

TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF PHARMACY

Emergency Regulation

Title of Regulation: 18VAC110-60. Regulations Governing Pharmaceutical Processors (amending 18VAC110-60-10, 18VAC110-60-20, 18VAC110-60-40, 18VAC110-60-50, 18VAC110-60-60, 18VAC110-60-90 through 18VAC110-60-270, 18VAC110-60-300 through 18VAC110-60-330; adding 18VAC110-60-135, 18VAC110-60-136, 18VAC110-60-251, 18VAC110-60-321).

Statutory Authority: §§ 54.1-2400 and 54.1-3442.6 of the Code of Virginia.

Effective Dates: February 8, 2021, through August 7, 2022.

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Preamble:

Section 2.2-4011 B of the Code of Virginia states that agencies may adopt emergency regulations in situations in which Virginia statutory law requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of § 2.2-4006 A 4 of the Code of Virginia. Chapter 1278 of the 2020 Acts of Assembly authorizes the Board of Pharmacy to issue permits for cannabis dispensing facilities and mandates certain requirements for the permitting as well as for pharmaceutical processors.

The emergency action (i) establishes provisions for cannabis dispensing facilities, including an application process and fee; (ii) allows patients who are temporary residents to register; (iii) permits access to cultivation areas of the processor when a pharmacist is not present; (iv) establishes standards for laboratories that provide testing to obtain a controlled substance registration; (v) permits the sale of devices and inert sample products; (vi) allows wholesale distribution between processors and dispensing facilities; and (vii) modifies other regulatory provisions as applicable to align with the statutory amendments and requirements of Chapter 1278.

Chapter 60

Regulations Governing Pharmaceutical Processors and Cannabis Dispensing Facilities

18VAC110-60-10. Definitions.

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

"90-day supply" means the amount of cannabis oil reasonably necessary to ensure an uninterrupted availability of supply for a 90-day period for registered patients.

"Batch" means a quantity of cannabis oil from a production lot that is identified by a batch number or other unique identifier.

"Board" means the Board of Pharmacy.

"Certification" means a written statement, consistent with requirements of § 54.1-3408.3 of the Code of Virginia, issued by a practitioner for the use of cannabis oil for treatment of or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use.

"Dispensing error" means one or more of the following was discovered after the final verification by the pharmacist, regardless of whether the patient received the oil:

1. Variation from the intended oil to be dispensed, including:
 - a. Incorrect oil;
 - b. Incorrect oil strength;
 - c. Incorrect dosage form;

- d. Incorrect patient; or
 - e. Inadequate or incorrect packaging, labeling, or directions.
2. Failure to exercise professional judgment in identifying and managing:
 - a. Known therapeutic duplication;
 - b. Known drug-disease contraindications;
 - c. Known drug-drug interactions;
 - d. Incorrect drug dosage or duration of drug treatment;
 - e. Known drug-allergy interactions;
 - f. A clinically significant, avoidable delay in therapy; or
 - g. Any other significant, actual, or potential problem with a patient's drug therapy.
 3. Delivery of an oil to the incorrect patient.
 4. An act or omission relating to the dispensing of cannabis oil that results in, or may reasonably be expected to result in, injury to or death of a registered patient or results in any detrimental change to the medical treatment for the patient.

"Electronic tracking system" means an electronic radio-frequency identification (RFID) seed-to-sale tracking system that tracks the Cannabis from either the seed or immature plant stage until the cannabis oil is sold to a registered patient, parent, or legal guardian or until the Cannabis, including the seeds, parts of plants, and extracts, are destroyed. The electronic tracking system shall include, at a minimum, a central inventory management system and standard and ad hoc reporting functions as required by the board and shall be capable of otherwise satisfying required recordkeeping.

"ISO/IEC" means the joint technical committee of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).

"ISO/IEC 17025" means the general requirements specified by the ISO/IEC for the competence of testing and calibration laboratories.

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

"Perpetual inventory" means an ongoing system for recording quantities of cannabis oil received, dispensed, or otherwise distributed by a cannabis dispensing facility.

"PIC" means the pharmacist-in-charge.

"Production" or "produce" means the manufacture, planting, preparation, cultivation, growing, harvesting, propagation, conversion, or processing of marijuana, (i) directly or indirectly by extraction from substances of natural origin, (ii) independently by means of chemical synthesis, or (iii) by a combination of extraction and chemical synthesis. "Production" or "produce" includes any packaging or repackaging of the substance or labeling or relabeling of its container.

"Qualifying patient" means a Virginia resident or a person who temporarily resides in Virginia who has received from a practitioner, as defined in § 54.1-3408.3 of the Code of Virginia, a written certification for the use of cannabis oil for treatment of or to alleviate the symptoms of any diagnosed condition or disease.

"Registered patient" means a qualifying patient who has been issued a registration by the board for the dispensing of cannabis oil to such patient.

"Registration" means an identification card or other document issued by the board that identifies a person as a practitioner or a qualifying patient, parent, or legal guardian.

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

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

Room or Phase	Temperature	Humidity
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Mother room	65 - 75° 85° F	50% - 60% 75%
Nursery phase	74 65 - 85° F	65% 50% - 75%
Vegetation phase	74 65 - 85° F	55% 50% - 65% 75%
Flower/harvest phase	74 65 - 85° F	55% 40% - 60% 75%
Drying/extraction rooms	< 75° F	55% 40% - 60% 75%

"Temporarily resides" means a person that does not maintain a principle place of residence within Virginia but resides in Virginia on a temporary basis as evidenced by documentation substantiating such temporary residence.

18VAC110-60-20. Fees.

A. Fees are required by the board as specified in this section. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Registration of practitioner.

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

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

1. Initial registration of a patient.	\$50
2. Annual renewal of registration of a patient.	\$50
3. Initial registration of a parent or legal guardian.	\$25
4. Annual renewal of registration of a parent or guardian.	\$25
5. Replacement of registration for a qualifying patient, parent, or legal guardian whose original registration certificate has been lost, stolen, or destroyed.	\$25

D. Pharmaceutical processor permit.

1. Application.	\$10,000
2. Initial permit.	\$60,000
3. Annual renewal of permit.	\$10,000
4. Change of name of processor.	\$100
5. Change of PIC or any other information provided on the permit application.	\$100
6. Change of ownership not requiring a criminal background check.	\$100
7. Change of ownership requiring a criminal background check.	\$250
8. Any acquisition, expansion, remodel, or change of location requiring an inspection.	\$1,000
9. Reinspection fee.	\$1,000
10. Registration of each cannabis oil product.	\$25

E. Cannabis dispensing facility permit.

<u>1. Initial permit.</u>	<u>\$5.00</u> <u>0</u>
<u>2. Annual renewal of permit.</u>	<u>\$1.50</u> <u>0</u>
<u>3. Change of name of dispensing facility.</u>	<u>\$100</u>
<u>4. Change of PIC or any other information provided on the permit application.</u>	<u>\$100</u>
<u>5. Change of ownership not requiring a criminal background check.</u>	<u>\$100</u>
<u>6. Change of ownership requiring a criminal background check.</u>	<u>\$250</u>
<u>7. Any acquisition, expansion, remodel, or change of location requiring an inspection.</u>	<u>\$1.00</u> <u>0</u>
<u>8. Reinspection fee.</u>	<u>\$1.00</u> <u>0</u>

18VAC110-60-40. Prohibited practices for practitioners.

