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

July 26, 2016

10AM

TOPIC	PAGES
Call to Order: *Ryan Logan, Chairman* • Welcome & Introductions • Approval of Agenda • Approval of Previous Meeting Minutes	1-7
Call for Public Comment	
Agenda Items • Reports, if any, on Action Items from Previous Meeting • Review Proposed Language for Draft Regulations Prepared by Staff, *Ryan Logan and Caroline Juran*	8-46
Adjourn	

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

DRAFT/UNAPPROVED

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

July 1, 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 (arrived 10:35am)
Cynthia Warriner (10:10am-10:35am)

MEMBERS PRESENT:
Cynthia Warriner, Board of Pharmacy
Jody H. Allen, Board of Pharmacy
Svinder Toor, MD, Board of Medicine/ child neurologist
William L. Harp, MD, Board of Medicine, Executive Director
Alexander Pytlarz, Virginia Pharmacists Association
Ed McCann, former owner of cannabis facility
Regina Whitsett, Substance Abuse Free Environment, Inc. (SAFE)
Beth Collins, Americans for Safe Access
Baylor Rice, community compounding pharmacist
Jake Bergman, Surterra Holdings
Julia Whiting, MD, concerned parent/physician
Chuck Moss, concerned family member (arrived 10:35am)
Paul Lyons, MD, child neurologist

MEMBERS ABSENT: Senator David W. Marsden

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: The agenda was approved as presented.

PUBLIC COMMENT: Lauren Schmitt, pharmacist representing Virginia Society of Health-System Pharmacists, provided comment and a letter from VSHP with suggested topics for the panel to consider. VSHP would like the panel to consider how cannabidiol oil and THC-A oil will be handled in hospitals with regard to patients being permitted to bring their own, hospitals having the ability to develop their own policy regarding administration, and where the oils for the certified patients will be stored. Ms. Schmitt requested that the panel consider these questions and include guidance in Regulation for hospitals on how to handle these oils.

Lennice Werth, an advocate for drug law reform, shared a personal account about her life with a seizure disorder and how marijuana positively affected her disorder and improved her life. Ms. Werth also commented that New Jersey's law on medical marijuana is too stringent and that she is glad to see Board of Pharmacy representation on the panel.

Mary Lynn Mathre, registered nurse and certified addiction specialist, is the co-founder of Patients Out of Time which educates the public and health professionals about the medical use of cannabis. Ms. Mathre also provided comment that she feels New Jersey's law is too stringent and requests that the panel consider ease of access for patients that require these oils.

AGENDA ITEMS:

- Presentation – summary of SB701 and Charge of Regulatory Advisory Panel

Caroline Juran, Executive Director for the Board of Pharmacy, provided an overview of SB 701 that permitted pharmaceutical processors to manufacture and provide cannabidiol oil and THC-A oil. Ms. Juran also provided a summary of the regulation 18VAC110-11-70 which affords the agency an allowance to appoint a regulatory advisory panel to provide professional or technical assistance and expertise to specific regulatory issues or actions.

- Presentation – general overview of the cannabis plant, methods for extracting cannabidiol oil and THC-A oil, treating intractable epilepsy with cannabidiol oil and THC-A oil

Dr. Paul Lyons provided a slideshow presentation of the medical literature regarding the use of medical marijuana in epilepsy patients. Several key points from the presentation are that there are 1% of the population with epilepsy and 2/3 of this population do not respond to currently approved drug therapy available. This translates to approximately 27,000 Virginians. Synthetic cannabidiol (dronabinol) was trialed and found not active enough to control seizure activity. The death rate in the U.S. due to epilepsy is 50,000 per year which would be 6,000 Virginians.

- Discussion questions

For the remainder of the meeting, Mr. Logan led a group discussion by soliciting feedback from the panel members in response to the discussion questions provided in the agenda packet and summarized below.

1. What standards in cultivating marijuana should be taken into consideration and/or regulated to ensure consistency in quality, potency, and mitigation of diversion?

Ms. Whitsett commented that pesticides should not be used at all in the production. Mr. Bergman agreed that pesticides should be prohibited or that at least fertilizers and pesticides used should require similar USDA standards for these products. Mr. McCann commented that regulations should not address how the processor does the manufacturing of the product. Mr. Bergman stated that the canopy size is generally based on the number of patients they are servicing. Mr. Bergman indicated a typical dose of oil is 200-500mg/patient/day and that 5-15gm of oil can be extracted from one plant. He estimates the facility would need approximately 1 plant per patient per month. Mr. Moss stated that there should be specific guidelines for cultivating the plant. Other comments

included: extraction process for the two oils is different and therefore, may need different number of plants depending on which oil is being produced; suggestion for gloves to be worn; reference to US organic standards; need a buffer amount of plants in case crop fails; standardization throughout the processors should be focused on potency expectation of 90-95%; need consistency in lab testing; suggestion to look at accreditation standards; need to track what works best; patients are interested in the ratio of ingredients in the oil and the ratios can be very patient-specific.

Action Item:

Mr. Bergman to provide information regarding basic requirements for temperature and humidity.

2. What other physical standards must the pharmaceutical processor meet, e.g., room size, separate rooms, or space for various functions, etc.?

Ms. Whitsett stated there should be separate rooms for vegetation, cloning, flowering, drying, cultivating, clipping and quarantine. There should be a requirement for weights and scales and also proper ventilation in the rooms due to the strong odor of the additives used. Also a requirement that this facility be an indoor greenhouse. Other comments included: recommendation for indoor greenhouse without artificial light, but this may have impact on utilization of water; artificial lighting increases usage of power; need a controlled environment; not feasible to have walls in place for the vegetation to flowering stages; suggestion for seed to sale software requiring measurements in every step throughout the process.

3. What security requirements are appropriate to mitigate diversion, e.g., motion sensors throughout, video surveillance with 24 hour tape, etc.?

The discussion centered on that there should be possible requirements for security guards, cameras on all exterior and interior areas, and the area entirely fenced. Some members agreed that depending on the location of the facility, fencing the area may not be feasible. The panel agreed that, at minimum, there should be the same requirement for these facilities as there are for pharmacies and other facilities which are motion sensors throughout facility with back up monitoring.

4. What location restrictions should apply to pharmaceutical processors?

Ms. Whitsett commented that possibly should limit how close the facilities are to schools or recreational centers similar to ABC stores. Ms. Whitsett also commented that not placing these facilities in low income areas due to increased diversion should be discussed. Mr. Moss commented that since the amount grown would not be large we should not compare these facilities to that in Colorado or Washington DC which have facilities for recreational use. Ms. Collins stated that the facilities should be in proximity to the patients due to the fact that the patients must appear in person to pick up the medication. Dr. Whiting disagrees that the location should be limited and Mr. McCann agreed with Dr. Whiting.

Action Item:

Counsel to research whether SB701 would allow for a pharmaceutical processor to deliver dispensed oil to a patient's residence or if the registered patient/parent/legal guardian must pick up the oil at the site of the pharmaceutical processor.

