in full and complete charge of the Quality Control Unit. However, the Quality Control Unit would give the PIC needed flexibility to rely on the expertise of certain experts (e.g. cultivation, security, technical) and develop a feasible chain-of-command to monitor and record compliance.

The Quality Control Unit SOPs would restrict access to specifically designated areas in the facility based on employee role; time restrictions for ingress/egress would further restrict access. Moreover, security cameras, alarms, and point-of-access locks could accurately record the presence of anyone in the building. This data could be reviewed daily by a security supervisor, who would be responsible for reporting any suspicious activity. The daily reports could be aggregated into weekly reports, which the PIC must sign and record. These reports could be further enhanced by operating procedures that estimate projected yields and measure the actual yield at every stop in the process. Thus, the quality control unit could narrow any irregularity to a specific time frame.

Pharmaceutical processor employee licenses and registrations

(a) A pharmacist with an unrestricted current active pharmacist license, practicing at the location of the address on the Pharmaceutical Processor application shall be in full and actual charge of a pharmaceutical processor and serve as the Pharmacist-In-Charge

(b) A Pharmacist-In-Charge shall be responsible for ensuring that the Pharmaceutical Processor is in compliance with state law at all times.

(c) No person shall perform the following duties without maintaining an unrestricted current active pharmacy technician registration pursuant to 54.1-3321:

1. The entry of drug dispensing information and drug history into a data system or other record keeping system;
2. The preparation of labels for dispensing the oils or patient information;
3. The removal of the oil to be dispensed from inventory
4. The counting, measuring, or producing of the oil to be dispensed;
5. The packaging and labeling of the oil to be dispensed and the repackaging thereof;
6. The stocking or loading of devices used in the dispensing process; and
7. The performance of any other task restricted to pharmacy technicians by the Board's regulations;

(d) A pharmacist with an unrestricted current active pharmacist license shall provide personal supervision on the premises of the pharmaceutical processor whenever a pharmacy technician is preforming an activity listed under subsection (c).

(e) A pharmacist with an unrestricted current active pharmacist license shall provide personal supervision on the premises of the pharmaceutical processor at all times during hours of operation. Despite the preceding sentence, the Pharmacist-In-Charge may delegate personal supervision over certain tasks to a member of the Quality Control Unit, pursuant to the requirements set forth in section [Quality Control Unit section].

Quality Control Unit

a) A Pharmaceutical Processor shall establish a Quality Control Unit. The PIC shall be in full and actual charge of the Quality Control Unit.

b) The Quality Control Unit shall implement a program for continuous quality improvement. Such program shall provide for a systematic, ongoing process of analysis that uses a pharmaceutical processor's operating data and industry best practices to formulate an appropriate response and to develop or improve pharmacy systems and workflow processes related to:
   1. Cultivation;
   2. Production;
   3. Security; and
   4. Dispensing

c) The Quality Control Unit shall establish Standard Operating Procedures ("SOPs") for the following:

1. record keeping
2. security measures to deter and prevent theft of medical cannabis;
3. unauthorized entrance into areas containing medical cannabis;
4. types and quantities of medical cannabis products that are produced at the manufacturing facility;
5. methods of planting, harvesting, drying, and storage of medical cannabis;
6. estimated quantity of all crop inputs used in production;
7. estimated quantity of waste material to be generated;
8. disposal methods for all waste materials;
9. employee training methods for the specific phases of production;
10. biosecurity measures used in production and in manufacturing;
11. strategies for reconciling discrepancies in plant material or medical cannabis;
12. sampling strategy and quality testing for labeling purposes;
13. medical cannabis packaging and labeling procedures;
14. procedures for the mandatory and voluntary recall of medical cannabis;
15. plans for responding to a security breach at a manufacturing or distribution facility, or while medical cannabis is in transit to a manufacturing or distribution facility; and
16. business continuity plan; and

d) The PIC may appoint any qualified personnel to the Quality Control Unit to advise, consult, or enforce any operating procedure related to security, cultivation, or delivery.

1. The name, credentials, and contact information of any person appointed to the Quality Control Unit shall be disclosed to the Board.

2. A PIC may consider the following factors to determine whether a person is qualified to serve on the quality control unit:
    i. Employment history or technical experience;
    ii. Education;
    iii. Specialized training or professional licenses;
    iv. Character references;
    v. Any other factor that the PIC deems relevant

3. The PIC shall include any factor deemed relevant under subsection 2 under the credentials disclosure to the Board in subsection 1.

4. Any person appointed to the Quality Control Unit must pass a level 2 federal background check.

Standard Operating Procedures

(a) The Quality Control Unit shall establish operating procedures that, at minimum, comply with State law.

(b) The Quality Control Unit shall file its operating procedures with the Board. All operating procedures filed with the Board shall remain confidential and shall not be subject to open records requests.

(c) If an employee or consultant assists the Quality Control Unit in creating an operating procedure, the Quality Control unit shall disclose the name, credentials, and any potential conflict of interest of that employee or consultant.

(d) The Quality Control Unit shall notify the Board of any change made to its operating procedures. The Quality Control Unit shall provide the Board with a rationale for the change.

(e) The Quality Control Unit shall provide the Board with any requested information about the Pharmaceutical Processor's operations, unless such information is not reasonably attainable.

(f) The responsibilities and procedures applicable to the Quality Control Unit shall be in writing; such written procedures shall be followed.

Compliance, Data Collection, and Recordkeeping

(a) The Quality Control Unit shall design operating procedures in a manner that is documented, recorded, or otherwise verifiable.

(b) The Quality Control Unit shall document compliance with all of its operating procedure and set-forth the recordkeeping requirements and retention schedules for each type of evidence necessary to verify its SOPs.

(c) The PIC may delegate supervision of compliance procedures to other members of the Quality Control Unit, provided that the PIC routinely reviews the process and documentation to ensure its accuracy and compliance with the SOPs.

(d) The PIC may not delegate supervision of any activity involved in the manufacturing process.

Quality Assurance Monitoring, Reporting, and Inspections.

(a) The Quality Control Unit shall periodically review all SOPs and either re-approve or amend the procedures based on the Pharmaceutical Processor's operating data.

(b) The Quality Control Unit shall conduct annual inventory counts to ensure that its records are accurate.

(c) The Quality Control Unit shall routinely monitor all operating data, as well as financial data, to identify any irregularity between its projected yields, sales, or defective products and the actual yield, sales, or defective product. The Quality Control Unit shall report any significant discrepancy to the Board.

DRAFT REGULATIONS FOR CANNABIDIOL OIL AND THC-A OIL

Part I. General Provisions.

Definitions

In addition to words and terms defined in §§ 54.1-3408.3 and 54.1-3442.5 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"Certification" means a written statement, consistent with requirements of § 54.1-3408.3 of the Code of Virginia, issued by a practitioner certifying a patient for cannabidiol oil or THC-A oil.

"Code" means the Code of Virginia.

"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.

"On duty" means that a pharmacist is on the premises at the address of the permitted pharmaceutical processor and is available as needed.

"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 registered patients, which amounts shall be determined by the board and cannot exceed 20 fluid ounces.

"PIC" means the pharmacist-in-charge.

"Production" or "produce" means the manufacture, planting, preparation, cultivation, growing, harvesting, propagation, conversion 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.

"Resident" means a person whose principal place of residence is within the Commonwealth as evidenced by a federal or state income tax return or a current Virginia driver's license. If a person is a minor, residency may be established by evidence of Virginia residency by a parent or legal guardian.

"Qualifying patient" means a Virginia resident who has received a written certification for the use of cannabidiol or THC-A oil for treatment of intractable epilepsy from a practitioner, as defined in § 54.1-3408.3 of the Code.

"Registered patient" means a qualifying patient who has been issued a registration by the board for the dispensing of cannabidiol oil or THC-A oil.

"Registration" 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;

"Temperature and humidity" means temperature and humidity maintained in the following ranges:

	TEMPERATURE	HUMIDITY
"Mother" room	65-75 F	50-60 %
Nursery phase	77-85 F	65-75 %
Vegetation phase	77-85 F	55-65 %
Flower/Harvest phase	77-85 F	55-60 %
Drying/Extraction rooms	< 75 F	55-60 %

Fees.