A. A practitioner who issues certifications shall not:

1. Directly or indirectly accept, solicit, or receive anything of value from any person associated with a pharmaceutical processor or provider of paraphernalia, excluding information on products or educational materials on the benefits and risks of cannabis oil;
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 cannabis oil product;
3. Examine a qualifying patient for purposes of diagnosing the condition or disease at a location where cannabis oil is dispensed or produced; or
4. Directly or indirectly benefit from a patient obtaining a certification. Such prohibition shall not prohibit a practitioner from charging an appropriate fee for the patient visit.

B. A practitioner who issues certifications, and such practitioner's coworker, employee, spouse, parent, or child, shall not have a direct or indirect financial interest in a pharmaceutical processor, a cannabis dispensing facility, or any other entity that may benefit from a qualifying patient's acquisition, purchase, or use of cannabis 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 cannabis oil product.

C. A practitioner shall not issue a certification for himself or for family members, employees, or coworkers.

D. A practitioner shall not provide product samples containing cannabis oil other than those approved by the U.S. Food and Drug Administration.

18VAC110-60-50. Registration of a patient, parent, or legal guardian.

A. A qualifying patient for whom a practitioner has issued a certification shall register with the board in accordance with this section. If the qualifying patient is a minor or an incapacitated adult, the qualifying patient's parent or legal guardian shall register with the board in accordance with this section. For a registration application to be considered complete, the following items shall be submitted:

1. A copy of the certification issued by a registered practitioner;
2. Proof of residency of the qualifying patient and proof of residency of a parent or legal guardian, if applicable, such as a government-issued identification card or tax receipt or proof of temporary residency, if applicable, such as a current academic identification card from a Virginia institution of higher learning, rental agreement, utility bill, or attestation on a form prescribed by the board that contains information sufficient to document temporary residency in Virginia;

3. Proof of identity of the qualifying patient and, if the patient is a minor, proof of identity of the parent or legal guardian in the form of a government-issued identification card;
4. Proof of the qualifying patient's age in the form of a birth certificate or other government-issued identification;
5. Payment of the appropriate fees; and
6. Such other information as the board may require to determine the applicant's suitability for registration or to protect public health and safety.

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

C. Patients, parents, and legal guardians issued a registration shall carry their registrations with them whenever they are in possession of cannabis oil.

18VAC110-60-60. Denial of a qualifying patient, parent, or legal guardian registration application.

A. The board may deny an application or renewal of the registration of a qualifying patient, 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 temporary 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, parent, or legal guardian denied, suspended, or revoked by the board in the previous six months;
5. Has a certification issued by a practitioner who is not authorized to certify patients for cannabis oil; or
6. Has a prior conviction of a violation of any law pertaining to controlled substances.

B. If the board denies an application or renewal of a qualifying patient, 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 of Virginia.

18VAC110-60-90. Revocation or suspension of a qualifying patient, parent, or legal guardian registration.

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

1. The patient's practitioner notifies the board that the practitioner is withdrawing the written certification submitted on behalf of the patient, and 30 days after the practitioner's withdrawal of the written certification the patient has not obtained a valid written certification from a different practitioner;
2. The patient, parent, or legal guardian provided false, misleading, or incorrect information to the board;
3. The patient, parent, or legal guardian is no longer a resident of Virginia or is no longer temporarily residing in Virginia;
4. The patient, parent, or legal guardian obtained more than a 90-day supply of cannabis oil in a 90-day period;
5. The patient, parent, or legal guardian provided or sold cannabis oil to any person, including another registered patient, parent, or legal guardian;
6. The patient, parent, or legal guardian permitted another person to use the registration of the patient, parent, or legal guardian;
7. The patient, parent, or legal guardian tampered, falsified, altered, modified, or allowed another person to tamper, falsify, alter, or modify the registration of the patient, parent, or legal guardian;
8. The registration of the patient, parent, or legal guardian was lost, stolen, or destroyed, and the patient, parent, or legal guardian failed to notify the board or notified the board of such incident more than five business days after becoming aware that the registration was lost, stolen, or destroyed;
9. The patient, parent, or legal guardian failed to notify the board of a change in registration information or notified the board of such change more than 14 days after the change; or
10. The patient, parent, or legal guardian violated any federal or state law or regulation.

Part III

Application and Approval Process for Pharmaceutical Processors and Cannabis Dispensing Facilities

18VAC110-60-100. Publication of notice for submission of applications for a pharmaceutical processor permit.

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

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

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

18VAC110-60-135. Application process for and granting of cannabis dispensing facility.

A. Pursuant to § 54.1-3442.6 of the Code of Virginia, the board may issue up to five cannabis dispensing facility permits for each health service area. A permit may be issued to a facility that is owned, at least in part, by the pharmaceutical processor located in that health service area for the dispensing of cannabis oil that has been cultivated and produced on the premises of a pharmaceutical processor. Each cannabis dispensing facility shall be located within the same health service area as the pharmaceutical processor.

B. A separate application and fee for each cannabis dispensing facility permit shall be submitted to the board, along with the following information and documentation:

1. The name and address of the facility, which shall not be within 1,000 feet of a school or daycare;
2. The name and address of the facility's owners with 5% or greater ownership;
3. Name and signature of pharmacist-in-charge practicing at the facility;
4. Details regarding the applicant's plans for security to maintain adequate control against the diversion, theft, or loss of cannabis oil products; and
5. Information necessary for the board to conduct a criminal background check on the applicant.

C. Prior to issuing the permit, an inspection of the facility shall be performed by an agent of the board. The permit shall not be awarded until any deficiency identified by inspectors has been corrected and the facility has been satisfactorily reinspected if warranted.

D. A cannabis dispensing facility shall comply with all state and local laws and ordinances.

E. A cannabis dispensing facility permit shall not be issued to any person to operate from a private dwelling or residence.

F. No person who has been convicted of (i) a felony under the laws of the Commonwealth or another jurisdiction or (ii) within the last five years, any offense in violation of Article 1 (§ 18.2-247 et seq.) or Article 1.1 (§ 18.2-265.1 et seq.) of Chapter 7 of Title 18.2 or a substantially similar offense under the laws of another jurisdiction shall be employed by or act as an agent of a pharmaceutical processor or cannabis dispensing facility.