5. What is the maximum number of plants that a pharmaceutical processor should be allowed to possess at any given time?	One plant per person was discussed based on typical dose administered and typical amount of oil from each plant, however, difficult to define a maximum number of plants to be possessed. Will depend on cultivation techniques. Does a single tissue cell culture constitute a plant? Do cloning techniques impact the number of plants possessed? Need a buffer number of plants in case crop fails. The amount of cannabinoid is more associated with the canopy size, not the number of plants which will be at varying growing stages. DEA model references allowable number of mg of cannabinoid per facility.
Action Item:	**Mr. Bergman may be able to provide additional information on this subject to facilitate discussion.**
6. What minimum equipment and resources are necessary?	It was agreed that scales and weights are necessary equipment and ability to track inventory.
7. What recordkeeping should be required for the cultivation?	Mr. Bergman stated that there is seed to sale tracking software that the Board may want to require that a processor use which tracks all phases of growth, quality, and disposal. Examples include Priva, Agrisoft, and Biotrack THC. Suggested that some form of certificate of analysis be provided.
8. How and at what frequency is an inventory recordkeeping best performed to prevent or identify theft or loss of product?	It was agreed by the panel that the recordkeeping should be real-time, ongoing, and possibly through a tracking software.
9. What are the recommended methods for disposing of plant remains?	Mr. McCann suggested on site composting for disposing of the plant remains. Ms. Whitsett referenced concerns in Colorado for using dumpsters for disposal and that in Washington they mix the plant with a product prior to disposal.
10. Are there certain strains known to be better for producing cannabidiol oil or THC-A oil for the treatment of intractable epilepsy?	Dr. Lyons and Dr. Toor agreed that this depends on the patient and there needs to be flexibility in choice of strain. Suggested that a list of cultivars and ratios of ingredients be maintained in facility recordkeeping and shared with patients. Should test for ratios and terpenes. No one gold standard to identify preferred strain for patient.
11. How is cannabidiol oil and THC-A oil produced? What part of the plant is used? Comparison of the methods pros and cons? Should certain methods be permitted and others	Recommended that butane not be allowed in the extraction method and that carbon dioxide should be acceptable. Facility must use appropriate safety measures.

not due to a concern with safety or quality?

12. To what standards should the production of oils be held, e.g. USP standards for non-sterile compounding or FDA good manufacturing practices for dietary supplements?

Mr. Rice commented that USP would be a better standard to rely on for this production as this is a drug and pharmacists are familiar with USP guidelines. Mr. Bergman agreed. Reference also made to the American Herbal Products Association. Dr. Toor stated that patients with Dravet Syndrome often start therapy at 2-3 weeks of age, therefore, need stringent requirements since not much room for error.

Action Item:

Ms. Juran will research what standards are being required in other states.

13. How is cannabidiol oil and THC-A administered? Any paraphernalia involved?

Normally this is administered orally or sublingually via oral syringe, however, it is possible to inhale via vaping or via nebulizer. Some may prefer capsules.

14. Are there public locations where it would be inappropriate for the oils to be administered?

There was some discussion that school nurses be allowed to administer to students and for hospital employees to administer to patients. This discussion will need to be further addressed in subsequent meetings. There should be no limitation on where it may be administered. Some hospitals in Washington, DC have parent/guardian sign waiver and family administers oil.

15. What are appropriate dosages for the cannabidiol oil and THC-A oil in treating epilepsy, i.e., what constitutes a 30 day supply?

The panel agreed this is a difficult question to answer as it can vary much from patient to patient, however, an approximation is between 20 – 30 mg/day of cannabidiol oil and between 1-100 mg/day of THC-A oil. Mr. Juran indicated she was informed by the Connecticut Department of Consumer Protection that a dispenser in CT may dispense no more than 2.5oz of oil and that a record of equivalency for how much flower was used to create the 2.5oz of oil must be maintained by the facility and recorded on the product's label.

Action Item:

Mr. Juran will research how other states define a 30-day supply and counsel will research how the board may interpret the legal requirement for essentially defining a 30-day supply.

16. Should there be any minimal age restrictions for who may be administered the oils?

The agreement of the panel is there should be no age restriction.

17. How should one test for quality and potency, e.g., methods, in-house testing, outside laboratory, acceptable

The panel discussed the differences between independent lab testing and in-house testing methods for quality and potency. It was thought that independent lab testing may be preferred and more economical. However, it may be difficult to find independent labs in Virginia to test the product. Testing would need to occur in Virginia. Existing labs with

levels, etc.?	DEA registration may need to build new facility not associated with DEA registration. Testing should include cannabinoid profiling, analysis of pesticides and residual solvents, terpene testing/analysis, and microbial screening. Florida is moving toward independent third-party testing. Dr. Toor indicated bioavailability should also be determined. Neurologists often run tests to determine blood level of cannabinoids.
18. If outside labs are used, do they maintain a particular accreditation? Are there labs in Virginia that could perform the appropriate testing?	Discussed with item #17.
19. Are there population groups that should not be eligible for the oils, e.g., inmates within the Department of Corrections?	The panel agreed that the oils should be available to all populations.
20. What is the maximum number of patients that a practitioner should be allowed to issue a written certification?	The panel discussed the concern that limiting the number may exclude patients in areas where only one or two physicians may be permitted to prescribe the oils in certain geographical areas. Many felt there should not be a maximum number. The panel agreed upon a number of 600 active patients per physician with ability to petition for a greater number, if necessary.
Action Item:	**Ms. Juran will research if other states address the number of patients that a practitioner may issue a written certification and counsel will research how broadly this requirement in law may be interpreted.**
21. Is it reasonable that all persons working in a pharmaceutical processor should be registered with the Board? Should they all be required to be a pharmacist or pharmacy technician?	The discussion on the panel was mixed responses and it was agreed that the board does not currently have the authority to license individuals other than pharmacists and pharmacy technicians.
22. Is it appropriate to require either the physician or the patient to submit a copy of the written certification to the board, issue the patient a registration card with or without a photo,	Ms. Whitsett stated that she agreed with a photo ID for the patient. Dr. Toor and Dr. Whiting both agreed that this is an undue burden for the patient. There was discussion that the patients should be able to register at the prescribers' office if the patient is unable to register on their own.

and require the patient, parent or guardian to carry the registration and original written certification when in possession of the oil?

Action Item:

Ms. Juran to report back on how DHP could possibly structure the registration process.

There were comments that there is a general need for education regarding the positive use of cannabinoids medically. Additionally, a panel member questioned whether pharmaceutical processors could legally continue to produce oil if FDA were to approve a commercially produced oil.

ADJOURN:

Next meeting will take place on July 26, 2016 at 10:00am.

With all business concluded, the meeting adjourned at approximately 3:00 pm.

Ryan K. Logan, Chairman

Caroline D. Juran, Executive Director

DATE

DATE

DRAFT REGULATIONS FOR CANNABIDIOL OIL AND THC-A OIL

Part I. General Provisions.

Definitions

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

"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.

"Cultivation"

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

"Disqualifying conviction" means a conviction for the violation of any statute or regulation pertaining to the illegal manufacture, sale or distribution of a controlled substance or controlled substance analog unless the violation resulting in the conviction occurred when the person held a valid permit or registration certificate from the board and the violation was of a federal statute or regulation related to the possession, purchase or sale of cannabidiol oil or THC-A oil;

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

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

"Laboratory" -?

"Produce"

"Cannabidiol oil or THC-A oil" - ?

"On duty" means that a pharmacist is on the premises at the address of the permitted pharmacy 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 qualifying patients, which amounts shall be determined by the board on the basis of practical administration of the Act and available research;

"Pesticide chemical"

"Pharmaceutical grade cannabidiol oil or THC-A oil" means cannabidiol oil or THC-A oil or cannabidiol oil or THC-A oil products that are not adulterated and are:

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

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

and

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

"Pharmaceutical Processor"

"PIC"

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

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

"Production facility" means a secure, indoor facility where the production of marijuana occurs and that is operated by a person to whom the board has issued a producer permit;

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

"Qualifying patient"

"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;

Fees.

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

B. Registration of practitioner $25

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

1. Initial registration $ 50
2. Annual renewal of registration $ 25
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 $ 15

C. Pharmaceutical processor permit

1. Application $5,000
2. Initial permit $15,000
3. Annual renewal of permit $5,000
4. Change of name of processor $100
5. Change of PIC $100
6. Expansion, remodel, or change the location requiring a re-inspection $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 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; and
8. Be registered with and able to access the Virginia Prescription Monitoring Program.