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Registration of practitioner

1. Initial registration	$50
2. Annual renewal of registration	$50
3. Replacement of registration for a qualifying patient or parent or legal guardian whose information has changed or whose original registration certificate has been lost, stolen or destroyed	$50

C. Registration by a qualifying patient or by a parent or legal guardian

1. Initial registration	$ 50
2. Annual renewal of registration	$ 50
3. Replacement of registration for a qualifying patient or parent or legal guardian whose information has changed or whose original registration certificate has been lost, stolen or destroyed	$ 50

C. Pharmaceutical processor permit

1. Application	$10,000
2. Initial permit	$60,000
3. Annual renewal of permit	$10,000
4. Change of name of processor	$100
5. Change of PIC or any other information provided on the permit application	$100
6. Any acquisition, expansion, remodel, or change of location requiring an inspection	$1,000
7. Reinspection fee	$1,000

Part II. Requirements for Practitioners and Patients.

Requirements for Practitioner Issuing a Certification

A. Prior to issuing a certification for cannabidiol oil or THC-A oil for the treatment or to alleviate symptoms of intractable epilepsy, the practitioner shall meet the requirements of § 54.1-3408.3 of the Code and shall register with the board.

B. A practitioner issuing a certification shall:

1. Have a current, 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. 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;
6. 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;
7. 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;
8. Maintain medical records for all patients for whom the practitioner has issued a certification in accordance with 18VAC85-20-26; and
9. Be registered with and able to access the Virginia Prescription Monitoring Program.

B. Patient care and evaluation shall not occur by telemedicine for at least the first year of certification. Thereafter, the practitioner shall use his professional judgement to determine the manner and frequency of patient care and evaluation.

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

D. The practitioner shall provide instructions for the use of cannabidiol oil or THC-A oil to the patient, or parent or guardian, as applicable, and shall also securely transmit such instructions to the permitted pharmaceutical processor.

E. A practitioner shall not issue certifications for cannabidiol oil or THC-A oil to more than 600 patients at any given time. However, the practitioner may petition the Boards of Pharmacy and Medicine for an increased number of patients for whom certifications may be issued, upon submission of evidence that the limitation represents potential patient harm.

F. A practitioner shall make a copy of medical records reasonably available to an agent of the Boards of Medicine or 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 to investigate a possible violation.

Prohibited practices for practitioners

A. A practitioner who issues certifications 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, parent or guardian based on the patient's agreement or decision to use a particular 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 certification. Such prohibition shall not prohibit a practitioner from charging an appropriate fee for the patient visit.

B. A practitioner who issues 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 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 certification for a qualifying patient or steers a qualifying patient to a specific pharmaceutical processor or cannabidiol oil or THC-A oil product.

C. A practitioner shall not issue a 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.

Registration of a patient, parent or legal guardian.

A. A qualifying patient for whom a practitioner has issued a certification, and, if such patient is a minor or an incapacitated adult, the qualifying patient's parent or legal guardian shall register with the board 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 certification issued by a qualifying practitioner;

(2) Proof of residency of the qualifying patient and proof of residency of a parent or legal guardian, if applicable, 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 parent or legal guardian form, if applicable;

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

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

(8) Payment of the appropriate fees; and

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

B. A qualifying patient shall not be issued a written certification by more than one practitioner during a given time period.

C. Patients, parents, and legal guardians issued a registration shall carry their registration with them whenever they are in possession of cannabidiol oil or THC-A oil.

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

A. The board shall consider issuance of a registration to a patient, parent, or guardian that is in the best interest of the qualifying patient but may deny an application or renewal of the registration of a qualifying patient or parent or legal guardian if the applicant:

(1) Does not meet the requirements set forth in law or regulation or fails to provide complete information on the application form;

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

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

(4) Has had a qualifying registration of a qualifying patient or parent or legal guardian denied, suspended or revoked by the board in the previous six months;

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

(6) Has a prior conviction of a violation of any law pertaining to controlled substances.

B. 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 pursuant to § 2.2-4019 of the Code.

Reporting requirements for practitioners, patients, parents, or legal guardians

A. A practitioner shall report to the board, in a manner prescribed by the board, the death of a registered patient or a change in status involving a registered patient for whom the practitioner has issued a certification, if such change affects the patient's continued eligibility to use cannabidiol oil or THC-A oil, or his inability to continue treating the patient. A practitioner shall report such death or change of status, or inability to continue treatment not more than 14 days after the practitioner becomes aware of such fact.

B. A patient, 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 14 days after such change. The patient, parent, or legal guardian shall report changes that include, but are not limited to, a change in name, address, contact information, medical status of the patient or change of the certifying practitioner. The patient, parent, or legal guardian shall report such changes in a manner prescribed by the board.

C. A parent, legal guardian, or practitioner treating the patient may notify the board of any changes on behalf of the registered patient using the same forms and process prescribed for registered patients.

D. If a patient or parent or legal guardian notifies the board of any change that results in information on the patient, parent, or legal guardian's registration being inaccurate, the patient or parent or legal guardian shall submit the fee for a replacement registration. Upon receipt of a new registration, the qualifying patient or parent or legal guardian shall destroy in a non-recoverable manner the registration that was replaced.

E. If a patient or parent or legal guardian becomes aware of the loss, theft or destruction of the registration of such patient or parent or legal guardian, the patient or parent or legal guardian shall notify the board 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.

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

A. A registered patient, parent, or legal guardian shall exercise reasonable caution to store cannabidiol oil or THC-A oil in a manner to prevent theft, loss or access by unauthorized persons.

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

1. By removing the oil from the original container and mixing it with an undesirable substance, such as used coffee grounds, dirt or kitty litter. Place the mixture in a sealable bag, empty can or other container to prevent the drug from leaking or breaking out of a garbage bag.
2. By transferring it to law enforcement via a medication drop-box or drug take-back event, if permissible under state and federal law.

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

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

(1) The patient's practitioner notifies the board that the practitioner is withdrawing the written certification submitted on behalf of the 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;

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

(3) The patient, parent, or legal guardian is no longer a resident of Virginia;

(4) The patient, parent, or legal guardian obtained more than a one-month supply of cannabidiol oil or THC-A oil in a one-month period;

(5) The patient, parent, or guardian provided or sold cannabidiol oil or THC-A oil to any person, including another registered patient or parent or legal guardian;

(6) The patient, parent, or legal guardian permitted another person to use the patient, parent, or legal guardian's registration;

(7) The patient, parent, or legal guardian tampered, falsified, altered, modified or allowed another person to tamper, falsify, alter or modify, the patient, parent, or legal guardian's registration;

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

(9) The patient, parent, or legal guardian failed to notify the board of a change in registration information or notified the board of such change more than 14 days after the change; or

(10) The patient, parent, or legal guardian violated any section of the law or regulation.

Part III. Application and Approval Process for Pharmaceutical Processors.

Publication of notice for submission of applications.

A. The board shall publish a notice of open applications for pharmaceutical processor

permits. Such notice shall include information on how to obtain and complete an application, the required fees, the criteria for issuance of a permit, and the deadline for receipt of applications.

B. The board shall have the right to amend the notice of open applications prior to the deadline for submitting an application. Such amended notice shall be published in the same manner as the original notice of open applications.

C. The board shall have the right to cancel a notice of open applications prior to the award of a pharmaceutical processor permit.

Application process for pharmaceutical processor permits.

A. The application process for permits shall occur in three stages: submission of initial application, awarding of conditional approval, and granting of a pharmaceutical processor permit.