G. If the cannabis dispensing facility is not operational within 90 days from the date the permit is issued, the board shall rescind the permit unless an extension is granted for good cause shown.

H. A cannabis dispensing facility shall be deemed to have commenced operation if it is in receipt of cannabis oil from a pharmaceutical processor.

I. Once the facility is in possession of cannabis oil, a pharmacist shall be on site at all times during the declared hours of operation.

18VAC110-60-136. Denial of a cannabis dispensing facility permit application.

A. The board may deny an application for a cannabis dispensing facility if the applicant:

1. Submits an incomplete, false, inaccurate, or misleading application;
2. Fails to pay all applicable fees; or
3. Fails to comply with all requirements for a cannabis dispensing facility.

B. If the board denies an application of cannabis dispensing facility, 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 of Virginia.

18VAC110-60-140. Notification of changes by pharmaceutical processor or cannabis dispensing facility.

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 or cannabis dispensing facility shall provide any notification or information that is required from a pharmaceutical processor or cannabis dispensing facility.

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

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

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

2. Cannabis, oil acquired from industrial hemp extract, or cannabis oil shall not be moved to a new location until approval is granted by the inspector or board staff.

18VAC110-60-150. Pharmaceutical processor or cannabis dispensing facility closings; going out of business; change of ownership.

A. At least 30 days prior to the date a pharmaceutical processor or cannabis dispensing facility closes, either temporarily or permanently, the owner shall:

1. Notify the board;

2. Send written notification to patients with current certification; and

3. Post a notice on the window or door of the pharmaceutical processor or cannabis dispensing facility.

B. The proposed disposition of all Cannabis, oil from industrial hemp, cannabis oil, dispensing records, patient information records, and other required records, as applicable, shall be reported to the board. If the Cannabis, oils, and records are to be transferred to another processor located in Virginia or to another cannabis dispensing facility in the same health service area, the owner shall inform the board and the patients and include on the public notice the name and address of the processor or cannabis dispensing facility to whom the Cannabis, oils, and records are being transferred and the date of transfer.

C. 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 or cannabis dispensing facility is not able to meet the notification requirements, the owner shall ensure that the board and public are properly notified as soon as the owner knows of the closure and shall disclose the emergency circumstances preventing the notification within the required deadlines.

D. 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.

E. At least 14 days prior to any change in ownership of an existing pharmaceutical processor or cannabis dispensing facility, the owner shall notify the board of the pending change.

1. Upon any change in ownership of an existing pharmaceutical processor or cannabis dispensing facility, 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.

3. If a new owner's share constitutes 5.0% or greater of the total ownership, the new owner shall submit to fingerprinting and the criminal history record search required by of § 54.1-3442.6 E of the Code of Virginia.

18VAC110-60-160. Grounds for action against a pharmaceutical processor permit or cannabis dispensing facility.

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

1. Any criminal conviction under federal or state statutes or regulations or local ordinances, unless the conviction was based on a federal statute or regulation related to the possession, purchase, or sale of cannabis oil that is authorized under state law and regulations;
2. Any civil action under any federal or state statute or regulation or local ordinance (i) relating to the applicant's, licensee's, permit holder's, or registrant's profession or (ii) involving drugs, medical devices, or fraudulent practices, including fraudulent billing practices;
3. Failure to maintain effective controls against diversion, theft, or loss of Cannabis, cannabis oil, or other controlled substances;
4. Intentionally or through negligence obscuring, damaging, or defacing a permit or registration card;
5. Permitting another person to use the permit of a permit holder or registration of a qualifying patient, parent, or legal guardian;
6. Failure to cooperate or give information to the board on any matter arising out of conduct at a pharmaceutical processor; or
7. Discontinuance of business for more than 60 days, unless the board approves an extension of such period for good cause shown upon a written request from a pharmaceutical processor or cannabis dispensing facility. 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~~ cannabis dispensing facility.

Part IV

Requirements for Pharmaceutical Processor or Cannabis Dispensing Facility Personnel

18VAC110-60-170. Pharmaceutical processor or cannabis dispensing facility employee licenses and registrations.

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

~~B. A pharmacist with a current, unrestricted license issued by the board shall provide personal supervision on the premises of the pharmaceutical processor at all times during hours of operation or whenever the processor is being accessed. Except when employees authorized by the PIC pursuant to § 54.1-3442.6 of the Code of Virginia access the secured area designated for cultivation, the pharmacist on duty at the pharmaceutical processor or cannabis dispensing facility shall directly supervise the activities in all areas designated for cultivation, extraction, and dispensing, and the pharmaceutical processor or cannabis dispensing facility shall not operate or be accessed when no pharmacist is on duty. The PIC shall ensure security measures are adequate to protect cannabis from diversion at all times.~~

C. A person who holds a current, unrestricted registration as a pharmacy technician pursuant to § 54.1-3321 of the Code of Virginia and who has had at least two years of experience practicing as a pharmacy technician may perform the following duties under supervision of a pharmacist:

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

D. A pharmacist with a current, unrestricted license; a registered pharmacy intern who has completed the first professional year of pharmacy school; or a pharmacy technician with a current, unrestricted registration issued by the board may perform duties associated with the cultivation, extraction, and dispensing of the oils as authorized by the PIC or as otherwise authorized in law.

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

F. A person who does not maintain licensure as a pharmacist or registration as a pharmacy technician but has received a degree in chemistry or pharmacology or has at least two years of experience extracting chemicals from plants may perform duties associated with the extraction of cannabis oil as authorized by the PIC.

~~G. A pharmacist on duty shall directly supervise the activities in all areas designated for cultivation, extraction, and dispensing or have a process in place, approved by the board, that provides adequate supervision to protect the security of the Cannabis, seeds, extracts, and cannabis oil and shall ensure quality of the dispensed oils. Pursuant to § 54.1-3442.6 of the Code of Virginia, the PIC may authorize certain employee access to secured areas designated for cultivation. No pharmacist shall be required to be on the premises during such authorized access. The PIC shall ensure security measures are adequate to protect the cannabis from diversion at all times. A pharmaceutical processor may employ individuals who may have less than two years of experience to perform (i) cultivation-related duties under the supervision of an individual who has received a degree in horticulture or a certification recognized by the board or who has at least two years of experience cultivating plants and (ii) extraction-related duties under the supervision of an individual who has a degree in chemistry or pharmacology or at least two years of experience extracting chemicals from plants.~~

~~H. Except for certain employee access to secured areas designated for cultivation and authorized by the PIC pursuant § 54.1-3442.6 of the Code of Virginia, at no time shall a pharmaceutical processor operate or be accessed without a pharmacist on duty.~~

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

~~J. I. No person who has had a license or registration suspended or revoked or been denied issuance of such license or registration shall serve as an employee or agent of the pharmaceutical processor or cannabis dispensing facility unless such license or registration has been reinstated and is current and unrestricted.~~

18VAC110-60-180. Employee training.