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 submitted to the board.

D. The practitioner shall provide instructions for the use of cannabidiol oil or THC-A oil to the patient, parent, or guardian, shall also securely transmit such instructions to the qualifying patient's designated 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 practitioner who has issued or intends to issue a certification shall not:

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

(2) Offer a discount or any other thing of value to a qualifying patient, 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 that 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.

€ 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 and parent or legal guardian.

A. A qualifying patient for whom a practitioner has issued a certification, and the qualifying patient's parent or legal guardian, where applicable, 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 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;

(6) A parent or legal guardian form, if applicable;

(7) 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;

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

(9) Payment of the appropriate fees; and

(10) 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.

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

A. The board 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; or

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

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 and parent or legal guardians

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

(b) A qualifying patient or parent or legal guardian, who has been issued a registration, shall notify the board of any change in the information provided to the board not later than 14 days after such change. A qualifying patient or parent or legal guardian shall report changes that include, but are not limited to, a change in the qualifying patient's name, address, contact information, medical status. A qualifying patient or parent or legal guardian shall report such changes in a manner prescribed by the board.

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

(d) If a qualifying patient or parent or legal guardian notifies the board of any change that results in information on the registration being inaccurate, the qualifying 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.

€ If a qualifying patient or parent or legal guardian becomes aware of the loss, theft or destruction of the registration of such qualifying patient or parent or legal guardian, the qualifying 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.

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

(a) A qualifying patient and parent or legal guardian shall store cannabidiol oil or

THC-A oil in a secure location to prevent theft, loss or access by unauthorized persons.

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

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

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

1. By 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

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

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

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

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

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

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

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

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

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

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

(10) The qualifying patient fails to notify the board of a change in registration information or notifies the board of such change more than 14 days after the change; or

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

Part III. Requirements for Pharmaceutical Processors.

Applications for pharmaceutical processor permits.

A. Publication of notice.

1. 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;
2. 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.
3. The board shall have the right to cancel a notice of open applications prior to the award of a pharmaceutical processor permit.

B. A pharmaceutical processor permit applicant shall submit the required application fee, all documentation prescribed in regulation, and the application form provided by the board.

C. The applicant shall provide the following information in the application process:

(1) The name and address of the applicant, the applicant's owners, and the person who will serve as the PIC if the application is approved;

(2) The location for the pharmaceutical processor that is to be operated under such permit;

(3) A financial statement setting forth all elements and details of any business transactions connected with the application;

(4) 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, produce, and dispense cannabidiol oil and THC-A oil;

(5) Details regarding the applicant's plans to maintain adequate control against the diversion, theft or loss of cannabidiol oil or THC-A oil;

(6) 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;

(7) Information necessary for the board to conduct a criminal background check on the PIC, the pharmacists providing personal supervision on the premises of the pharmaceutical processor, owners and any other person who may have control or influence over the operation of the proposed pharmaceutical processor;

(8) Information about any previous or current involvement in the medical cannabidiol oil or THC-A oil industry;

(9) 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;

(10) Any business and marketing plans related to the operation of the pharmaceutical

processor or the sale of cannabidiol oil or THC-A oil;

(11) Text and graphic materials showing the exterior appearance of the proposed pharmaceutical processor and its site compatibility with commercial or residential structures already constructed or under construction within the immediate neighborhood;

(12) 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 oils and the location of all areas that may contain cannabidiol oil or THC-A oil showing the placement of walls, partitions, counters and all areas of ingress and egress;

(13) Documents related to any compassionate need program the pharmaceutical processor intends to offer;

(14) 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;

(15) Proof acceptable to the board that the applicant can establish and maintain an escrow account in a financial institution in Virginia, a letter of credit drawn from a financial institution in Virginia or a surety bond issued by a surety company licensed by the Commonwealth of Virginia and of a capacity and rating acceptable to the board, in the secured amount of two million dollars. Any escrow account agreement, letter of credit or surety bond shall adhere to the terms and conditions set forth by the board in the request for applications. The establishment of such escrow account, letter of credit or surety bond shall be required prior to issuance of a pharmaceutical processor permit.

(16) 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.

D. 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.

E. The board shall conduct criminal background checks on the PIC and 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.

Consideration and issuance of a pharmaceutical processor permit.

A. Following the deadline for receipt of applications, the board shall evaluate each complete and timely submitted application and issue a pharmaceutical processor permits on a competitive basis based on the criteria set out in the notice for applications. In the event the board determines that there are an insufficient number of qualified applicants to award the pharmaceutical processor permits, the board may republish, in accordance with this section, a notice of open applications for pharmaceutical processor permits.

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

(1) The background of the pharmaceutical processor, the designated pharmacist to be in full and actual charge of the pharmaceutical processor, the pharmacists providing personal supervision on the premises of the pharmaceutical processor, owners 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 including, but not limited to:

(a) Its proximity to previously approved pharmaceutical processors or pending pharmaceutical processor applications;

(b) Whether the registered patient population in the area proposed by the pharmaceutical processor applicant justifies the need for a pharmaceutical processor in that area;

(c) 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 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; and

(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.

C. 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; or

(3) Fails to pay all applicable fees;

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.

E. The decision of the board not to award a pharmaceutical processor permit to an applicant shall be final.

F. The permit shall not be awarded until an inspection of the facility has been performed and any identified deficiencies corrected.

G. 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.

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 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.

(c) No person shall perform the following duties under pharmacist supervision without maintaining an unrestricted current active pharmacy technician registration pursuant to 54.1-3321 and having been registered with the board as a pharmacy technician for the previous five 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 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;
8. The performance of any other task restricted to pharmacy technicians by the Board's regulations.

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

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.

(c) Prior to making any change to the pharmaceutical processor name, the pharmaceutical processor shall submit an application, on a form prescribed by the board, for such change to the board and pay the fee.

(d) Prior to changing a pharmaceutical processor location, the pharmaceutical processor shall submit an application, on a form prescribed by the board, for such change to the board and pay the fee. No pharmaceutical processor shall make such change until approved by the board.

(e) A. 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 file an application with the board.

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

D. Cannabis shall not be stocked within the proposed pharmaceutical processor or moved to a new location until approval is granted by the inspector or board staff.

E. Once the permit is issued, cannabis may not be stocked earlier than two weeks prior to the designated opening date. Once cannabis has been placed in the pharmaceutical processor, a pharmacist shall be present on a daily basis to ensure the safety and integrity of the canabis. 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.

Pharmaceutical processor permits generally.

A. A pharmaceutical processor permit shall not be issued to a pharmacist to be simultaneously in charge of more than one pharmaceutical processor.

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. 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.

D. An outgoing PIC shall have the opportunity to take a complete and accurate inventory of cannabis 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.

E. A PIC who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the PIC. Pharmacists-in-charge having knowledge of upcoming absences for longer than 30 days 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 owner shall immediately notify the board and shall obtain a new PIC.

F. 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.

H. Before any permit is issued, the applicant shall attest to compliance with all federal, 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.

I. If a pharmaceutical processor will be closing, the PIC for the facility shall notify the board of the closing not less than fifteen days prior to the closing.

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. 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 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.

(NEW) Sec. 21a-408-31. Disciplinary action against pharmaceutical processor, pharmaceutical processor employee

(a) For sufficient cause found in accordance with subsection (b) of this section, the board may, in the board's discretion, suspend, revoke or refuse to grant or renew a permit, license, or registration issued, or place such permit, license, or registration on probation, place conditions on such permit, license, or registration, or take other actions permitted by statute or regulation. For purposes of this section, each instance of qualifying patient or parent or legal guardian contact or consultation that is in violation of any provision of law or regulation shall be deemed a separate offense.