B. Submission of initial application.

1. A pharmaceutical processor permit applicant shall submit the required application fee and form with the following information and documentation:
   a. The name and address of the applicant and the applicant's owners;
   b. The location within the health service area established by the Board of Health for the pharmaceutical processor that is to be operated under such permit;
   c. A financial statement setting forth all elements and details of any business transactions connected with the application;
   d. Detailed information regarding the applicant's financial position, indicating all assets, liabilities, income and net worth, to demonstrate the financial capacity of the applicant to build and operate a facility to cultivate Cannabis plants intended only for the production and dispensing of cannabidiol oil and THC-A oil pursuant to 54.1-3442.6, which may include evidence of an escrow account, letter of credit or performance surety bond;
   e. Details regarding the applicant's plans to maintain adequate control against the diversion, theft or loss of the Cannabis plants and the cannabidiol oil or THC-A oil;
   f. Documents sufficient to establish that the applicant is authorized to conduct business in Virginia and that all applicable state and local building, fire and zoning requirements and local ordinances will be met;
   g. Information necessary for the board to conduct a criminal background check on owners and any other person who may have control or influence over the operation of the proposed pharmaceutical processor;
   h. Information about any previous or current involvement in the medical cannabidiol oil or THC-A oil industry;
   i. Whether the person has ever applied for a permit or registration related to medical cannabidiol oil or THC-A oil in any state and, if so, the status of that application, permit or registration, to include any disciplinary action taken by any state on the permit, registration, or an associated license;
   j. Any business and marketing plans related to the operation of the pharmaceutical processor or the sale of cannabidiol oil or THC-A oil;
   k. Text and graphic materials showing the exterior appearance of the proposed pharmaceutical processor;

l. A blueprint of the proposed pharmaceutical processor, which shall show and identify the square footage of each area of the facility, to include the location of all safes or vaults used to store the Cannabis plants and oils and the location of all areas that may contain Cannabis plants, cannabidiol oil or THC-A oil, showing the placement of walls, partitions, counters and all areas of ingress and egress;

m. Documents related to any compassionate need program the pharmaceutical processor intends to offer;

n. Information about the applicant's expertise in agriculture and other production techniques required to produce cannabidiol oil or THC-A oil and to safely dispense such products;

o. Such other documents and information reasonably required by the board to determine the applicant's suitability for permitting or to protect public health and safety.

2. In the event any information contained in the application or accompanying documents changes after being submitted to the board, the applicant shall immediately notify the board in writing and provide corrected information in a timely manner so as not to disrupt the permit selection process.

3. The board shall conduct criminal background checks on the owner or owners and may verify information contained in each application and accompanying documentation in order to assess the applicant's character and fitness to operate a pharmaceutical processor.

C. In the event the board determines that there are an insufficient number of qualified applicants to award conditional approval for a pharmaceutical processor permit, the board may republish, in accordance with (previous section), a notice of open applications for pharmaceutical processor permits.

D. No person who has been convicted of a felony or of any offense in violation of Article 1 (18.2-247 et seq) or Article 1.1 (18.2-265.1) of Chapter 7 of Title 18.2 shall have any form of ownership, be employed by or act as an agent of a pharmaceutical processor.

Conditional approval.

A. Following the deadline for receipt of applications, the board shall evaluate each complete and timely submitted application and may grant conditional approval on a competitive basis based on compliance with requirements set forth in (previous section).

B. The board shall consider, but is not limited to, the following criteria in evaluating pharmaceutical processor permit applications:

1. The character and fitness of the applicant and any other person who may have control or influence over the operation of the proposed pharmaceutical processor;

2. The location for the proposed pharmaceutical processor, which shall not be within 1,000 feet of a school, and whether the presence of the proposed pharmaceutical processor will have a detrimental effect upon the area in its proximity;

3. The applicant's ability to maintain adequate control against the diversion, theft and loss of the Cannabis, to include the seeds, any parts or extracts of the Cannabis plants, the cannabidiol oil or THC-A oil;

4. The applicant's ability to maintain the knowledge, understanding, judgment, procedures, security controls and ethics to ensure optimal safety and accuracy in the dispensing and sale of cannabidiol oil or THC-A oil;

5. The extent to which the applicant or any of the applicant's pharmaceutical processor owners have a financial interest in another license, permit, registrant or applicant; and

6. Any other reason provided by state or federal statute or state or federal regulation that is not inconsistent with the law and regulations regarding pharmaceutical processors.

B. The board may disqualify any applicant who:

1. Submits an incomplete, false, inaccurate or misleading application;
2. Fails to submit an application by the published deadline;
3. Fails to pay all applicable fees; or
4. Fails to comply with all requirements for a pharmaceutical processor.

C. Following review, the board shall notify applicants of denial or conditional approval. The decision of the board not to grant conditional approval to an applicant shall be final.

D. If granted conditional approval, an applicant may proceed with employment of a PIC and other personnel necessary for operation of a pharmaceutical processor and with the construction or remodeling of a facility.

Granting of a pharmaceutical processor permit.

A. The board may issue a pharmaceutical processor permit when all requirements of the board have been met to include:

1. Designation of a PIC;
2. Evidence of criminal background checks for all employees and agents of the processor to ensure compliance with § 54.1-3442.6 of the Code of Virginia;
3. A satisfactory inspection of the facility conducted by the board or its agents.

B. The permit shall not be awarded until any deficiencies identified by inspectors have been corrected and the facility has been satisfactorily re-inspected, if warranted.

C. Before any permit is issued, the applicant shall attest to compliance with all state and local laws and ordinances. A pharmaceutical processor permit shall not be issued to any person to operate from a private dwelling or residence.

D. If an applicant has been awarded a pharmaceutical processor permit and has not commenced operation of such facility within 180 days of being notified of the issuance of a pharmaceutical processor permit, the board may rescind such permit, unless such delay was caused by circumstances beyond the control of the permit holder.

1. A pharmaceutical processor shall be deemed to have commenced operation if the processor is capable of operating in accordance with the approved application.
2. In the event a permit is rescinded pursuant to this subsection, the board may award a pharmaceutical processor permit by selecting among the qualified applicants who applied for the pharmaceutical processor permit subject to rescission. If no other qualified applicant applied for such pharmaceutical processor permit satisfied the criteria for awarding a permit, the board shall publish, in accordance with this section, a notice of open applications for a pharmaceutical processor permit.

E. Once the permit is issued, Cannabis may not be grown or held in the pharmaceutical processor earlier than two weeks prior to the designated opening date. Once Cannabis has been placed in the pharmaceutical processor, a pharmacist shall be present during hours of operation to ensure the safety, security, and integrity of the Cannabis. If there is a change in the designated opening date, the pharmaceutical processor shall notify the board office, and a pharmacist shall continue to be on site on a daily basis.

Notification of changes by pharmaceutical processor

A. Unless otherwise provided in law or regulation, the PIC designated on the application to be in full and actual charge of the pharmaceutical processor shall provide any notification or information that is required from a pharmaceutical processor.

B. Prior to making any change to the pharmaceutical processor name, the pharmaceutical processor shall submit an application for such change to the board and pay the fee.

C. Any person wishing to engage in the acquisition of an existing pharmaceutical processor, change the location of an existing pharmaceutical processor, move the location or make structural changes to an existing pharmaceutical processor, or make changes to a previously approved security system shall submit an application to the board and pay the required fee.

1. The proposed location or structural changes shall be inspected by an authorized agent of the board prior to issuance of a permit.

2. Cannabis shall not be moved to a new location until approval is granted by the inspector or board staff.

Pharmaceutical processor closings; going out of business; change of ownership.

A. At least 30 days prior to the date a pharmaceutical processor closes or goes out of business, the owner shall notify the board and the public. The proposed disposition of all Cannabis, dispensing records, patient information records, and other required records shall be reported to the board. If the Cannabis and records are to be transferred to another processor located in Virginia, the owner shall inform the board and the public of the name and address of the processor to whom the Cannabis and records are being transferred and the date of transfer.

B. Exceptions to the public notice shall be approved by the board and may include sudden closing due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, or other emergency circumstances. If the pharmaceutical processor is not able to meet the notification requirements, the owner shall ensure that the board and public are properly notified as soon as he knows of the closure and shall disclose the emergency circumstances preventing the notification within the required deadlines.

C. In the event of an exception to the notice, the PIC or owner shall provide notice as far in advance of closing as allowed by the circumstances.

D. At least 14 days prior to any change in ownership of an existing pharmacy, the owner shall notify the board of the pending change.

1. Upon any change in ownership of an existing pharmaceutical processor, the dispensing records for the two years immediately preceding the date of change of ownership and other required patient information shall be provided to the new owners on the date of change of ownership in substantially the same format as previously used immediately prior to the transfer to provide continuity of services.

2. The previous owner shall be held responsible for assuring the proper and lawful transfer of records on the date of the transfer.

E. When a pharmaceutical processor closes temporarily or permanently, it shall make its complete dispensing records immediately available to a nearby pharmaceutical processor and post a notice of this availability on the window or door of the closed pharmaceutical processor. The pharmaceutical processor shall simultaneously provide such notice to the board.

Causes for action against a pharmaceutical processor permit.