A. All employees of a pharmaceutical processor or cannabis dispensing facility shall complete training prior to the employee commencing work at the pharmaceutical processor or cannabis dispensing facility. At a minimum, the training shall be in the following areas:

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

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

C. The PIC shall assure the continued competency of all employees through continuing in-service training that is provided at least annually, is designed to supplement initial training, and includes any guidance specified by the board.

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

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

5. The signatures of the person receiving the training and the PIC.

E. When a change of pharmaceutical processor or cannabis dispensing facility 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 or cannabis dispensing facility shall maintain the record documenting the employee training and make it available in accordance with regulations.

18VAC110-60-190. Pharmacy technicians; ratio; supervision and responsibility.

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

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

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

C. Pharmacy technicians shall not:

1. Counsel a registered patient or the patient's parent or legal guardian regarding (i) cannabis oil or other drugs either before or after cannabis oil has been dispensed or (ii) 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 cannabis oil or any other drug the patient may be taking;
3. Interpret the patient's clinical data or provide medical advice;
4. Determine whether a different formulation of cannabis oil should be substituted for the cannabis oil product or formulation recommended by the practitioner or requested by the registered patient or parent or legal guardian; or
5. Communicate with a practitioner who certified a registered patient, or the practitioner's agent, to obtain a clarification on a qualifying patient's written certification or instructions.

18VAC110-60-200. Responsibilities of the PIC.

A. ~~No person shall be PIC for more than one pharmaceutical processor or for one processor and a pharmacy~~ The PIC of a pharmaceutical processor shall not serve as PIC of any other facility at any one time. A processor shall employ the PIC at the pharmaceutical processor for at least 35 hours per week, except as otherwise authorized by the board. A person may serve simultaneously as the PIC for no more than two cannabis dispensing facilities located within the same health service area at any one time.

B. The PIC or the pharmacist on duty shall control all aspects of the practice of the pharmaceutical processor or cannabis dispensing facility. Any decision overriding such control of the PIC or other pharmacist on duty may be grounds for disciplinary action against the pharmaceutical processor or cannabis dispensing facility permit.

C. The PIC of a pharmaceutical processor ~~PIC~~ or cannabis dispensing facility shall be responsible for ensuring that:

1. Pharmacy technicians are registered and all employees are properly trained;
2. All record retention requirements are met;
3. All requirements for the physical security of the Cannabis, to include the seeds, any parts or extracts of the Cannabis plants and the cannabis oil are met;
4. The pharmaceutical processor or cannabis dispensing facility has appropriate pharmaceutical reference materials to ensure that cannabis oil can be properly dispensed;
5. The following items are conspicuously posted in the pharmaceutical processor or cannabis dispensing facility in a location and in a manner so as to be clearly and readily identifiable to registered patients, parents, or legal guardians:
 - a. Pharmaceutical processor permit or cannabis dispensing facility permit;
 - b. Licenses for all pharmacists practicing at the pharmaceutical processor or cannabis dispensing facility; and

c. The price of all cannabis oil products offered by the pharmaceutical processor or cannabis dispensing facility; and

6. Any other required filings or notifications are made on behalf of the pharmaceutical processor or dispensing facility as set forth in regulation.

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

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

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

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

Part V

Operation of a Pharmaceutical Processor or Cannabis Dispensing Facility

18VAC110-60-210. General provisions.

A. A pharmaceutical processor or cannabis dispensing facility shall sell cannabis oil only in a child-resistant, secure, and light-resistant container. Upon a written request from the registered patient, 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.

B. Only a pharmacist may dispense cannabis oil to registered patients or parents or legal guardians of patients who are minors or incapacitated adults and who are registered with the board. A pharmacy technician who meets the requirements of 18VAC110-60-170 C may assist, under the direct supervision of a pharmacist, in the dispensing and selling of cannabis oil.

C. The PIC or pharmacist on duty shall restrict access to the pharmaceutical processor or cannabis dispensing facility to:

1. A person whose responsibilities necessitate access to the pharmaceutical processor or cannabis dispensing facility and then for only as long as necessary to perform the person's job duties; or
2. A person who is a registered patient, parent, or legal guardian, in which case such person shall not be permitted behind the service counter or in other areas where Cannabis plants, extracts, or cannabis oil is stored.

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

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

F. A pharmaceutical processor or cannabis dispensing facility shall be open for registered patients, parents, or legal guardians to purchase cannabis oil products for a minimum of 35 hours a week, except as otherwise authorized by the board.

G. A pharmaceutical processor or cannabis dispensing facility that closes during its normal hours of operation shall implement procedures to notify registered patients, parents, and legal guardians of when the pharmaceutical processor or cannabis dispensing facility will resume normal hours of operation. Such procedures may include telephone system messages and conspicuously posted signs. If the pharmaceutical processor or cannabis dispensing facility is or will be closed during its normal hours of operation for longer than two business days, the pharmaceutical processor or cannabis dispensing facility shall immediately notify the board.

H. A pharmacist shall counsel registered patients, parents, and legal guardians regarding the use of cannabis oil. Such counseling shall include information related to safe techniques for proper use and storage of cannabis oil and for disposal of the oils in a manner that renders them nonrecoverable.

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

18VAC110-60-220. Pharmaceutical processor and cannabis dispensing facility prohibitions.

A. No pharmaceutical processor shall:

1. Cultivate Cannabis plants or produce or dispense cannabis 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 cannabis oil, to any other facility except for the wholesale distribution of cannabis oil products between pharmaceutical processors and to a cannabis dispensing facility;
3. Produce or manufacture cannabis oil for use outside of Virginia; or
4. Provide cannabis oil samples.

B. No cannabis dispensing facility shall:

1. Dispense cannabis oil in any place except the approved facility at the address of record on the application for the cannabis dispensing facility permit;
2. Sell, deliver, transport, or distribute cannabis oil to any other facility, except that it may distribute cannabis oil back to the pharmaceutical processor from which it obtained the oil; or
3. Provide cannabis oil samples.

C. Except for certain employee access to secured areas designated for cultivation and authorized by the PIC pursuant to § 54.1-3442.6 of the Code of Virginia, no pharmaceutical processor or cannabis dispensing facility shall be open or in operation, and no person shall be in the pharmaceutical processor or cannabis dispensing facility, unless a pharmacist is on the premises and directly supervising the activity within the pharmaceutical processor or cannabis dispensing facility. At all other times, the pharmaceutical processor or cannabis dispensing facility shall be closed and properly secured.

~~C.~~ D. No pharmaceutical processor or cannabis dispensing facility shall sell anything other than cannabis oil products ~~from the pharmaceutical processor~~ except for devices for administration of dispensed products.

