TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF PHARMACY

Emergency Regulation

Title of Regulation: **18VAC110-60. Regulations Governing Pharmaceutical Processors (amending 18VAC110-60-10 through 18VAC110-60-40, 18VAC110-60-90, 18VAC110-60-110, 18VAC110-60-220, 18VAC110-60-240, 18VAC110-60-290, 18VAC110-60-310; adding 18VAC110-60-285, 18VAC110-60-295).**

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

Effective Dates: October 1, 2018, through February 6, 2019.

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Preamble:

Section 2.2-4011 of the Code of Virginia states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation 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. Emergency regulations governing issuance of a permit for a pharmaceutical processor to manufacture and provide cannabidiol oil and THC-A oil were published in 33:25 VA.R. 2818-2835 August 7, 2017, and became effective August 7, 2017.

The Board of Pharmacy adopted amendments to the August 7, 2017, emergency regulation to conform to Chapters 246, 809, and 567 of the 2018 Acts of the Assembly. The amendments include (i) expanding the conditions for which patients may receive a certification from a physician to possess cannabidiol oil or THC-A oil and the types of physicians who may issue a certification; (ii) increasing to 90 days, the supply of oil that can be dispensed and the number of plants a processor may cultivate per patient; (iii) requiring criminal background checks for applicants for pharmaceutical processor permits; (iv) allowing for delivery of the oil after the initial dispensing; (v) providing requirements for registration and labeling; and (vi) establishing a $25 fee for registration of each cannabidiol oil or THC-A product.

CHAPTER 60

REGULATIONS GOVERNING PHARMACEUTICAL PROCESSORS

Part I

General Provisions

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 cannabidiol oil or THC-A oil reasonably necessary to ensure an uninterrupted availability of supply for a 90-day period for registered patients, which cannot exceed 60 fluid ounces.]

"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 cannabidiol oil or THC-A oil for treatment or to alleviate the symptoms of [~~a patient's intractable epilepsy~~ any diagnosed condition or disease determined by the practitioner to benefit from such use].

"Code" means the Code of Virginia.

"Dispensing error" means an act or omission relating to the dispensing of cannabidiol oil or THC-A oil that results in, or may reasonably be expected to result in, injury to or death of a 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 cannabidiol oil and THC-A oil are 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.

[~~"Intractable epilepsy" means drug-resistant epilepsy (DRE), which is defined as failure of adequate trials of two tolerated, appropriately chosen and used antiepileptic drug schedules (whether as monotherapies or in combination) to achieve sustained seizure freedom.~~

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

[~~"One-month supply" means the amount of cannabidiol oil or THC-A oil reasonably necessary to ensure an uninterrupted availability of supply for a 30-day period for registered patients, which cannot exceed 20 fluid ounces.~~]

"PIC" means the pharmacist-in-charge.

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

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

"Qualifying patient" means a Virginia resident who has received [from a practitioner, as defined in § 54.1-3408.3 of the Code,] a written certification for the use of cannabidiol oil or THC-A oil for treatment of [~~intractable epilepsy~~ or to alleviate the symptoms of any diagnosed condition or disease ~~from a practitioner, as defined in § 54.1-3408.3 of the Code~~].

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

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

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

Room or Phase	Temperature	Humidity
Mother room	65 - 75°	50% - 60%
Nursery phase	77 - 85° F	65% - 75%
Vegetation phase	77 - 85° F	55% - 65%
Flower/harvest phase	77 - 85° F	55% - 60%
Drying/extraction rooms	< 75° F	55% - 60%

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 or by a parent or legal guardian.

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

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. Any acquisition, expansion, remodel, or change of location requiring an inspection	$1,000
7. Reinspection fee	$1,000
[8. Registration of each cannabidiol oil or THC-A oil product	$25]

Part II

Requirements for Practitioners and Patients

18VAC110-60-30. 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~~ any diagnosed condition or disease], the practitioner shall meet the requirements of § 54.1-3408.3 of the Code, shall submit an application and fee as prescribed in 18VAC110-60-20, and shall be registered with the board.