A. In addition to the causes enumerated in § 54.1-3316 of the Code of Virginia, the board may, suspend, revoke or refuse to grant or renew a permit issued, or place such permit on probation, place conditions on such permit, or take other actions permitted by statute or regulation.

1. Any criminal conviction under federal or state statutes or regulations or local ordinances, unless the conviction was based on a federal statute or regulation related to the possession, purchase or sale of cannabidiol oil or THC-A oil that is authorized under State law and regulations;

2. Any civil action under any federal or state statute or regulation or local ordinance relating to the applicant's, licensee's, permit's or registrant's profession, or involving drugs, medical devices or fraudulent practices, including, but not limited to, fraudulent billing practices;

3. Failure to maintain effective controls against diversion, theft or loss of Cannabis, cannabidiol oil or THC-A oil or other controlled substances;

4. Intentionally, or through negligence, obscuring, damaging, or defacing a permit or registration card;

5. Permitting another person to use the permit of a permit holder or registration of a qualifying patient or parent or legal guardian;

6. Failure to cooperate or give information to the board, local law enforcement authorities or any other enforcement agency upon any matter arising out of conduct at a pharmaceutical processor;

7. Discontinuance of business for more than sixty days, unless the board approves an extension of such period for good cause shown, upon a written request from a pharmaceutical processor. Good cause includes exigent circumstances that necessitate the closing of the facility. Good cause shall not include a voluntary closing of the pharmaceutical processor or production facility.

Part IV. Requirements for Pharmaceutical Processor Personnel.

Pharmaceutical processor employee licenses and registrations

A. A pharmacist with a current, unrestricted license issued by the Virginia board, practicing at the location of the address on the pharmaceutical processor application shall be in full and actual charge of a pharmaceutical processor and serve as the pharmacist-in-charge.

B. A pharmacist with a current, unrestricted license issued by the Virginia board shall provide personal supervision on the premises of the pharmaceutical processor at all times during hours of operation.

C. No person shall perform the following duties under pharmacist supervision without maintaining a current, unrestricted registration as a pharmacy technician pursuant to §54.1-3321 of the Code of Virginia and having been registered with the board or registered or certified by the board of another U. S. jurisdiction as a pharmacy technician for the previous two years:

1. The entry of drug dispensing information and drug history into a data system or other record keeping system;
2. The preparation of labels for dispensing the oils or patient information;
3. The removal of the oil to be dispensed from inventory;
4. The measuring of the oil to be dispensed;

5. The packaging and labeling of the oil to be dispensed and the repackaging thereof;
6. The stocking or loading of devices used in the dispensing process;
7. The selling of the oil to the registered patient, parent, or legal guardian;
8. The performance of any other task restricted to pharmacy technicians by the board's regulations.

D. A pharmacist with a current, unrestricted license or pharmacy technician with a current, unrestricted registration issued by the Virginia board may perform duties associated with the cultivation, extraction and dispensing of the oils, as authorized by the PIC or as otherwise authorized in law.

E. Persons who do not maintain licensure as a pharmacist or registration as a pharmacy technician, but have received a degree in horticulture or have at least two years of experience cultivating plants may perform duties associated with the cultivation of Cannabis, as authorized by the PIC.

F. Persons who do not maintain licensure as a pharmacist or registration as a pharmacy technician, but have received a degree in chemistry, pharmacology, or have at least two years of experience extracting chemicals from plants may perform duties associated with the extraction of cannabidiol oil and THC-A oil.

G. A pharmacist on duty shall directly supervise the activities in all areas designated for cultivation, extraction, and dispensing or have a process in place, approved by the board, which provides adequate supervision to protect the security of the Cannabis, seeds, extracts, cannabidiol oil and THC-A oil and ensure quality of the dispensed oils.

H. At no time shall a pharmaceutical processor operate without a pharmacist on duty.

I. No person shall be employed by or serve as an agent of a pharmaceutical processor without being at least 18 years of age.

F. No person who has had a license or registration suspended or revoked or denied issuance of such license or registration shall serve as an employee or agent of the pharmaceutical processor.

Employee training

A. All employees of a pharmaceutical processor shall complete training, prior to the employee commencing work at the pharmaceutical processor, at a minimum, in the following:

1. The proper use of security measures and controls that have been adopted for the prevention of diversion, theft or loss of Cannabis, to include the seeds, any parts or extracts of the Cannabis plants, cannabidiol oil and THC-A oil;
2. Procedures and instructions for responding to an emergency;
3. State and federal statutes and regulations regarding patient confidentiality.
4. Professional conduct, ethics, and state and federal statutes and regulations regarding patient confidentiality; and
5. Developments in the field of the medical use of cannabidiol oil or THC-A oil.

B. Prior to regular performance of assigned tasks, the employee shall also receive on-the-job training and other related education, which shall be commensurate with the tasks assigned to the employee.

C. The PIC shall assure the continued competency of all employees through continuing in-service training designed to supplement initial training, which shall include any guidance specified by the board.

D. The PIC shall be responsible for maintaining a written record documenting the initial and continuing training of all employees, which shall contain:

1. The name of the person receiving the training;
2. The dates of the training;
3. A general description of the topics covered;
4. The name of the person supervising the training; and
5. The signatures of the person receiving the training and the PIC.

E. When a change of pharmaceutical processor PIC occurs, the new PIC shall review the training record and sign it, indicating that the new PIC understands its contents.

F. A pharmaceutical processor shall maintain the record documenting the employee training and make it available in accordance with regulations.

Pharmacy technicians; ratio; supervision and responsibility

A. The ratio of pharmacy technicians to pharmacist on-duty in the areas of a pharmaceutical processor designated for production or dispensing shall not exceed four pharmacy technicians to one pharmacist.

B. The pharmacist providing direct supervision of pharmacy technicians may be held responsible for their actions. Any violations relating to the dispensing of cannabidiol oil or THC-A oil resulting from the actions of a pharmacy technician shall constitute cause for action against the license of the pharmacist and the registration of the pharmacy technician. As used in this subsection, "direct supervision" means a supervising pharmacist who:

1. Is on duty where the pharmacy technician is performing routine cannabidiol oil or THC-A oil production or dispensing functions; and
2. Conducts in-process and final checks on the pharmacy technician's performance.

C. Pharmacy technicians shall not:

1. Consult with a registered patient or the patient's parent or legal guardian regarding cannabidiol oil or THC-A oil or other drugs, either before or after cannabidiol oil or THC-A oil has been dispensed, or regarding any medical information contained in a patient medication record;
2. Consult with the practitioner who certified the qualifying patient, or the practitioner's agent, regarding a patient or any medical information pertaining to the patient's cannabidiol oil or THC-A oil or any other drug the patient may be taking;
3. Interpret the patient's clinical data or provide medical advice;
4. Determine whether a different formulation of cannabidiol oil or THC-A oil should be substituted for the cannabidiol oil or THC-A oil product or formulation recommended by the practitioner or requested by the registered patient or parent or legal guardian; or
5. Communicate with a practitioner who certified a qualifying patient, or the practitioner's agent, to obtain a clarification on a qualifying patient's written certification or instructions.

Responsibilities of the PIC.

A. No person shall be PIC for more than one pharmaceutical processor at any time. A processor shall employ the PIC at the pharmaceutical processor for at least 35 hours per week, except as otherwise authorized by the board.

B. The pharmacist-in-charge (PIC) or the pharmacist on duty shall control all aspects of the practice of the pharmaceutical processor. Any decision overriding such control of the PIC or other pharmacist on duty may be grounds for disciplinary action against the pharmaceutical processor permit.

C. The pharmaceutical processor PIC shall be responsible for ensuring that:

1. Pharmacy technicians are registered and all employees are properly trained;

2. All record-retention requirements are met;

3. All requirements for the physical security of the Cannabis, to include the seeds, any parts or extracts of the Cannabis plants, the cannabidiol oil and THC-A oil are met;

4. The pharmaceutical processor has appropriate pharmaceutical reference materials to ensure that cannabidiol oil or THC-A oil can be properly dispensed;

5. The following items are conspicuously posted in the pharmaceutical processor in a location and in a manner so as to be clearly and readily identifiable to qualifying patients, parents, or legal guardians:

a. Pharmaceutical processor permit;

b. Licenses for all pharmacists practicing at the pharmaceutical processor; and

c. The price of all cannabidiol oil or THC-A oil products offered by the pharmaceutical processor; and

6. Any other filings or notifications required to be made on behalf of the processor as set forth in regulation.

D. When the PIC ceases practice at a pharmaceutical processor or no longer wishes to be designated as PIC, he shall immediately return the pharmaceutical processor permit to the board indicating the effective date on which he ceased to be the PIC.