~~D.~~ E. A pharmaceutical processor or cannabis dispensing facility shall not advertise cannabis oil products, except it may post the following information on websites:

1. Name and location of the processor or facility;
2. Contact information for the processor or facility;
3. Hours and days the pharmaceutical processor or cannabis dispensing facility is open for dispensing cannabis oil products;
4. Laboratory results;
5. Product information and pricing; and
6. Directions to the processor or facility.

~~E.~~ F. No cannabis oil shall be consumed on the premises of a pharmaceutical processor or cannabis dispensing facility, except for emergency administration to a registered patient.

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

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

1. An employee shall escort and monitor an authorized visitor at all times the visitor is in the pharmaceutical processor or cannabis dispensing facility.
2. A visitor shall visibly display the visitor identification badge at all times the visitor is in the pharmaceutical processor or cannabis dispensing facility and shall return the visitor identification badge to ~~a pharmaceutical processor~~ an employee upon exiting the ~~pharmaceutical processor~~ or facility.
3. All visitors shall log in and out. The pharmaceutical processor or cannabis dispensing facility shall maintain the visitor log that shall include the date, time, and purpose of the visit and that shall be available to the board.
4. If an emergency requires the presence of a visitor and makes it impractical for the pharmaceutical processor or cannabis dispensing facility to obtain a waiver from the board, the processor or facility 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 or cannabis dispensing facility shall monitor the visitor and maintain a log of such visit as required by this subsection.

~~H. I.~~ I. No cannabis oil shall be sold, dispensed, or distributed via a delivery service or any other manner outside of a pharmaceutical processor or cannabis dispensing facility, except that a registered parent or legal guardian or an agent of the processor or cannabis dispensing facility may deliver cannabis oil to the registered patient or in accordance with 18VAC110-60-310 A.

~~I. J.~~ J. Notwithstanding the requirements of subsection F of this section, an agent of the board or local law enforcement or other federal, state, or local government officials may enter any area of a pharmaceutical processor or cannabis dispensing facility if necessary to perform their governmental duties.

18VAC110-60-230. Inventory requirements.

A. Each pharmaceutical processor or cannabis dispensing facility prior to commencing business shall:

1. Conduct an initial comprehensive inventory of all Cannabis plants, including the seeds, parts of plants, extracts, and cannabis oil, at the facility. The inventory shall include, at a minimum, the date of the inventory, a summary of the inventory findings, and the name, signature, and title of the pharmacist or pharmacy technician who conducted the inventory. If a facility commences business with no Cannabis or cannabis oil on hand, the pharmacist shall record this fact as the initial inventory; and
2. Establish ongoing inventory controls and procedures for the conduct of inventory reviews and comprehensive inventories of all Cannabis plants, including the seeds, parts of plants, extracts, and cannabis oil, that shall enable the facility to detect any diversion, theft, or loss in a timely manner.

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

C. Upon commencing business, each cannabis dispensing facility shall maintain a perpetual inventory of all cannabis oil products received and dispensed that accurately indicates the physical count of each cannabis oil product on-hand at the time of performing the inventory. The perpetual inventory shall include a reconciliation of each cannabis oil product at least monthly with a written explanation for any difference between the physical count and the theoretical count.

~~D.~~ D. The record of all cannabis oil sold, dispensed, or otherwise disposed of shall show the date of sale or disposition; the name of the pharmaceutical processor; the name and address of the registered patient, parent, or legal guardian to whom the cannabis oil was sold; the kind and quantity of cannabis oil sold or disposed of; and the method of disposal.

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

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

~~F.~~ G. Inventory records shall be maintained for three years from the date the inventory was taken.

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

18VAC110-60-240. Security requirements.

A. A pharmaceutical processor shall initially cultivate only the number of Cannabis plants necessary to produce cannabis oil for the number of patients anticipated within the first nine months of operation. Thereafter, the processor shall:

1. Not maintain more than 12 Cannabis plants per patient at any given time based on dispensing data from the previous 90 days; and
2. Not maintain cannabis oil in excess of the quantity required for normal, efficient operation;

B. At no time shall a cannabis dispensing facility maintain cannabis oil in excess of the quantity required for normal, efficient operation.

C. Items a pharmaceutical processor shall properly secure include Cannabis plants, seeds, parts of plants, extracts and cannabis oil. A cannabis dispensing facility shall properly secure cannabis oil. To secure these items a pharmaceutical processor and a cannabis dispensing facility shall:

- ~~3.~~ 1. Maintain all Cannabis plants, seeds, parts of plants, extracts, and cannabis oil in a secure area or location accessible only by the minimum number of authorized employees essential for efficient operation;
- ~~4.~~ 2. Store all cut parts of Cannabis plants, extracts, or cannabis oil in an approved safe or approved vault within the pharmaceutical processor or cannabis dispensing facility and not sell cannabis oil products when the pharmaceutical processor or cannabis dispensing facility is closed;
- ~~5.~~ 3. Keep all approved safes, approved vaults, or any other approved equipment or areas used for the production, cultivation, harvesting, processing, manufacturing, or storage of cannabis oil securely locked or protected from entry, except for the actual time required to remove or replace the Cannabis, seeds, parts of plants, extracts, or cannabis oil;
- ~~6.~~ 4. Keep all locks and security equipment in good working order;
- ~~7.~~ 5. Restrict access to keys or codes to all safes, approved vaults, or other approved equipment or areas to pharmacists practicing at the pharmaceutical processor or cannabis dispensing facility, except for persons authorized by the PIC and § 54.1-3442.6 of the Code of Virginia to access secured areas designated for cultivation when no pharmacist is on the premises; and
- ~~8.~~ Not allow keys to be left in the locks or accessible to non-pharmacists.

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

1. The device shall be a sound, microwave, photoelectric, ultrasonic, or other generally accepted and suitable device;
2. The device shall be monitored in accordance with accepted industry standards, be maintained in operating order, have an auxiliary source of power, and be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational;
3. The device shall fully protect the entire processor or facility and shall be capable of detecting breaking by any means when activated;
4. The device shall include a duress alarm, a panic alarm, and an automatic voice dialer; and
5. Access to the alarm system for the pharmaceutical processor or cannabis dispensing facility shall be restricted to the pharmacists working at the pharmaceutical processor or cannabis dispensing facility, and the system shall be activated whenever the ~~pharmaceutical~~ processor or facility is closed for business. Pursuant to § 54.1-3442.6

of the Code of Virginia, the PIC of a pharmaceutical processor may authorize certain employee access to secured areas designated for cultivation. No pharmacist shall be required to be on the premises during such authorized access. The PIC of a pharmaceutical processor or a cannabis dispensing facility shall ensure security measures are adequate to protect the Cannabis and cannabis oil from diversion at all times.