(b) Any of the following shall be sufficient cause for such action by the board:

(1) Furnishing of false or fraudulent information in any application;

(2) Any criminal conviction under federal or state statutes or regulations or local ordinances, unless the act subject to the conviction occurred when the person held a valid permit, license, or registration to practice in or as a pharmaceutical processor and 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;

(3) 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;

(4) Failure to maintain effective controls against diversion, theft or loss of cannabis, cannabidiol oil or THC-A oil or other controlled substances;

(5) Discipline by, or a pending disciplinary action or unresolved complaint, with regard to any professional permit or registration of any federal, state or local government;

(6) Abuse or excessive use of drugs or alcohol;

(8) Failure to account for the disposition of cannabis, cannabidiol oil or THC-A oil;

(9) Failure to keep accurate records of all cannabidiol oil or THC-A oil dispensed to qualifying patients or parents or legal guardians;

(11) Denial, suspension or revocation of a permit, license, or registration, or the denial of a renewal of a permit, license, or registration, by any federal, state or local government or a foreign jurisdiction;

(12) False, misleading or deceptive representations to the public or the board or the board's authorized representative;

(13) Return to regular stock of any cannabidiol oil or THC-A oil where:

(A) The package or container containing the cannabidiol oil or THC-A oil has been opened, breached or tampered with; or

(B) The cannabidiol oil or THC-A oil has been sold to a patient or parent or legal guardian;

(14) Involvement in a fraudulent or deceitful practice or transaction; (15) Performance of incompetent or negligent work;

(16) Failure to maintain the entire pharmaceutical processor facility and contents in a clean, orderly and sanitary condition;

(17) Intentionally, or through negligence, obscuring, damaging, or defacing a permit or registration card;

(18) A determination by the board that the applicant or holder of the permit, license, or registration has a condition, including, but not limited to, physical illness or loss of skill or deterioration due to the aging process, emotional disorder or mental illness, abuse or excessive use of drugs or alcohol that would interfere with the practice of dispensing, operation of a pharmaceutical processor or activities as a pharmaceutical processor employee provided the board shall not, in taking action against a permit, license, or registration holder on the basis of such a condition, violate the provisions of the federal Americans with Disabilities Act;

(19) Permitting another person to use the permit's, license's or registrant's permit, license, or registration;

(20) 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;

(21) 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;

(22) A violation of any provision of the law or regulation established thereunder, related to the person's profession or occupation; or

(c) No person whose application for a permit, license, or registration has been denied due to the applicant's character and fitness may make another application for a permit or registration for at least one year from the date of denial.

(d) No person whose permit, license, or registration has been revoked may make an application for a permit, license, or registration for at least one year from the date of such revocation.

(e) If a permit, license, or registration is voluntarily surrendered or is not renewed, the board shall not be prohibited from suspending, revoking or imposing other penalties permitted by the law on any such permit, license, or registration.

Suspension of pharmaceutical processor permit or producer permit

During the period of any suspension of a pharmaceutical processor permit as a result of disciplinary action by the board:

(1) No person issued a pharmaceutical processor permit shall alter the pharmaceutical processor, unless the alterations have been expressly approved in writing by the board, or attach to the exterior or any other part of the facility any sign indicating that the premises are "closed for repairs," "closed for alterations" or any like signs.

(2) The pharmaceutical processor PIC or owner shall place on the pharmaceutical processor in the front window, or on the front door facing the street, a notice indicating the

length of the suspension and the reasons therefor. The sign shall measure a minimum of eight inches in height by ten inches in width and the lettering shall be in a size and style that allows such sign to be read without difficulty by persons standing outside the pharmaceutical processor. The pharmaceutical processor PIC or owner shall maintain the sign in place until the period of suspension has terminated.

(3) A pharmaceutical processor shall not offer, sell, or dispense cannabidiol oil or THC-A oil products unless expressly approved by the board.

(4) The pharmaceutical processor PIC shall close the entire pharmaceutical processor for business and shall securely lock all cannabidiol oil or THC-A oil products. Pharmaceutical processor employees may visit the facility only for the necessary care and maintenance of the premises. Only the PIC or pharmacist shall have a the code and access to the alarm system

(6) The board may, in the board's discretion, accept a monetary payment as an offer in compromise in lieu of, or so as to reduce a suspension, from a permit, licensee, or registrant whose permit, license, or registration is subject to a hearing that may result in a suspension or whose permit, license, or registration has been suspended after due hearing. Such offer shall include a waiver of appeal and judicial review and a check in the amount designated by the board.

Operation of pharmaceutical processor

(a) No pharmaceutical processor shall:

(1) Produce or manufacture 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 child-resistant, secure and light-resistant container. Upon a written request from the qualifying 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, and only a pharmacy technician may sell cannabidiol oil or THC-A oil, to qualifying patients and parent or legal guardians who are registered with the board. A pharmacy technician may assist, under the direct supervision of a pharmacist, in the dispensing 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 has a patient or parent or legal guardian registration, in which case such person shall not be permitted behind the service counter or in other areas where 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 authorized representative.

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

(g) A pharmaceutical processor shall be open for qualifying patients and parent 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 qualifying patients and parent or 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 qualifying patients and parent or legal guardians. Such disclosure may include posting the information on the pharmaceutical processor Internet web site.

(j) A pharmaceutical processor shall provide information to qualifying patients and parent or 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 qualifying patients and parent 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 authorized representative upon request.

(l) Cannabidiol oil or THC-A oil shall be stored in an approved safe or approved vault within the pharmaceutical processor.

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) No cannabidiol oil or THC-A oil shall be consumed on the premises of a pharmaceutical processor.

(f) Except as provided in subsection (g) of this section, no person, except a pharmaceutical processor employee shall be allowed on the premises of a pharmaceutical processor without a qualifying patient or parent or legal guardian registration certificate issued by the board.

(g) (1) Upon prior written request, the board or the board's authorized representative may waive the provisions of subsection (f) of this section.

(2) All persons not permitted on the premises of a pharmaceutical processor pursuant to subsection (f) of this section, but 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. An employee shall escort and monitor such a visitor at all times the visitor is in the pharmaceutical processor. 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 pursuant to subsection (g)(1) of this section, the pharmaceutical 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.

(i) 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 parent or legal guardian may deliver cannabidiol oil or THC-A oil to the parent or legal guardian's qualified patient.

(j) Notwithstanding the requirements of subsection f, 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.

Security System and Storage Requirements

A. A device for the detection of breaking 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 prescription department and shall be capable of detecting breaking by any means when activated.
4. 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.

B. A pharmaceutical processor shall store 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.

Rights and responsibilities of pharmaceutical processors

(a) A pharmacist, in good faith, may sell and dispense cannabidiol oil or THC-A oil to any qualifying patient or parent or legal guardian that is registered with the board. Except as otherwise provided, the pharmacist dispensing the cannabidiol oil or THC-A oil shall include the date of dispensing and the pharmacist's signature or initials on the pharmaceutical processor's dispensing record log.

(b) All pharmacists employed by pharmaceutical processors shall register for access to the prescription monitoring program.

(c) A pharmacist shall review a qualifying patient's controlled substance history report within the prescription monitoring program before dispensing any cannabidiol oil or THC-A oil to the qualifying patient or the qualifying patient's parent or legal guardian.

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

(e) A pharmacist may dispense a portion of a qualifying 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 qualifying patient or parent or legal guardian shall receive more than a one-month supply of cannabidiol oil or THC-A oil in a one-month period.