E. An outgoing PIC shall have the opportunity to take a complete and accurate inventory of all Cannabis, to include plants, extracts, cannabidiol oil or THC-A oil on hand on the date he ceases to be the PIC, unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed.

F. A PIC who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the PIC. If the PIC knows of an upcoming absence of longer than 30 days, he shall be responsible for notifying the board and returning the permit. For unanticipated absences by the PIC, which exceed 15 days with no known return date within the next 15 days, the permit holder shall immediately notify the board and shall obtain a new PIC.

G. An application for a permit designating the new PIC shall be filed with the required fee within 14 days of the original date of resignation or termination of the PIC on a form provided by the board. It shall be unlawful for a pharmaceutical processor to operate without a new permit past the 14-day deadline unless the board receives a request for an extension prior to the deadline. The executive director for the board may grant an extension for up to an additional 14 days for good cause shown.

Part V. Operation of Pharmaceutical Processor

General provisions.

A. No pharmaceutical processor shall:

1. Cultivate Cannabis plants, produce, or dispense cannabidiol oil or THC-A oil in any place except the approved facility at the address of record on the

application for the pharmaceutical processor permit;

2. Sell, deliver, transport or distribute Cannabis, including cannabidiol oil or THC-A oil, to any other facility;

3. Produce or manufacture cannabidiol oil or THC-A oil for use outside of Virginia;

4. Provide cannabidiol oil or THC-A oil samples.

B. A pharmaceutical processor shall sell cannabidiol oil or THC-A oil only in a child-resistant, secure and light-resistant container. Upon a written request from the registered patient or parent or legal guardian, the oil may be dispensed in a non-child-resistant container so long as all labeling is maintained with the product.

C. Only a pharmacist may dispense cannabidiol oil or THC-A oil to registered patients or parents or legal guardians of patients who are minors or incapacitated adults and who are registered with the board. A pharmacy technician may assist, under the direct supervision of a pharmacist, in the dispensing and selling of cannabidiol oil or THC-A oil.

D. The PIC or pharmacist on-duty shall restrict access to the pharmaceutical processor to:

1. Such persons whose responsibilities necessitate access to the pharmaceutical processor and then for only as long as necessary to perform the person's job duties; or

2. Such person who is a registered patient or parent or legal guardian, in which case such person shall not be permitted behind the service counter or in other areas where Cannabis plants, extracts, cannabidiol oil or THC-A oil is stored.

E. All pharmacists and pharmacy technicians shall, at all times while at the pharmaceutical processor, have their current license or registration available for inspection by the board or the board's agent.

F. While inside the pharmaceutical processor, all pharmaceutical processor employees shall wear name tags or similar forms of identification that clearly identify them, including their position at the pharmaceutical processor.

G. A pharmaceutical processor shall be open for registered patients, parents or legal guardians to purchase cannabidiol oil or THC-A oil products for a minimum of thirty-five hours a week, except as otherwise authorized by the board.

H. A pharmaceutical processor that closes during its normal hours of operation shall implement procedures to notify registered patients, parents, and legal guardians of when the pharmaceutical processor will resume normal hours of operation. Such procedures may include, but are not limited to, telephone system messages and conspicuously posted signs. If the pharmaceutical processor is, or will be, closed during its normal hours of operation for longer than two business days, the pharmaceutical processor shall immediately notify the board.

I. A pharmaceutical processor shall make publicly available the price of all cannabidiol oil or THC-A oil products offered by the pharmaceutical processor to prospective registered patients, parents, and, legal guardians. Such disclosure may include posting the information on the pharmaceutical processor Internet web site.

J. A pharmaceutical processor shall provide information to registered patients, parents, and legal guardians regarding the possession and use of cannabidiol oil or THC-A oil. The pharmaceutical processor PIC shall submit all informational material to the board for approval prior to being provided to registered patients, parents, or legal guardians. Such informational material shall include information related to:

1. Limitations on the right to possess and use cannabidiol oil or THC-A oil;
2. Safe techniques for proper use of cannabidiol oil or THC-A oil;

K. The pharmaceutical processor shall establish, implement and adhere to a written alcohol-free, drug-free and smoke-free work place policy, which shall be available to the board or the board's agent upon request.

Pharmaceutical processor prohibitions

A. No pharmaceutical processor shall be open or in operation, and no person shall be in the pharmaceutical processor, unless a pharmacist is on the premises and directly supervising the activity within the pharmaceutical processor. At all other times, the pharmaceutical processor shall be closed and properly secured.

B. No pharmaceutical processor shall sell anything other than cannabidiol oil or THC-A oil products from the pharmaceutical processor.

C. A pharmaceutical processor shall not market or advertise cannabidiol oil or THC-A oil products, except for posting the following information on websites:

1. Name and location of the processor;
2. Cost of the cannabidiol oil or THC-A oil products it sells;
3. Hours and days it is open for selling cannabidiol oil or THC-A oil products; and
4. Directions to the processor facility.

D. No cannabidiol oil or THC-A oil shall be consumed on the premises of a pharmaceutical processor, except for emergency administration to a registered patient.

E. No person, except a pharmaceutical processor employee or a registered patient, parent, or legal guardian shall be allowed on the premises of a processor with the following exceptions: laboratory staff may enter a processor for the sole purpose of identifying and collecting Cannabis, cannabidiol oil or THC-A oil samples for purposes of conducting laboratory tests; the board or the board's authorized representative may waive the prohibition upon prior written request.

F. All persons who have been authorized, in writing, to enter the facility by the board or the board's authorized representative shall obtain a visitor identification badge from a pharmaceutical processor employee, prior to entering the pharmaceutical processor.

1. An employee shall escort and monitor such a visitor at all times the visitor is in the pharmaceutical processor.
2. A visitor shall visibly display the visitor identification badge at all times the visitor is in the pharmaceutical processor and shall return the visitor identification badge to a pharmaceutical processor employee upon exiting the pharmaceutical processor.
3. All visitors shall log in and out. The pharmaceutical processor shall maintain the visitor log, which shall include the date, time and purpose of the visit and which shall be available to the board.
4. If an emergency requires the presence of a visitor and makes it impractical for the pharmaceutical processor to obtain a waiver from the board, the processor shall provide written notice to the board as soon as practicable after the onset of the emergency. Such notice shall include the name and company affiliation of the visitor, the purpose of the visit, and the date and time of the visit. A pharmaceutical processor shall monitor the visitor and maintain a log of such visit as required by this subsection.

G. No cannabidiol oil or THC-A oil shall be sold, dispensed or distributed via a delivery

service or any other manner outside of a pharmaceutical processor, except that a registered parent or legal guardian may deliver cannabidiol oil or THC-A oil to the registered patient.
H. Notwithstanding the requirements of subsection E, an agent of the board, local law enforcement or other federal, state or local government officials may enter any area of a pharmaceutical processor if necessary to perform their governmental duties.

Inventory requirements

A. Each pharmaceutical processor, prior to commencing business, shall:

1. Conduct an initial comprehensive inventory of all Cannabis plants, including the seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil at the facility. The inventory shall include, at a minimum, the date of the inventory, a summary of the inventory findings, the name, signature and title of the pharmacist or pharmacy technician who conducted the inventory. If a facility commences business with no Cannabis on hand, the pharmacist shall record this fact as the initial inventory; and

2. Establish ongoing inventory controls and procedures for the conduct of inventory reviews and comprehensive inventories of all Cannabis plants, including the seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil which shall enable the facility to detect any diversion, theft or loss in a timely manner.

B. Upon commencing business, each pharmaceutical processor and production facility shall conduct a weekly inventory of all Cannabis plants, including the seeds, parts of plants, cannabidiol oil, and THC-A oil in stock, which shall include, at a minimum, the date of the inventory, a summary of the inventory findings, the name, signature and title of the pharmacist or pharmacy technician who conducted the inventory. The record of all cannabidiol oil and THC-A oil sold, dispensed or otherwise disposed of shall show the date of sale, the name of the pharmaceutical processor, registered patient, parent, or legal guardian to whom the cannabidiol oil or THC-A oil was sold, the address of such person and the kind and quantity of cannabidiol oil or THC-A oil sold.