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

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

2. The video system shall have:

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

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

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

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

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

4. The processor or facility shall make 24-hour recordings from all video cameras available for immediate viewing by the board or the board's agent upon request and shall retain the recordings for at least 30 days. If a processor or facility is aware of a pending criminal, civil, or administrative investigation or legal proceeding for which a recording may contain relevant information, the processor or facility 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 or cannabis dispensing facility PIC that it is not necessary to retain the recording.

~~D.~~ F. The processor or facility shall maintain all security system equipment and recordings in a secure location so as to prevent theft, loss, destruction, or alterations. All security equipment shall be maintained in good working order and shall be tested at least every six months.

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

~~F.~~ H. If diversion, theft, or loss of Cannabis plants, seeds, parts of plants, extracts, or cannabis oil has occurred from a pharmaceutical processor, the board may require additional safeguards to ensure the security of the products.

18VAC110-60-250. Requirements for the storage and handling of Cannabis or cannabis oil.

A. A pharmaceutical processor or cannabis dispensing facility shall:

1. Have storage areas that provide adequate lighting, ventilation, sanitation, temperature, and humidity as defined in 18VAC110-60-10 and space, equipment, and security conditions for the cultivation of Cannabis and the production and dispensing of cannabis oil;
2. Separate for storage in a quarantined area Cannabis plants, seeds, parts of plants, extracts, including cannabis oil, that is outdated, damaged, deteriorated, misbranded, or adulterated, or whose containers or packaging have been opened or breached, until such Cannabis plants, seeds, parts of plants, extracts, or cannabis oil are destroyed;
3. Be maintained in a clean, sanitary, and orderly condition; and
4. Be free from infestation by insects, rodents, birds, or vermin of any kind.

B. A pharmaceutical processor shall compartmentalize all areas in the facility based on function and shall restrict access between compartments. The processor shall establish, maintain, and comply with written policies and procedures regarding best practices for the secure and proper cultivation of Cannabis and production of cannabis oil. These shall include policies and procedures that:

1. Restrict movement between compartments;
2. Provide for different colored identification cards for facility employees based on the compartment to which they are assigned at a given time so as to ensure that only employees necessary for a particular function have access to that compartment of the facility;
3. Require pocketless clothing for all ~~production facility~~ employees working in an area containing Cannabis plants, seeds, and extracts, including cannabis oil; and
4. Document the chain of custody of all Cannabis plants, parts of plants, seeds, extracts, and cannabis oil products.

C. A cannabis dispensing facility shall establish, maintain, and comply with written policies and procedures regarding best practices for the secure and proper dispensing of cannabis oil, including a requirement for pocketless clothing for all facility employees working in an area containing cannabis oil.

D. The PIC of a pharmaceutical processor or a cannabis dispensing facility shall establish, maintain, and comply with written policies and procedures for the cultivation, production, security, storage, and inventory of Cannabis, including the seeds, parts of plants, extracts, and the cannabis oil, as applicable. 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 and cannabis dispensing facilities shall include in their written policies and procedures a process for the following:

1. Handling mandatory and voluntary recalls of cannabis oil. The process shall be adequate to deal with recalls due to any action initiated at the request of the board and any voluntary action by the pharmaceutical processor or cannabis dispensing facility to (i) remove defective or potentially defective cannabis oil from the market or (ii) promote public health and safety by replacing existing cannabis oil with improved products or packaging;
2. Preparing for, protecting against, and handling any crises that affect the security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency;
3. Ensuring that any outdated, damaged, deteriorated, misbranded, or adulterated Cannabis, including seeds, parts of plants, extracts, and cannabis oil, is segregated from all other Cannabis, seeds, parts of plants, extracts, and cannabis oil and destroyed. This procedure shall provide for written documentation of the Cannabis, including seeds, parts of plants, extracts, and cannabis oil disposition; and
4. Ensuring the oldest stock of Cannabis, including seeds, parts of plants, extracts, and cannabis oil product is used first. The procedure may permit deviation from this requirement if such deviation is temporary and appropriate.

~~D.~~ E. The pharmaceutical processor shall store all Cannabis, including seeds, parts of plants, extracts, and cannabis oil, in the process of production, transfer, or analysis in such a manner as to prevent diversion, theft, or loss; shall make Cannabis, including the seeds, parts of plants, extracts, and cannabis oil accessible only to the minimum number of specifically authorized employees essential for efficient operation; and shall return the aforementioned items to their secure location immediately after completion of the production, transfer, or analysis process or at the end of the scheduled business day. If a production process cannot be completed at the end of a working day, the pharmacist shall securely lock the processing area or tanks, vessels, bins, or bulk containers containing Cannabis,

including the seeds, parts of plants, extracts, and cannabis oil, inside an area or building that affords adequate security.

F. The cannabis dispensing facility shall store all cannabis oil in such a manner as to prevent diversion, theft, or loss; shall make cannabis oil accessible only to the minimum number of specifically authorized employees essential for efficient operation; and shall return the oil to its secure location at the completion of the dispensing or at end of the scheduled business day.

18VAC110-60-251. Wholesale distribution of cannabis oil products.

A. Cannabis oil products from a batch that passed the microbiological, mycotoxin, heavy metal, residual solvent, and pesticide chemical residue tests and are packaged and labeled for sale with an appropriate expiration date in accordance with 18VAC110-60-300 may be wholesale distributed between pharmaceutical processors and between a pharmaceutical processor and a cannabis dispensing facility.

B. A pharmaceutical processor wholesale distributing the oil products shall create a record of the transaction that shows (i) the date of distribution, (ii) the names and addresses of the processor distributing the product and the processor or cannabis dispensing facility receiving the product, and (iii) the kind and quantity of product being distributed. The record of the transaction shall be maintained by the distributing pharmaceutical processor with its records of distribution, and a copy of the record shall be provided to and maintained by the processor or facility receiving the product in its records of receipt. Such records shall be maintained by each process or facility for three years in compliance with 18VAC110-60-260.

C. A pharmaceutical processor wholesale distributing the oil products shall provide the receiving processor or cannabis dispensing facility with a copy of the lab results for the distributed product or electronic access to the information that can be shared upon request to registered patients, parents, legal guardians, registered agents, registered practitioners who have certified qualifying patients, or an agent of the board.

D. A pharmaceutical processor wholesale distributing cannabis oil products shall store and handle products and maintain policies and procedures, to include a process for executing or responding to mandatory and voluntary recalls, in a manner that complies with 18VAC110-60-250.

E. If a pharmaceutical processor wholesale distributing cannabis oil products uses an electronic system for the storage and retrieval of records related to distributing cannabis oil, the pharmaceutical processor shall use a system that is compliant with 18VAC110-60-260.

18VAC110-60-260. Recordkeeping requirements.

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

1. Guarantees the confidentiality of the information contained in the system;
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.

B. All records relating to the inventory, laboratory results, and dispensing shall be maintained for a period of three years and shall be made available to the board upon request.