(f) A pharmacist or pharmacy technician shall require the presentation of a current active registration, current active written certification, and valid photographic identification issued to a qualifying patient or parent or legal guardian, prior to selling cannabidiol oil or THC-A oil to such qualifying patient or parent or legal guardian.

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

Pharmaceutical processors to assign serial number and maintain records. Transfer of records to another pharmaceutical processor

(a) A pharmacist shall assign and record a sequential serial number to each cannabidiol oil or THC-A oil product dispensed to a patient and shall keep all dispensing records in numerical order in a suitable file, electronic file or ledger. The records shall indicate:

(1) The date of dispensing;

(2) The name and address of the certifying practitioner;

(3) The name and address of the qualifying patient, or parent or legal guardian, if

applicable;

(4) The initials of the pharmacist who dispensed the cannabidiol oil or THC-A oil; and

(5) Whether a full or partial one-month supply of cannabidiol oil or THC-A oil was dispensed.

(b) A pharmaceutical processor shall maintain records created under this section and shall make such records available in accordance with the regulations.

(c) When a pharmaceutical processor closes temporarily or permanently, the pharmaceutical processor shall, in the interest of public health, safety and convenience, 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.

Labeling of cannabidiol oil or THC-A oil products by pharmacist

(a) A pharmacist, or a pharmacy technician under the direct supervision of the pharmacist, shall completely and properly label all cannabidiol oil or THC-A oil products dispensed with all required information as follows:

(1) The serial number, as assigned by the pharmaceutical processor;

(2) The date of dispensing the cannabidiol oil or THC-A oil;

(3) The quantity of cannabidiol oil or THC-A oil dispensed;

(4) The name and registration number of the qualifying patient and, where applicable, the parent or legal guardian;

(5) The name 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;

(7) Name of the pharmacist;

(8) Name and address 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) 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.

Responsibilities of pharmaceutical processor PIC

(a) A pharmaceutical processor shall employ the pharmaceutical processor PIC at the pharmaceutical processor for at least thirty-five hours per week, except as otherwise authorized by the board.

(b) No person shall be a pharmaceutical processor PIC for more than one pharmaceutical processor at a time.

(c) The pharmaceutical processor PIC shall be responsible for ensuring that:

(1) Pharmacy technicians are registered and properly trained;

(2) All record-retention requirements are met;

(3) All requirements for the physical security of the cannabis, 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) The name of the pharmaceutical processor PIC; 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 pharmaceutical processor as set forth in regulation.

Pharmacy technicians. Ratio. Supervision and responsibility

(a) The ratio of pharmacy technicians to pharmacist on-duty in a pharmaceutical processor shall not exceed four pharmacy technicians to one pharmacist.

(c) The pharmacist providing direct supervision of pharmacy technicians shall be responsible for the pharmacy technicians' 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. As used in this subsection, "direct supervision" means a supervising pharmacist who:

(1) Is on duty as defined in ____ where the pharmacy technician is performing routine cannabidiol oil or THC-A oil dispensing functions; and

(2) Conducts in-process and final checks on the pharmacy technician's performance.

Pharmacy technician limitations

(a) Pharmacy technicians shall not:

(1) Consult with a qualifying 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) Perform professional consultation with practitioners, nurses or other health care professionals or their authorized agents;

(5) Determine whether a different brand or 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 qualifying patient or parent or legal guardian; or

(6) 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.

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, 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 pharmaceutical processor 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 pharmaceutical processor 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 pharmaceutical processor 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 pharmacy technician training and make it available in accordance with regulations.

Dispensing error 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.

(d) A pharmaceutical processor shall use the findings of its quality assurance program to develop systems and workflow processes designed to prevent dispensing errors.

(e) A pharmaceutical processor PIC shall inform pharmaceutical processor employees of changes to policy, procedure, systems, or processes made as a result of recommendations generated by the quality assurance program.

Review of dispensing errors

(a) A pharmaceutical processor PIC shall notify all pharmacist employees that the discovery or reporting of a dispensing error shall be relayed immediately to a pharmacist on duty.

(b) A pharmaceutical processor PIC shall 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.

(c) A pharmaceutical processor PIC shall create a record of every quality assurance review. This record shall contain at least the following:

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

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

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

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

(5) Recommended changes to pharmaceutical processor policy, procedure, systems, or

processes, if any.

(d) A pharmaceutical processor shall maintain quality assurance review records in an orderly manner and filed by date.

(e) 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.

Electronic system record-keeping safeguards

(a) If a pharmaceutical processor uses an electronic system for the storage and retrieval of patient information or other 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.

Pharmacist reporting into the prescription monitoring program

(a) At least once per day, a pharmacist shall transmit electronically to the Drug Control Division of the board the information set forth in the most recent edition of the Standard for Prescription Monitoring Programs established by the American Society for Automation in Pharmacy, a copy of which may be purchased from the American Society for Automation in Pharmacy on their Internet web site: www.asapnet.org.

(b) A pharmacist shall transmit to the board, in a format approved by the board, the fields listed in this subsection, including, but not limited to, the following:

(1) Drug Enforcement Administration Pharmacy number, which shall be populated by a number provided by the board;

(2) Birth date;

(3) Sex code;

(4) Date order filled, which shall be the date cannabidiol oil or THC-A oil is dispensed;

(5) Order number, which shall be the serial number assigned to each cannabidiol oil or THC-A oil product dispensed to a patient;

(6) New-refill code;

(7) Quantity;

(8) Days supply;

(9) National Drug Code number, which shall be provided by the board; (10) Drug Enforcement Administration Prescriber identification number;

(11) Date order written, which shall be the date the written certification was issued;

(12) Number of refills authorized;

(13) Order origin code, which shall be provided by the board; (14)

Patient last name;

(15) Patient first name;

(16) Patient street address;

(17) State;

(18) Payment code for either cash or third-party provider; and

(19) Drug name, which shall be the brand name of the cannabidiol oil or THC-A oil product.

(c) A pharmacist shall transmit the information required pursuant to this section in such a manner as to insure the confidentiality of the information in compliance with all federal and Connecticut state statutes and regulations, including the federal Health Insurance Portability and Accountability Act of 1996, Public Law 104-191.

Security requirements

(a) A pharmaceutical processor shall:

(1) Not maintain cannabidiol oil or THC-A oil in excess of the quantity required for normal, efficient operation;

(2) Store all cannabidiol oil or THC-A oil in an approved safe or approved vault and in such a manner as to prevent diversion, theft or loss;

(3) Maintain all cannabis and parts in a secure area or location accessible only to specifically authorized employees, which shall include only the minimum number of employees essential for efficient operation;

(4) Keep all approved safes and approved vaults securely locked and protected from entry, except for the actual time required to remove or replace cannabidiol oil or THC-A oil;

(5) Keep all locks and security equipment in good working order;

(6) Not allow keys to be left in the locks and not store or place keys in a location accessible to persons other than specifically authorized employees;

(7) Not allow other security measures, such as combination numbers, passwords or electronic or biometric security systems, to be accessible to persons other than specifically authorized employees; and

(8) Keep the pharmaceutical processor securely locked and protected from entry by unauthorized employees

large stock of cannabidiol oil or THC-A oil, exposed handling or unusual vulnerability to diversion, theft or loss, the board may require additional safeguards, including, but not limited to, a supervised watchman service.

(b) If a pharmaceutical processor presents special security issues, such as an

(c) If diversion, theft, or loss of cannabidiol oil or THC-A oil has occurred from a pharmaceutical processor, the board shall determine the appropriate storage and security requirements for all cannabidiol oil or THC-A oil in such pharmaceutical processor, and may require additional safeguards to ensure the security of the cannabidiol oil or THC-A oil.