C. A complete and accurate record of all Cannabis plants, including the seeds, parts of plants, cannabidiol oil, and THC-A oil on hand shall be prepared annually on the anniversary of the initial inventory or such other date that the PIC may choose, so long as it is not more than one year following the prior year's inventory.

D. All inventories, procedures and other documents required by this section shall be maintained on the premises and made available to the board or its agent.

E. Inventory records shall be maintained for three years from the date the inventory was taken.

E. Whenever any sample or record is removed by a person authorized to enforce the provisions of law for the purpose of investigation or as evidence, such person shall tender a receipt in lieu thereof and the receipt shall be kept for a period of at least three years.

Security Requirements

A. A pharmaceutical processor shall:

1. Not maintain more than four Cannabis plants per patient at any given time based on dispensing data from the previous 30 days.
2. Only maintain Cannabis plants with low THC concentrations reasonably conducive for the production of cannabidiol oil or THC-A oil.
3. Not maintain cannabidiol oil or THC-A oil in excess of the quantity required for

normal, efficient operation;

4. Maintain all Cannabis plants, seeds, parts of plants, extracts, cannabidiol oil and THC-A oil in a secure area or location accessible only by the minimum number of authorized employees essential for efficient operation;
5. Store all cut parts of Cannabis plants, extracts, cannabidiol oil or THC-A oil in an approved safe or approved vault within the pharmaceutical processor and shall not sell cannabidiol oil or THC-A oil products when the pharmaceutical processor is closed;

4. Keep all approved safes, approved vaults, or any other approved equipment or areas used for the production, cultivation, harvesting, processing, manufacturing or storage of cannabidiol oil or THC-A oil, securely locked or protected from entry, except for the actual time required to remove or replace the Cannabis, seeds, parts of plants, extracts, cannabidiol oil or THC-A oil;
5. Keep all locks and security equipment in good working order; and
6. Restrict access to keys or codes to all safes, approved vaults, or other approved equipment or areas to pharmacists practicing at the pharmaceutical processor;
6. Not allow keys to be left in the locks or accessible to non-pharmacists;

B. The pharmaceutical processor shall have an adequate security system to prevent and detect diversion, theft or loss of Cannabis seeds, plants, extracts, cannabidiol oil or THC-A oil. A device for the detection of breaking and a back-up alarm system with an ability to remain operational during a power outage shall be installed in each pharmaceutical processor. The installation and the device shall be based on accepted alarm industry standards, and shall be subject to the following conditions:

1. The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.
2. The device shall be monitored in accordance with accepted industry standards, maintained in operating order, have an auxiliary source of power, and be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational.
3. The device shall fully protect the entire processor facility and shall be capable of detecting breaking by any means when activated.
4. The device shall include a duress alarm, a panic alarm, and automatic voice dialer.
5. Access to the alarm system for the pharmaceutical processor shall be restricted to the pharmacists working at the pharmaceutical processor and the system shall be activated whenever the pharmaceutical processor is closed for business.

C. A pharmaceutical processor shall keep the outside perimeter of the premises well-lit. A processor shall have video cameras in all areas that may contain Cannabis plants, seeds, parts of plants, extracts, cannabidiol oil, or THC-A oil and at all points of entry and exit, which shall be appropriate for the normal lighting conditions of the area under surveillance.

1. The processor shall direct cameras at all approved safes, approved vaults, dispensing areas, cannabidiol oil or THC-A oil sales areas and any other area where Cannabis plants, seeds, extracts, cannabidiol oil or THC-A oil are being produced, harvested, manufactured, stored or handled. At entry and exit points, the processor shall angle cameras so as to allow for the capture of clear and certain identification of any person entering or exiting the facility;

2. Twenty-four hour recordings from all video cameras, which the processor shall make available for immediate viewing by the board or the board's agent upon request and shall retain for at least thirty days. If a processor is aware of a pending criminal, civil or administrative investigation or legal proceeding for which a recording may contain relevant information, it shall retain an unaltered copy of the recording until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the pharmaceutical processor PIC that it is not necessary to retain the recording;

3. The video system shall have:

a. A failure notification system that provides an audible, text or visual notification of any failure in the surveillance system. The failure notification system shall provide an alert to processor within five minutes of the failure, either by telephone, email, or text message;

b. The ability to immediately produce a clear color still photo that is a minimum of 9600 dpi from any camera image (live or recorded);

c. A date and time stamp embedded on all recordings. The date and time shall be synchronized and set correctly and shall not significantly obscure the picture; and

d. The ability to remain operational during a power outage.

4. All video recording shall allow for the exporting of still images in an industry standard image format. Exported video shall have the ability to be archived in a proprietary format that ensures authentication of the video and guarantees that no alteration of the recorded image has taken place. Exported video shall also have the ability to be saved in an industry standard file format that can be played on a standard computer operating system. A pharmaceutical processor shall erase all recordings prior to disposal or sale of the facility.

D. The processor shall maintain all security system equipment and recordings in a secure location so as to prevent theft, loss, destruction or alterations. All security equipment shall be maintained good- working order and shall be tested no less than two times per year.

E. A pharmaceutical processor shall limit access to surveillance areas to persons that are essential to surveillance operations, law enforcement agencies, security system service employees, the board or the board's authorized representative, and others when approved by the board. A processor shall make available a current list of authorized employees and service employees that have access to the surveillance room to the processor shall keep all on-site surveillance rooms locked and shall not use such rooms for any other function.

F. If diversion, theft, or loss of Cannabis plants, seeds, parts of plants, extracts, cannabidiol oil or THC-A oil has occurred from a pharmaceutical processor, the board shall determine the appropriate storage and security requirements for all Cannabis plants, seeds, parts of plants, extracts, cannabidiol oil or THC-A oil in such pharmaceutical processor, and may require additional safeguards to ensure the security of the products.

Requirements for the storage and handling of Cannabis, cannabidiol oil or THC-A oil

A. A pharmaceutical processor shall:

1. Have storage areas that provide adequate lighting, ventilation, sanitation, temperature and humidity as defined in (section), space, equipment, and security conditions for the cultivation

of Cannabis, and the production and dispensing of cannabidiol oil or THC-A oil;

2. Separate for storage, in a quarantined area, Cannabis, seeds, parts of plants, extracts, including cannabidiol oil or THC-A oil, that is outdated, damaged, deteriorated, misbranded, or adulterated, or whose containers or packaging have been opened or breached, until such Cannabis, seeds, parts of plants, extracts, cannabidiol oil or THC-A oil is destroyed;

3. Be maintained in a clean, sanitary, and orderly condition; and

4. Be free from infestation by insects, rodents, birds, or vermin of any kind.

B. A processor shall compartmentalize all areas in the facility based on function and shall restrict access between compartments. The processor shall establish, maintain and comply with written policies and procedures regarding best practices for the secure and proper cultivation of Cannabis and production of cannabidiol oil or THC-A oil. These shall include, but not be limited to, policies and procedures that:

1. Restrict movement between compartments;

2. Provide for different colored identification cards for facility employees based on the compartment to which they are assigned at a given time so as to ensure that only employees necessary for a particular function have access to that compartment of the facility;

3. Require pocketless clothing for all production facility employees working in an area containing Cannabis plants, seeds, and extracts, including cannabidiol oil or THC-A oil; and

4. Document the chain of custody of all Cannabis plants, parts of plants, seeds, extracts, cannabidiol oil and THC-A oil products.