18VAC110-60-270. Reportable events; security.

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

B. A pharmacist, ~~or pharmaceutical processor, or cannabis dispensing facility~~ shall provide the notice required by subsection A of this section to the board by way of a signed statement that details the circumstances of the event, including an accurate inventory of the quantity and brand names of cannabis oil diverted, stolen, lost, destroyed, or damaged and confirmation that the local law-enforcement authorities were notified. A pharmacist, ~~or processor, or facility~~ shall make such notice no later than 24 hours after discovery of the event.

C. A pharmacist, ~~or pharmaceutical processor,~~ or cannabis dispensing facility shall notify the board no later than the next business day, followed by written notification no later than 10 business days, of any of the following:

1. An alarm activation or other event that requires a 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.

D. A pharmacist, ~~or pharmaceutical processor,~~ or cannabis dispensing facility shall immediately notify the board of an employee convicted of a felony or any offense referenced in § 54.1-3442.6 of the Code of Virginia.

18VAC110-60-300. Laboratory requirements; testing.

A. No pharmaceutical processor shall utilize a laboratory to handle, test, or analyze cannabis oil unless such laboratory:

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

3. Has obtained a controlled substances registration certificate pursuant to § 54.1-3423 of the Code of Virginia authorizing the testing of cannabis products.

4. Has provided proof to the board of accreditation in testing and calibration in accordance with the most current version of the International Standard for Organization and the ISO/IEC 17025 or proof that the laboratory has applied for accreditation in testing and calibration in the most current version of ISO/IEC 17025. Any testing and calibration method utilized to perform a Cannabis-related analysis for pharmaceutical processors shall be in accordance with the laboratory's ISO/IEC 17025 accreditation. The accrediting body shall be recognized by International Laboratory Accreditation Cooperation.

a. A laboratory applying for authorization to provide cannabis-related analytical tests for pharmaceutical processors shall receive ISO/IEC 17025 accreditation within two years from the date the laboratory applied for ISO/IEC 17025 accreditation. A laboratory may request, and the board may grant for good cause shown, additional time for the laboratory to receive ISO/IEC 17025 accreditation.

b. A laboratory shall send proof of ISO/IEC 17025 accreditation to the board for cannabis-related analytical test methods for pharmaceutical processors for which it has received ISO/IEC 17025 accreditation no later than five business days after the date in which the accreditation was received.

c. A laboratory may use nonaccredited analytical test methods so long as the laboratory has commenced an application for ISO/IEC 17025 accreditation for analytical test methods for cannabis-related analysis for pharmaceutical processors. No laboratory shall use nonaccredited analytical test methods for cannabis-related analysis for pharmaceutical processors if it has applied for and has not received ISO/IEC 17025 accreditation within two years. The laboratory may request and the board may grant for good cause shown additional time for the laboratory to utilize non-accredited analytical test methods for cannabis-related analysis.

d. At such time that a laboratory loses its ISO/IEC 17025 accreditation for any cannabis-related analytical test methods for pharmaceutical processors, it shall inform the board within twenty-four hours. The laboratory shall immediately stop handling, testing or analyzing Cannabis for pharmaceutical processors.

5. Complies with a transportation protocol for transporting Cannabis or cannabis oil products to or from itself or to or from pharmaceutical processors.

B. After processing and before dispensing the cannabis oil product, a pharmaceutical processor shall make a sample available from each homogenized batch of product for a laboratory to (i) test for microbiological

contaminants, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue and (ii) conduct an active ingredient analysis and terpenes profile. Each laboratory shall determine a valid sample size for testing, which may vary due to sample matrix, analytical method, and laboratory-specific procedures. A minimum sample size of 0.5% of individual units for dispensing or distribution from each homogenized batch is required to achieve a representative sample for analysis.

C. From the time that a batch of cannabis oil product has been homogenized for sample testing until the laboratory provides the results from its tests and analysis, the pharmaceutical processor shall segregate and withhold from use the entire batch, except the samples that have been removed by the laboratory for testing. During this period of segregation, the pharmaceutical processor shall maintain the batch in a secure, cool, and dry location so as to prevent the batch from becoming contaminated or losing its efficacy.

D. Under no circumstances shall a pharmaceutical processor or cannabis dispensing facility sell a cannabis oil product prior to the time that the laboratory has completed its testing and analysis and provided a certificate of analysis to the pharmaceutical processor or other designated facility employee.

E. The processor shall require the laboratory to immediately return or properly dispose of any cannabis oil products and materials upon the completion of any testing, use, or research.

F. If a sample of cannabis oil product does not pass the microbiological, mycotoxin, heavy metal, or pesticide chemical residue test based on the standards set forth in this subsection, the pharmaceutical processor shall dispose of the entire batch from which the sample was taken.

1. For purposes of the microbiological test, a cannabis oil sample shall be deemed to have passed if it satisfies the standards set forth in Section 1111 of the United States Pharmacopeia.

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

Test Specification	
Aflatoxin B1	<20 ug/kg of Substance
Aflatoxin B2	<20 ug/kg of Substance
Aflatoxin G1	<20 ug/kg of Substance
Aflatoxin G2	<20 ug/kg of Substance
Ochratoxin A	<20 ug/kg of Substance

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

Metal	Limits - parts per million (ppm)
Arsenic	<10 ppm
Cadmium	<4.1 ppm
Lead	<10 ppm
Mercury	<2 ppm

4. For purposes of the pesticide chemical residue test, a sample of cannabis oil product 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 Part 180.

5. For purposes of the active ingredient analysis, a sample of the cannabis oil product shall be tested for:

- a. Tetrahydrocannabinol (THC);
- b. Tetrahydrocannabinol acid (THC-A);
- c. Cannabidiols (CBD); and

d. Cannabidiolic acid (CBDA).

6. For the purposes of the residual solvent test, a sample of the cannabis oil product shall be deemed to have passed if it meets the standards and limits recommended by the American Herbal Pharmacopia for Cannabis Inflorescence. If a sample does not pass the residual solvents test, the batch can be remediated with further processing. After further processing, the batch must be retested for microbiological, mycotoxin, heavy metal, residual solvents, and pesticide chemical residue, and an active ingredient analysis and terpenes profile must be conducted.

G. If a sample of cannabis oil product passes the microbiological, mycotoxin, heavy metal, residual solvent, and pesticide chemical residue test, the entire batch may be utilized by the processor for immediate packaging and labeling for sale. An expiration date shall be assigned to the product that is based upon validated stability testing that addresses product stability when opened and the shelf-life for unopened products.

H. The processor shall require the laboratory to file with the board an electronic copy of each laboratory test result for any batch that does not pass the microbiological, mycotoxin, heavy metal, residual solvents, or pesticide chemical residue test at the same time that it transmits those results to the pharmaceutical processor. In addition, the laboratory shall maintain the laboratory test results and make them available to the board or an agent of the board.