(d) Any cannabidiol oil or THC-A oil not stored in compliance or stored at a location other than that for which the pharmaceutical processor permit was issued, shall be subject to embargo or seizure by the board.

(e) Any pharmaceutical processor whose permit is revoked or not renewed shall dispose of its entire stock of cannabis, cannabidiol oil, and THC-A oil in accordance with regulation.

(f) If a pharmaceutical processor has provided other safeguards which can be regarded in total as an adequate substitute for some element of protection required of such facility, such added protection may be taken into account by the board in evaluating overall required security measures.

Minimum requirements for the storage and handling of cannabidiol oil or THC-A oil by producers

(a) All pharmaceutical processors shall:

(1) Have storage areas that provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions for the production and manufacture of cannabis;

(2) Separate for storage, in a quarantined area, cannabis, 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 cannabidiol oil or THC-A oil is destroyed;

(3) Be maintained in a clean and orderly condition; and

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

(c) A producer shall compartmentalize all areas in the facility based on function and shall restrict access between compartments. The producer shall establish, maintain and comply with written policies and procedures, approved by the board, regarding best practices for the secure and proper production and manufacturing 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, including cannabidiol oil or THC-A oil; and

(4) Document the chain of custody of all cannabis and cannabidiol oil orTHC-A oil products.

(d) The pharmaceutical PIC shall establish, maintain, and comply with written policies and procedures, approved by the board, for the manufacture, security, storage, and Inventory of cannabis, including cannabidiol oil or 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 cannabis, including cannabidiol oil or THC-A oil products. 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 producer to remove defective or potentially defective cannabidiol oil or THC-A oil products from the market or any action undertaken to promote public health and safety by replacing existing cannabidiol oil or THC-A oil products 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 cannabidiol oil or THC-A oil, is segregated from all other cannabis, cannabidiol oil or THC-A oil and destroyed. This procedure shall provide for written documentation of the cannabis, cannabidiol oil and THC-A oil disposition; and

(4) Ensuring the oldest stock of a cannabis, 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.

(e) A producer shall store all cannabis, including cannabidiol oil or THC-A oil, in the process of manufacturing or analysis in such a manner as to prevent diversion, theft or loss, shall make cannabis, cannabidiol oil and THC-A oil accessible only to the minimum number of specifically authorized employees essential for efficient operation, and shall return cannabis, cannabidiol oil, and THC-A oil to its secure location immediately after completion of the process or at the end of the scheduled business day. If a manufacturing process cannot be completed at the end of a working day, the employee shall securely lock the processing area or tanks, vessels, bins, or bulk containers containing cannabis, cannabidiol oil, or THC-A oil inside an area or building that affords adequate security.

(1) Laboratory staff may enter a production facility for the sole purpose of identifying and collecting cannabidiol oil or THC-A oil samples for purposes of conducting laboratory tests; and

Producer record keeping

Employees producing cannabidiol oil or THC-A oil shall keep records of all cannabidiol oil or THC-A oil produced or manufactured and of all cannabis disposed of by them. Such records shall be maintained and made available in accordance with regulations and, in each case shall show:

(1) The brand name, kind and quantity of cannabis, cannabidiol oil, or THC-A oil involved;

(2) The date of such production or removal from production;

(3) A record of all cannabidiol oil or THC-A oil sold, transported or otherwise disposed of;

(4) The date and time of selling, transporting or disposing of the cannabidiol oil or THC-A oil;

(5) The name and address of the pharmaceutical processor to which the cannabidiol oil or THC-A oil was
sold;

(6) The name of the pharmacist who took custody of the cannabidiol oil or THC-A oil; and
(7) The name of the production facility employee responsible for transporting the cannabidiol oil or THC-A oil to the pharmacist, if appropriate.

Manufacturing of cannabidiol oil or THC-A oil products

(a) No cannabidiol oil or THC-A oil product shall:
(1) Be manufactured or sold in a form or with a design that: (A) Is
obscene or indecent;
(B) May encourage the use of cannabidiol oil or THC-A oil for recreational purposes;
(C) May encourage the use of cannabidiol oil or THC-A oil for a condition other than intractable epilepsy; or
(D) Is customarily associated with persons under the age of eighteen;

(2) Have had pesticide chemicals or organic solvents used during the 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.

(c) Any cannabis, cannabidiol oil, or THC-A oil product not in compliance with this section shall be deemed adulterated.

Packaging and labeling by pharmaceutical processor

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).

(c) A producer shall label each cannabidiol oil or THC-A oil product prior to sale to a pharmacist and shall securely affix to the package a label that states in legible English:

(1) The name and address of the producer;

(2) The brand name of the cannabidiol oil or THC-A oil ;

(3) A unique serial number that will match the product with a producer batch and lot number so as to facilitate any warnings or recalls the board or producer deem appropriate;

(4) The date of final testing and packaging; (5)

The expiration date;

(6) The quantity of cannabidiol oil or THC-A oil contained therein;

(7) A terpenes profile and a list of all active ingredients, including:

(A) tetrahydrocannabinol (THC);

(B) tetrahydrocannabinol acid (THCA);

and

(C) cannabidiol (CBD).

(8) A pass or fail rating based on the laboratory's microbiological, mycotoxins, heavy metals and chemical residue analysis; and

(d) A producer shall not label cannabidiol oil or THC-A oil products as "organic" unless the cannabis plants have been organically grown as defined in law_____ 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 _____.

Laboratory requirements

No laboratory shall handle, test or analyze cannabidiol oil or THC-A oil unless such laboratory: (1) Is registered with the board as a controlled substance laboratory;

(2) Is independent from all other persons involved in the cannabidiol oil or THC-A oil industry in Connecticut, 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

(3) 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 manufacturing any cannabidiol oil or THC-A oil product, a producer shall segregate all harvested cannabis into homogenized batches.

(b) A producer shall make available each such batch at the production 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 producer 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 producer shall maintain the cannabis in a secure, cool and dry location so as to prevent the cannabis from becoming contaminated or losing its efficacy. Under no circumstances shall a producer 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 producer or other designated production facility employee.

(d) A laboratory shall immediately return or dispose of any cannabis upon the completion of any testing, use, or research.

(e) 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 producer 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	

(3) For purposes of the heavy metal test, a cannabis sample shall be deemed to have passed if it meets the following standards:

Metal BW/Day	Natural Health Products Acceptable limits uG/KG
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.

(f) 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.

(g) 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 producer. In addition, the laboratory shall maintain the laboratory test results and make them available.

(h) Each pharmaceutical processor shall have such laboratory results available upon request to qualifying patients, parent or legal guardians and practitioners who have certified qualifying patients.

Brand name

(a) A producer shall assign a brand name to each cannabidiol oil or THC-A oil product. The pharmaceutical processor shall associate each brand 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

(b) A producer shall not label two cannabidiol oil or THC-A oil products with the same brand name unless the laboratory test results for each product indicate that they contain the same level of each active ingredient listed within subsection (a)(1) to (4), inclusive, of this section within a range of 97% to 103%.

(c) 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 a previously approved cannabidiol oil or THC-A oil product brand 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.