C. The PIC shall establish, maintain, and comply with written policies and procedures for the cultivation, production, security, storage, and inventory of Cannabis, including seeds, parts of plants, extracts, cannabidiol oil and THC-A oil. Such policies and procedures shall include methods for identifying, recording, and reporting diversion, theft or loss, and for correcting all errors and inaccuracies in inventories. Pharmaceutical processors shall include in their written policies and procedures, a process for the following:

(1) Handling mandatory and voluntary recalls of cannabidiol oil or THC-A oil. Such process shall be adequate to deal with recalls due to any action initiated at the request of the board and any voluntary action by the pharmaceutical processor to remove defective or potentially defective cannabidiol oil or THC-A oil from the market or any action undertaken to promote public health and safety by replacing existing cannabidiol oil or THC-A oil with improved products or packaging;

(2) Preparing for, protecting against, and handling any crises that affects the security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency;

(3) Ensuring that any outdated, damaged, deteriorated, misbranded, or adulterated Cannabis, including seeds, parts of plants, extracts, cannabidiol oil and THC-A oil, is segregated from all other Cannabis, seeds, parts of plants, extracts, cannabidiol oil and THC-A oil and destroyed. This procedure shall provide for written documentation of the Cannabis, including seeds, parts of plants, extracts, cannabidiol oil and THC-A oil disposition; and

(4) Ensuring the oldest stock of Cannabis, including seeds, parts of plants, extracts, cannabidiol oil and THC-A oil product is used first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

D. The processor shall store all Cannabis, including seeds, parts of plants, extracts, cannabidiol

oil and THC-A oil, in the process of production, transfer, or analysis in such a manner as to prevent diversion, theft or loss, shall make Cannabis, including the seeds, parts of plants, extracts, cannabidiol oil and THC-A oil accessible only to the minimum number of specifically authorized employees essential for efficient operation, and shall return the items to their secure location immediately after completion of the process or at the end of the scheduled business day. If a production process cannot be completed at the end of a working day, the pharmacist shall securely lock the processing area or tanks, vessels, bins, or bulk containers containing Cannabis, including the seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil inside an area or building that affords adequate security.

Recordkeeping requirements

A. If a pharmaceutical processor uses an electronic system for the storage and retrieval of patient information or other records related to cultivating, producing, and dispensing cannabidiol oil or THC-A oil records, the pharmaceutical processor shall use a system that:

1. Guarantees the confidentiality of the information contained therein;

2. Is capable of providing safeguards against erasures and unauthorized changes in data after the information has been entered and verified by the pharmacist; and

3. Is capable of being reconstructed in the event of a computer malfunction or accident resulting in the destruction of the data bank.

Reportable events

A. Upon becoming aware of discrepancies identified during inventory, diversion, theft, loss, or unauthorized destruction of any cannabidiol oil or THC-A oil or of any loss or unauthorized alteration of records related to cannabidiol oil or THC-A oil or qualifying patients, a pharmacist or pharmaceutical processor shall immediately notify appropriate law enforcement authorities; and the board.

B. A pharmacist or processor shall provide the notice required by subsection A of this section to the board by way of a signed statement which details the circumstances of the event, including an accurate inventory of the quantity and brand names of cannabidiol oil or THC-A oil diverted, stolen, lost, destroyed or damaged and confirmation that the local law enforcement authorities were notified. A pharmacist or processor shall make such notice no later than twenty-four hours after discovery of the event.

C. A pharmacist or pharmaceutical processor shall notify the board no later than the next business day, followed by written notification no later than ten business days, of any of the following:

1. An alarm activation or other event that requires response by public safety personnel;

2. A breach of security;

3. The failure of the security alarm system due to a loss of electrical support or mechanical malfunction that is expected to last longer than eight hours; and

4. Corrective measures taken, if any.

Part VI. Cultivation, Production and Dispensing of Cannabidiol oil or THC-A oil

Cultivation and production of cannabidiol oil or THC-A oil

A. No cannabidiol oil or THC-A oil shall have had pesticide chemicals or organic solvents used during the cultivation, extraction, production or manufacturing process, except that the board may authorize the use of pesticide chemicals for purposes of addressing an infestation that could result in a catastrophic loss of Cannabis crops.

B. Cultivation methods for Cannabis plants and extraction methods used to produce the cannabidiol oil and THC-A shall be performed in a manner deemed safe and effective based on current standards or scientific literature.

C. Any Cannabis plant, seed, parts of plant, extract, cannabidiol oil, or THC-A oil not in compliance with this section shall be deemed adulterated.

Labeling of batch of cannabidiol oil or THC-A oil products

A. Cannabidiol oil or THC-A oil produced for dispensing shall not be adulterated and shall be:

1. 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; and,

2. 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.

B. The pharmaceutical processor shall assign a name to each cannabidiol oil or THC-A oil product and associate each name with a specific laboratory test that includes a terpenes profile and a list of all active ingredients, including:

1. Tetrahydrocannabinol (THC);
2. Tetrahydrocannabinol acid (THCA);
3. Cannabidiol (CBD); and

C. The pharmaceutical processor shall not label two cannabidiol oil or THC-A oil products with the same name unless the laboratory test results for each product indicate that they contain the same level of each active ingredient listed in subsection A of this section within a range of 97% to 103%.

D. The pharmaceutical processor shall not name a product that:

1. Is identical to, or confusingly similar to, the name of an existing non-cannabidiol oil or THC-A oil product;

2. Is identical to, or confusingly similar to, the name of an unlawful product or substance;

3. Is confusingly similar to the name of another cannabidiol oil or THC-A oil product name;

4. Is obscene or indecent;

5. May encourage the use of cannabidiol oil or THC-A oil for recreational purposes;

6. May encourage the use of cannabidiol oil or THC-A oil for a condition other than intractable epilepsy;

7. Is customarily associated with persons under the age of 18; or

8. Is related to the benefits, safety or efficacy of the cannabidiol oil or THC-A oil

product unless supported by substantial evidence or substantial clinical data.
E. A pharmaceutical processor shall label each cannabidiol oil or THC-A oil product prior to dispensing by a pharmacist and shall securely affix to the package a label that states in legible English:

1. The name of the cannabidiol oil or THC-A oil;
2. A unique serial number that will match the product with a pharmaceutical processor batch and lot number so as to facilitate any warnings or recalls the board or pharmaceutical processor deem appropriate;
3. The date of final testing and packaging;
4. The expiration date;
5. The quantity of cannabidiol oil or THC-A oil contained therein;
6. A terpenes profile and a list of all active ingredients, including:
   (a) tetrahydrocannabinol (THC);
   (b) tetrahydrocannabinol acid (THCA); and
   (c) cannabidiol (CBD).
7. A pass or fail rating based on the laboratory's microbiological, mycotoxins, heavy metals and chemical residue analysis; and

F. A pharmaceutical processor shall not label cannabidiol oil or THC-A oil products as "organic" unless the Cannabis plants have been organically grown and the cannabidiol oil or THC-A oil products have been produced, processed, manufactured and certified to be consistent with organic standards in compliance with 7 CFR Part 205.

Laboratory requirements

A. No laboratory shall handle, test or analyze cannabidiol oil or THC-A oil unless such laboratory:

1. Is independent from all other persons involved in the cannabidiol oil or THC-A oil industry in Virginia, which shall mean that no person with a direct or indirect interest in the laboratory shall have a direct or indirect financial interest in a pharmacist, pharmaceutical processor, certifying practitioner or any other entity that may benefit from the production, manufacture, dispensing, sale, purchase or use of cannabidiol oil or THC-A oil; and
2. Has employed at least one person to oversee and be responsible for the laboratory testing who has earned, from a college or university accredited by a national or regional certifying authority, at least a master's level degree in chemical or biological sciences and a minimum of two years of post-degree laboratory experience or a bachelor's degree in biological sciences and a minimum of four years of post-degree laboratory experience.

Laboratory testing

A. Immediately prior to producing any cannabidiol oil or THC-A oil product, a pharmaceutical processor shall segregate all harvested Cannabis into homogenized batches.
B. A pharmaceutical processor shall make available each such batch at the facility for a laboratory employee to select a random sample. The laboratory shall test each sample for microbiological contaminants, mycotoxins, heavy metals and pesticide chemical residue, and for purposes of conducting an active ingredient analysis.

C. From the time that a batch of Cannabis has been homogenized for sample testing and eventual packaging, until the laboratory provides the results from its tests and analysis, the pharmaceutical processor shall segregate and withhold from use the entire batch of Cannabis, except the samples that have been removed by the laboratory for testing. During this period of segregation, the pharmaceutical processor shall maintain the Cannabis in a secure, cool and dry location so as to prevent the Cannabis from becoming contaminated or losing its efficacy.
D. Under no circumstances shall a pharmaceutical processor include Cannabis in a cannabidiol oil or THC-A oil product or sell it prior to the time that the laboratory has completed its testing and analysis and provided those results, in writing, to the pharmaceutical processor or other designated facility employee.
E. A laboratory shall immediately return or dispose of any Cannabis upon the completion of any testing, use, or research.
F. If a sample of Cannabis does not pass the microbiological, mycotoxin, heavy metal or pesticide chemical residue test, based on the standards set forth in this subsection, the pharmaceutical processor shall dispose of the entire batch from which the sample was taken.