I. Each pharmaceutical processor or cannabis dispensing facility shall have such laboratory results available upon request to registered patients, parents or legal guardians, ~~and~~ registered practitioners who have certified qualifying patients, the board, or an agent of the board.

18VAC110-60-310. Dispensing of cannabis oil.

A. A pharmacist in good faith may dispense cannabis oil to any registered patient, parent, or legal guardian as indicated on the written certification.

1. Prior to the initial dispensing of cannabis oil pursuant to each written certification, the pharmacist or pharmacy technician at the location of the pharmaceutical processor or cannabis dispensing facility shall view a current photo identification of the patient, parent, or legal guardian. The pharmacist or pharmacy technician shall verify in the Virginia Prescription Monitoring Program of the Department of Health Professions or other program recognized by the board that the registrations are current, the written certification has not expired, and the date and quantity of the last dispensing of cannabis oil to the registered patient.

2. The pharmacist or pharmacy technician shall make and maintain for three years a paper or electronic copy of the current written certification that provides an exact image of the document that is clearly legible.

3. Prior to any subsequent dispensing, the pharmacist, pharmacy technician, or delivery agent shall view the current written certification and a current photo identification and current registration of the patient, parent, or legal guardian and shall maintain record of such viewing in accordance with policies and procedures of the pharmaceutical processor or cannabis dispensing facility.

B. A pharmacist may dispense a portion of a registered patient's 90-day supply of cannabis oil. The pharmacist may dispense the remaining portion of the 90-day supply of cannabis oil at any time except that no registered patient, parent, or legal guardian shall receive more than a 90-day supply of cannabis oil in a 90-day period from any pharmaceutical processor or cannabis dispensing facility.

C. A dispensing record shall be maintained for three years from the date of dispensing, and the pharmacist or pharmacy technician under the direct supervision of the pharmacist shall affix a label to the container of oil that contains:

1. A serial number assigned to the dispensing of the oil;
2. The brand name of cannabis oil that was registered with the board pursuant to 18VAC110-60-285 and its strength;
3. The serial number assigned to the oil during production;
4. The date of dispensing the cannabis oil;
5. The quantity of cannabis oil dispensed;
6. A terpenes profile and a list of all active ingredients, including:
 - a. Tetrahydrocannabinol (THC);
 - b. Tetrahydrocannabinol acid (THC-A);

c. Cannabidiol (CBD); and

d. Cannabidiolic acid (CBDA);

7. A pass rating based on the laboratory's microbiological, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue analysis;

8. The name and registration number of the registered patient;

9. The name and registration number of the certifying practitioner;

10. Directions for use as may be included in the practitioner's written certification or otherwise provided by the practitioner;

11. The name or initials of the dispensing pharmacist;

12. Name, address, and telephone number of the pharmaceutical processor or cannabis dispensing facility;

13. Any necessary cautionary statement; and

14. A prominently printed expiration date based on stability testing and the pharmaceutical processor's or cannabis dispensing facility's recommended conditions of use and storage that can be read and understood by the ordinary individual.

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

E. The cannabis oil shall be dispensed in child-resistant packaging, except as provided in 18VAC110-60-210 A. 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).

F. 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.

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

H. A pharmacist shall document a registered patient's self-assessment of the effects of cannabis oil in treating the registered patient's diagnosed condition or disease or the symptoms thereof. A pharmaceutical processor or cannabis dispensing facility shall maintain such documentation in writing or electronically for three years from the date of dispensing and such documentation shall be made available in accordance with regulation.

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

18VAC110-60-320. Dispensing error review and reporting; quality assurance program.

A. A pharmaceutical processor or cannabis dispensing facility 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 or cannabis dispensing facility shall distribute the written policies and procedures to all pharmaceutical processor or cannabis dispensing facility employees and shall make the written policies and procedures readily available on the premises of the pharmaceutical processor or cannabis dispensing facility. The 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. The communication shall describe methods of correcting the dispensing error or reducing the negative impact of the error on the qualifying patient; and

2. A process to document and assess dispensing errors to determine the cause of the error and an appropriate response.

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

1. Inform pharmaceutical processor or cannabis dispensing facility employees of changes to policy, procedure, systems, or processes made as a result of recommendations generated by the quality assurance program;
2. Notify all processor or facility employees that the discovery or reporting of a dispensing error shall be relayed immediately to a pharmacist on duty;
3. Ensure that a pharmacist performs a quality assurance review for each dispensing error. A pharmacist shall commence such review as soon as is reasonably possible, but no later than two business days from the date the dispensing error is discovered; and
4. Create a record of every quality assurance review. This record shall contain at least the following:
 - a. The date of the quality assurance review and the names and titles of the persons performing the review;
 - b. The pertinent data and other information relating to the dispensing error reviewed;
 - c. Documentation of contact with the registered patient, parent, or legal guardian where applicable, and the practitioner who certified the patient;
 - d. The findings and determinations generated by the quality assurance review; and
 - e. Recommended changes to pharmaceutical processor or cannabis dispensing facility policy, procedure, systems, or processes if any.

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

18VAC110-60-321. Devices and inert product samples.

A. A pharmaceutical processor or cannabis dispensing facility may have for sale, on-site, devices intended for the administration of dispensed cannabis oil products.

B. The pharmaceutical processor or cannabis dispensing facility may use and distribute inert product samples that do not contain any active cannabinoids for patient demonstration exclusively at the pharmaceutical processor or cannabis dispensing facility without the need for a written certification. Such inert product samples may not be sold or further distributed.

18VAC110-60-330. Disposal of cannabis oil.

A. To mitigate the risk of diversion, a pharmaceutical processor shall routinely and promptly dispose of undesired, excess, unauthorized, obsolete, adulterated, misbranded, or deteriorated green waste, extracts, and cannabis oil, as applicable. Green waste includes Cannabis plants, including seeds, and parts of plants, extracts, or cannabis oil by disposal in accordance with a plan approved by the board and in a manner as to render the cannabis oil nonrecoverable. Green waste shall be weighed, ground, and combined with a minimum of 51% non-cannabis waste to render it unrecognizable.

B. The destruction and disposal of green waste, extracts, and cannabis oil, as applicable, shall be witnessed by ~~the PIC and an agent of the board or another pharmacist not employed by the pharmaceutical processor~~ a pharmacist and at least one other employee of the pharmaceutical processor or cannabis dispensing facility, respectively, and shall be conducted under video surveillance. The persons disposing of the green waste, extracts, or cannabis oil shall maintain and make available a separate record of each such disposal indicating:

1. The date and time of disposal;
2. The manner of disposal;
3. The name and quantity of ~~cannabis oil~~ product disposed of; and
4. The signatures of the persons destroying or disposing of the green waste, extracts, or cannabis oil.

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