(NEW) Sec. 21a-408-61. Security requirements for producers

(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 cannabidiol oil or THC-A oil;

(5) Keep all locks and security equipment in good working order;

(6) Not allow keys to be left in the locks and not store or place keys in a location

accessible to persons other than specifically authorized employees;

Security alarm systems; minimum requirements for pharmacist facilities and production facilities

(a) All pharmacist facilities and production facilities shall have an adequate security system to prevent and detect diversion, theft or loss of cannabidiol oil or THC-A oil utilizing commercial grade equipment, which shall, at a minimum, include:

(1) A perimeter alarm;

(2) Motion detector;

(3) Video cameras in all areas that may contain 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. The pharmaceutical processor or production facility shall direct cameras at all approved safes, approved vaults, dispensing areas, cannabidiol oil or THC-A oil sales areas and any other area where cannabidiol oil or THC-A oil is being produced, harvested, manufactured, stored or handled. At entry and exit points, the pharmaceutical processor or production facility shall angle cameras so as to allow for the capture of clear and certain identification of any person entering or exiting the facility;

(4) Twenty-four hour recordings from all video cameras, which the pharmaceutical processor or production facility shall make available for immediate viewing by the board or the board's authorized representative upon request and shall retain for at least thirty days. If a pharmaceutical processor or producer is aware of a pending criminal, civil or administrative investigation or legal proceeding for which a recording may contain relevant information, the pharmaceutical processor or producer 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 or producer that it is not necessary to retain the recording;

(5) Duress alarm, which for purposes of this subsection means a silent security alarm system signal generated by the entry of a designated code into an arming station in order to signal that the alarm user is being forced to turn off the system;

(6) Panic alarm, which for purposes of this subsection means an audible security alarm system signal generated by the manual activation of a device intended to signal a life threatening or emergency situation requiring a law enforcement response;

(7) Holdup alarm, which for purposes of this subsection means a silent alarm signal generated by the manual activation of a device intended to signal a robbery in progress;

(8) Automatic voice dialer, which for purposes of this subsection means any electrical, electronic, mechanical, or other device capable of being programmed to send a prerecorded voice message, when activated, over a telephone line, radio or other communication system, to a law enforcement, public safety or emergency services agency requesting dispatch;

(9) 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 the pharmaceutical processor or producer within five minutes of the failure, either by telephone, email, or text message;

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

(11) 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

(12) The ability to remain operational during a power outage.

(b) A pharmaceutical processor or a production facility shall maintain all security system equipment and recordings in a secure location so as to prevent theft, loss, destruction or alterations.

(c) In addition to the requirements listed in subsection (a) of this section, each production facility shall have a back-up alarm system approved by the board that shall detect unauthorized entry during times when no employees are present at the facility and that shall be provided by a company supplying commercial grade equipment, which shall not be the same company supplying the primary security system.

(d) A pharmaceutical processor or a production facility 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 pharmaceutical processor and producer shall make available a current list of authorized employees and service employees that have access to the surveillance room to the pharmaceutical processor and producer shall keep all on-site surveillance rooms locked and shall not use such rooms for any other function.

(e) A pharmaceutical processor and producer shall keep the outside perimeter of the pharmaceutical processor and production facility premises well-lit.

(f) All video recording shall allow for the exporting of still images in an industry standard image format, including .jpg, .bmp, and .gif. 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 and producer shall erase all recordings prior to disposal or sale of the facility.

(g) A pharmaceutical processor and producer shall keep all security equipment in good-working order and shall test such equipment no less than two times per year.

Pharmacist and producer 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 producer shall immediately notify:

(1) Appropriate law enforcement authorities; and

(2) The Drug Control Division of the board.

(b) A pharmacist or producer 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 producer shall make such notice no later than twenty-four hours after discovery of the event.

(c) A pharmacist or producer shall notify the Drug Control Division of 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.

documentation related to an occurrence that is reportable pursuant to subsections (a) through (c), inclusive, of this section in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies.

(NEW) Sec. 21a-408-64. Disposal of cannabidiol oil or THC-A oil

(a) A pharmacist, producer, laboratory, law enforcement or court official or the board or the board's authorized representative shall dispose of undesired, excess, unauthorized, obsolete, adulterated, misbranded or deteriorated cannabidiol oil or THC-A oil in the following manner:

(1) By surrender without compensation of such cannabidiol oil or THC-A oil to the board or the board's authorized representative; or

(2) 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 in accordance with section 21a-408-70 of the Regulations of Connecticut State Agencies a separate record of each such disposal indicating:

(1) The date and time of disposal; (2)

The manner of disposal;

(3) The brand 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.

(NEW) Sec. 21a-408-65. Inventory

(a) Each pharmaceutical processor and production facility, prior to commencing business, shall:

(1) Conduct an initial comprehensive inventory of all marijuana, including the seeds, cannabidiol oil, and THC-A oil at the facility. If a facility commences business with no marijuana on hand, the pharmacist or producer 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 marijuana, 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 marijuana, 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 individuals who conducted the inventory. The record of all marijuana, cannabidiol oil, and THC-A oil sold, dispensed or otherwise disposed of shall show the date of sale, the name of the pharmaceutical processor, qualifying patient or parent or legal guardian to whom the cannabidiol oil or THC-A oil was sold, the address of such person and the brand and quantity of cannabidiol oil or THC-A oil sold.

(c) A complete and accurate record of all marijuana, 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 pharmaceutical processor PIC or producer 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.

(e) Whenever any sample or record is removed by a person authorized to enforce the provisions of Virginia food, drug and cosmetic statutes and regulations 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.

(NEW) Sec. 21a-408-66. Marketing: prohibited conduct, statements and illustrations; board review of advertisements

(a) A producer, production facility employee, producer backer, pharmaceutical processor employee, pharmaceutical processor backer or practitioner, in any combination, shall not cooperate, directly or indirectly, in any advertising if such advertising has the purpose or effect of steering or influencing patient or parent or legal guardian choice with regard to the selection of a practitioner, pharmacist or cannabidiol oil or THC-A oil product.

(b) An advertisement for cannabidiol oil or THC-A oil or any cannabidiol oil or THC-A oil product shall not contain: (1) Any statement that is false or misleading in any material particular or is otherwise in violation of the Connecticut Unfair Trade Practices Act, sections 42-110a to 42-110q, inclusive, of the Connecticut General Statutes;

(2) Any statement that falsely disparages a competitor's products;

(3) Any statement, design, or representation, picture or illustration that is obscene or indecent;

(4) Any statement, design, representation, picture or illustration that encourages or represents the use of cannabidiol oil or THC-A oil for a condition other than a debilitating medical condition;

(5) Any statement, design, representation, picture or illustration that encourages or represents the recreational use of cannabidiol oil or THC-A oil;

(6) Any statement, design, representation, picture or illustration related to the safety or efficacy of cannabidiol oil or THC-A oil, unless supported by substantial evidence or substantial clinical data;

(7) Any statement, design, representation, picture or illustration portraying anyone under the age of eighteen, objects suggestive of the presence of anyone under the age of eighteen, or containing the use of a figure, symbol or language that is customarily associated with anyone under the age of eighteen;

(8) Any offer of a prize, award or inducement to a qualifying patient, parent or legal guardian or practitioner related to the purchase of cannabidiol oil or THC-A oil or a certification for the use of cannabidiol oil or THC-A oil; or

(9) Any statement that indicates or implies that the product or entity in the advertisement has been approved or endorsed by the board, board, the state of Connecticut or any person or entity associated with the state of Connecticut.

(c) Any advertisement for cannabidiol oil or THC-A oil or a cannabidiol oil or THC-A oil product shall be submitted to the board at the same time as, or prior to, the dissemination of

the advertisement.