1. For purposes of the microbiological test, a cannabidiol oil or THC-A oil sample shall be deemed to have passed if it satisfies the standards set forth in Section 1111 of the United States Pharmacopeia, which can be obtained at http://www.usp.org.

2. For purposes of the mycotoxin test, a Cannabis sample shall be deemed to have passed if it meets the following standards:

Test	**Specification**
Alfatoxin B1	<20 uG/KG of Substance
Alfatoxin B2	<20 uG/KG of Substance
Alfatoxin O1	<20 uG/KG of Substance
Alfatoxin O2	<20 uG/KG of Substance
Ochratoxin A	<20 uG/KG of Substance

1. For purposes of the heavy metal test, a Cannabis sample shall be deemed to have passed if it meets the following standards:

Metal	**Natural Health Products Acceptable limits uG/KG BW/Day**
Arsenic	<0.14
Cadmium	<0.09
Lead	<0.29
Mercury	<0.29

4. For purposes of the pesticide chemical residue test, a Cannabis sample shall be deemed to have passed if it satisfies the most stringent acceptable standard for a pesticide chemical residue in any food item as set forth in Subpart C of the federal Environmental Protection Agency's regulations for Tolerances and Exemptions for Pesticide Chemical Residues in Food, 40 CFR 180.
G. If a sample of Cannabis passes the microbiological, mycotoxin, heavy metal and pesticide chemical residue test, the laboratory shall release the entire batch for immediate manufacturing, packaging and labeling for sale to a pharmaceutical processor.

H. The laboratory shall file with the board an electronic copy of each laboratory test result for any batch that does not pass the microbiological, mycotoxin, heavy metal or pesticide chemical residue test, at the same time that it transmits those results to the pharmaceutical processor. In addition, the laboratory shall maintain the laboratory test results and make them available to the board or an agent of the board.
I. Each pharmaceutical processor shall have such laboratory results available upon request to registered patients, parent or legal guardians and practitioners who have certified qualifying patients.

Dispensing of cannabidiol oil or THC-oil

A. A pharmacist, in good faith, may dispense cannabidiol oil or THC-A oil to any registered patient, parent, or legal guardian as indicated on the written certification. A pharmacist or pharmacy technician shall require the presentation of a current active registration for the patient and parent or legal guardian, if applicable, current active written certification and current valid photographic identification issued to a registered patient or parent or legal guardian, prior to selling oil to such registered patient or parent or legal guardian. The pharmacist or pharmacy technician shall verify in the prescription monitoring program or other program recognized by the State that the registrations are current active, the written certification has not expired, and the date and quantity of the last dispensing of cannabidiol oil or THC-A oil to the registered patient.
B. A pharmacist may dispense a portion of a registered patient's one-month supply of cannabidiol oil or THC-A oil. The pharmacist may dispense the remaining portion of the one-month supply of cannabidiol oil or THC-A oil at any time except that no registered patient, parent, or legal guardian shall receive more than a one-month supply of cannabidiol oil or THC-A oil in a one-month period from any pharmaceutical processor.
C. A dispensing record shall be maintained for two years from the date of dispensing and the pharmacist or pharmacy technician under the direct supervision of the pharmacist shall affix a label to the container of oil which contains:

1. A serial number assigned to the dispensing of the oil;
2. The name or kind of cannabidiol oil or THC-A oil and strength;
3. The serial number assigned to the oil during production;
2. The date of dispensing the cannabidiol oil or THC-A oil;
3. The quantity of cannabidiol oil or THC-A oil dispensed which cannot exceed 20 fluid ounces;
4. The name and registration number of the registered patient;
5. The name and registration number of the certifying practitioner;
6. Such directions for use as may be included in the practitioner's written certification or otherwise provided by the practitioner; and,
7. The name or initials of the dispensing pharmacist.
8. Name, address, and telephone number of the pharmaceutical processor;
9. Any cautionary statement as may be necessary; and
10. A prominently printed expiration date based on the pharmaceutical processor's recommended conditions of use and storage that can be read and understood by the ordinary individual.

D. The dispensed cannabidiol oil or THC-A oil shall be dispensed in child-resistant

packaging. A package shall be deemed child-resistant if it satisfies the standard for "special packaging" as set forth in the Poison Prevention Packaging Act of 1970 Regulations, 16 CFR 1700.1(b)(4).

E. No person except a pharmacist, or a pharmacy technician operating under the direct supervision of a pharmacist, shall alter, deface or remove any label so affixed.

F. A pharmacist shall be responsible for verifying the accuracy of the dispensed oil in all respects prior to dispensing and shall document that each verification has been performed.

G. A pharmacist shall document a registered patient's self-assessment of the effects of cannabidiol oil or THC-A oil in treating the registered patient's debilitating medical condition or the symptoms thereof. A pharmaceutical processor shall maintain such documentation in writing or electronically for two years from the date of dispensing and such documentation shall be made available in accordance with regulation.

H.A pharmacist shall exercise professional judgment to determine whether to dispense cannabidiol oil or THC-A oil to a registered patient, parent or legal guardian if the pharmacist suspects that dispensing cannabidiol oil or THC-A oil to the registered patient or parent or legal guardian may have negative health or safety consequences for the registered patient or the public.

Dispensing error review and reporting; quality assurance program

A. A pharmaceutical processor shall implement and comply with a quality assurance program that describes, in writing, policies and procedures to detect, identify and prevent dispensing errors. A pharmaceutical processor shall distribute it to all pharmaceutical processor employees, and shall make it readily available on the premises of the pharmaceutical processor. Such policies and procedures shall include:

1. Directions for communicating the details of a dispensing error to the practitioner who certified a qualifying patient and to the qualifying patient, the patient's parent or legal guardian or appropriate family member if the patient is deceased or is unable to fully comprehend the communication. Such communication shall describe methods of correcting the dispensing error or reducing the negative impact of the error on the qualifying patient; and
2. A process to document and assess dispensing errors to determine the cause of the error and an appropriate response.

B. A pharmaceutical processor shall use the findings of its quality assurance program to develop systems and workflow processes designed to prevent dispensing errors. A pharmaceutical processor PIC shall:

1. Inform pharmaceutical processor employees of changes to policy, procedure, systems, or processes made as a result of recommendations generated by the quality assurance program.
2. Notify all pharmacist employees that the discovery or reporting of a dispensing error shall be relayed immediately to a pharmacist on duty.
3. Ensure that a pharmacist performs a quality assurance review for each dispensing error. A pharmacist shall commence such review as soon as is reasonably possible, but no later than two business days from the date the dispensing error is discovered.
4. Create a record of every quality assurance review. This record shall contain at least

the following:

(a) The date or dates of the quality assurance review and the names and titles of the persons performing the review;

(b) The pertinent data and other information relating to the dispensing error reviewed;

(c) Documentation of contact with the qualifying patient, parent or legal guardian where applicable, and the practitioner who certified the patient;

(d) The findings and determinations generated by the quality assurance review;

(e) Recommended changes to pharmaceutical processor policy, procedure, systems, or processes, if any.

C. A pharmaceutical processor shall maintain a copy of the pharmaceutical processor's quality assurance program and records of all reported dispensing errors and quality assurance reviews in an orderly manner and filed by date.

Disposal of cannabidiol oil or THC-A oil

A. A pharmaceutical processor, an agent of the board, or the board's authorized representative shall dispose of undesired, excess, unauthorized, obsolete, adulterated, misbranded or deteriorated Cannabis plants, including seeds, parts of plants, extracts, cannabidiol oil or THC-A oil by disposal in the presence of an authorized representative of the board in such a manner as to render the cannabidiol oil or THC-A oil non-recoverable.

B. The person disposing of the cannabidiol oil or THC-A oil shall maintain and make available a separate record of each such disposal indicating:

(1) The date and time of disposal;

(2) The manner of disposal;

(3) The name and quantity of cannabidiol oil or THC-A oil disposed of; and

(4) The signatures of the persons disposing of the cannabidiol oil or THC-A oil, the authorized representative of the board and any other persons present during the disposal.

C. The record of disposal shall be maintained at the pharmaceutical processor for three years from the date of disposal.