(d) The submitter of the advertisement shall provide the following information in addition to the advertisement itself:

(1) A cover letter that:

(A) Provides the following subject line: Medical cannabidiol oil or THC-A oil advertisement review package for a proposed advertisement for (Brand Name);

(B) Provides a brief description of the format and expected distribution of the proposed advertisement; and

(C) Provides the submitter's name, title, address, telephone number, fax number, and email address;

(2) An annotated summary of the proposed advertisement showing every claim being made in the advertisement and which references support for each claim;

(3) Verification that a person identified in an advertisement as an actual patient or health care practitioner is an actual patient or health care practitioner and not a model or actor;

(4) Verification that a spokesperson who is represented as an actual patient is indeed an actual patient;

(5) Verification that an official translation of a foreign language advertisement is accurate;

(6) Annotated references to support disease or epidemiology information, cross-referenced to the advertisement summary; and

(7) A final copy of the advertisement, including a video where applicable, in a format acceptable to the board.

(e) Advertising packages that are missing any of the elements in subsection (d) of this section, or that fail to follow the specific instructions for submissions, shall be considered incomplete. If the board receives an incomplete package, it shall so notify the submitter.

(f) The board may:

(1) Require a specific disclosure be made in the advertisement in a clear and conspicuous manner if the board determines that the advertisement would be false or misleading without such a disclosure; or

(2) Make recommendations with respect to changes that are:

(A) Necessary to protect the public health, safety and welfare; or

(B) Consistent with dispensing information for the product under review.

(3) If appropriate and if information exists, recommend statements for inclusion in the advertisement to address the specific efficacy of the drug as it relates to specific disease states, disease symptoms and population groups.

(NEW) Sec. 21a-408-67. Cannabidiol oil or THC-A oil advertising; requirements for true statements and fair balance

(a) All advertisements for cannabidiol oil or THC-A oil or cannabidiol oil or THC-A oil products that make a statement relating to side effects, consequences, contraindications and effectiveness shall present a true statement of such information. When applicable, advertisements broadcast through media such as radio, television, or other electronic media shall include such information in the audio or audio and visual parts of the presentation.

(b) False or misleading information in any part of the advertisement shall not be corrected by the inclusion of a true statement in another distinct part of the advertisement.

(c) An advertisement does not satisfy the requirement that it present a "true statement" of information relating to side effects, consequences, contraindications, and effectiveness if it fails to present a fair balance between information relating to side effects, consequences, contraindications and effectiveness in that the information relating to effectiveness is presented in greater scope, depth, or detail than is the information relating to side effects, consequences and contraindications, taking into account all implementing factors such as typography, layout, contrast, headlines, paragraphing, white space, and any other techniques apt to achieve emphasis.

(d) An advertisement is false, lacking in fair balance, or otherwise misleading if it: (1) Contains a representation or suggestion that a cannabidiol oil or THC-A oil strain, brand or

product is better, more effective, useful in a broader range of conditions or patients or safer than other drugs or treatments including other cannabidiol oil or THC-A oil strains or products, unless such a claim has been demonstrated by substantial evidence or substantial clinical experience;

(2) Contains favorable information or opinions about a cannabidiol oil or THC-A oil product previously regarded as valid but which have been rendered invalid by contrary and more credible recent information;

(3) Uses a quote or paraphrase out of context or without citing conflicting information from the same source, to convey a false or misleading idea;

(4) Uses a study on individuals without a debilitating medical condition without disclosing that the subjects were not suffering from a debilitating medical condition;

(5) Uses data favorable to a cannabidiol oil or THC-A oil product derived from patients treated with a different product or dosages different from those approved in the state of Connecticut; (6) Contains favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions; or

(7) Fails to provide adequate emphasis for the fact that two or more facing pages are part of the same advertisement when only one page contains information relating to side effects, consequences and contraindications.

(e) No advertisement may be disseminated if the submitter of the advertisement has received information that has not been widely publicized in medical literature that the use of the cannabidiol oil or THC-A oil product or strain may cause fatalities or serious damage to a patient.

(NEW) Sec. 21a-408-68. Cannabidiol oil or THC-A oil marketing; advertising at a pharmaceutical processor;producer advertising of prices

(a) A pharmaceutical processor shall:

(1) Except as otherwise provided in sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, restrict external signage to a single sign no larger than sixteen inches in height by eighteen inches in width;

(2) Not illuminate a pharmaceutical processor sign advertising a cannabidiol oil or THC-A oil product at any

time;
(3) Not advertise cannabidiol oil or THC-A oil brand names or utilize graphics related to cannabidiol oil or THC-A oil or paraphernalia on the exterior of the pharmaceutical processor or the building in which the pharmaceutical processor is located; and

(4) Not display cannabidiol oil or THC-A oil and paraphernalia so as to be clearly visible from the exterior of a pharmaceutical processor.

(b) A producer shall not advertise the price of its cannabidiol oil or THC-A oil, except that it may make a price list available to a pharmaceutical processor.

(NEW) Sec. 21a-408-69. Pharmaceutical processor and producer records; furnishing of information; audits

(a) Each pharmaceutical processor and producer shall maintain a complete set of all records necessary to fully show the business transactions related to cannabidiol oil or THC-A oil for a period of the current tax year and the three immediately prior tax years, all of which shall be made available in accordance with section 21a-408-70 of the Regulations of
Connecticut State Agencies.

(b) The board may require any permite or registrant to furnish such information as the board considers necessary for the proper administration of the Act and sections 21a-408-1 to 21a-408-70, inclusive, of the Regulations of Connecticut State Agencies, and may require an audit of the business of any pharmaceutical processor or producer and the expense thereof shall be paid by such pharmaceutical processor or producer.

(NEW) Sec. 21a-408-70. Inspection of records; entry on premises

(a) Every person required by sections 21a-408-1 to 21a-408-69, inclusive, of the Regulations of Connecticut State Agencies, to prepare, obtain or keep records, logs, reports or other documents, and every person in charge, or having custody, of such documents, shall maintain such documents in an auditable format for no less than three years. Upon request, such person shall make such documents immediately available for inspection and copying by the board, the board's authorized representative or others authorized by the Act or sections 21a-408-1 to 21a-408-69, inclusive, of the Regulations of Connecticut State Agencies, to review the documents.
In complying with this section, no person shall use a foreign language, codes or symbols to designate cannabidiol oil or THC-A oil types or persons in the keeping of any required document.

(b) For purposes of the supervision and enforcement of the medical cannabidiol oil or THC-A oil program established pursuant to chapter 420f of the Connecticut General Statutes, the board or the board's authorized representative, is authorized:

(1) To enter, at reasonable times, any place, including a vehicle, in which cannabidiol oil or THC-A oil is held, dispensed, sold, produced, delivered, transported, manufactured or otherwise disposed of;

(2) To inspect within reasonable limits and in a reasonable manner, such place and all pertinent equipment, finished and unfinished material, containers and labeling, and all things therein including records, files, financial data, sales data, shipping data, pricing data,

employee data, research, papers, processes, controls and facilities; and

(3) To inventory any stock of cannabidiol oil or THC-A oil therein and obtain samples of any cannabidiol oil or THC-A oil or cannabidiol oil or THC-A oil product, any labels or containers for cannabidiol oil or THC-A oil, paraphernalia, and of any finished and unfinished material.

1. Registration process for patient, parent, guardian, practitioner
2. Issuance of a written certification
3. Application process for permit as a processor
    a. Compartments of a processor
    b. Competitive bidding
    c. Information to be submitted with application
    d. Role of the PIC
    e. Changes to permit, PIC
4. Employees who can work at a processor
    a. Training, registration depending on compartment
5. What a processor can and cannot do
6. Physical and security requirements for each compartment
7. Lab testing of cannabis (not oil, right?), record of analysis
8. Naming, labeling prior to dispensing (need to fix this section)
9. Labeling for specific patient
10. Requirements for picking up oil, documentation to present, recordkeeping of obtaining oil, feedback on how it's going
11. Advertising prohibitions
12. Inventory requirements
13. Destruction for patient and processor