B. A practitioner issuing a certification shall:

1. 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;

2. Diagnose the patient [~~as having intractable epilepsy~~];

3. 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;

4. Explain proper administration and 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;

5. Be available or ensure that another practitioner, as defined in § 54.1-3408.3 of the Code, is available to provide follow-up care and treatment to the qualifying patient, including physical examinations, to determine the efficacy of cannabidiol oil or THC-A oil for treating the [~~intractable epilepsy~~ diagnosed condition or disease];

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

8. Maintain medical records for all patients for whom the practitioner has issued a certification in accordance with 18VAC85-20-26; and

9. [~~Be registered with and able to access~~ Access or direct the practitioner's delegate to access the Virginia Prescription Monitoring Program for the purpose of determining which, if any, covered substances have been dispensed to the patient].

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

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

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

F. 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 Board of Pharmacy and Board of Medicine for an increased number of patients for whom certifications may be issued, upon submission of evidence that the limitation represents potential patient harm.

G. Upon request, a practitioner shall make a copy of medical records available to an agent of the Board of Medicine or Board of Pharmacy for the purpose of enabling the board to ensure compliance with the law and regulations or to investigate a possible violation.

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;

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~~ the condition or disease] at a location where cannabidiol oil or THC-A oil is dispensed or produced; or

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

B. A practitioner who issues certifications, and such practitioner's coworker, employee, spouse, parent, or child, shall not have a direct or indirect financial interest in a pharmaceutical processor or any other entity that may benefit from a qualifying patient's acquisition, purchase, or use of cannabidiol oil or THC-A oil, including any formal or informal agreement whereby a pharmaceutical processor or other person provides compensation if the practitioner issues a certification for a qualifying patient or steers a qualifying patient to a specific pharmaceutical processor or cannabidiol oil or THC-A oil product.

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

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

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, a parent, or a 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;

4. The patient, parent, or legal guardian obtained more than a [~~one-month~~ 90-day] supply of cannabidiol oil or THC-A oil in a [~~one-month~~ 90-day] period;

5. The patient, parent, or legal guardian provided or sold cannabidiol oil or THC-A 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 patient, parent, or legal guardian's registration;

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

8. The patient, parent, or legal guardian's registration was lost, stolen, or destroyed, and the patient, parent, or legal guardian failed to notify the board or notified the board of such

incident more than five business days after becoming aware that the registration was lost, stolen, or destroyed;

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

10. The patient, parent, or legal guardian violated any federal or state law or regulation.

Part III

Application and Approval Process for Pharmaceutical Processors

18VAC110-60-110. Application process for pharmaceutical processor permits.

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

B. Submission of initial application.

1. A pharmaceutical processor permit applicant shall submit the required application fee and form with the following information and documentation:

a. The name and address of the applicant and the applicant's owners;

b. The location within the health service area established by the State Board of Health for the pharmaceutical processor that is to be operated under such permit;

c. Detailed information regarding the applicant's financial position, indicating all assets, liabilities, income, and net worth, to demonstrate the financial capacity of the applicant to build and operate a facility to cultivate Cannabis plants intended only for the production and dispensing of cannabidiol oil and THC-A oil pursuant to §§ 54.1-3442.6 and 54.1-3442.7 of the Code of Virginia, which may include evidence of an escrow account, letter of credit, or performance surety bond;

d. Details regarding the applicant's plans for security to maintain adequate control against the diversion, theft, or loss of the Cannabis plants and the cannabidiol oil or THC-A oil;

e. 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 are met or will be met prior to issuance of a permit;

f. Information necessary for the board to conduct a criminal background check on [~~owners and any other person who is employed by or acts as an agent of the proposed pharmaceutical processor~~ applicants];

g. Information about any previous or current involvement in the medical cannabidiol oil or THC-A oil industry;

h. Whether the person has ever applied for a permit or registration related to medical cannabidiol oil or THC-A oil in any state and, if so, the status of that application, permit, or registration, to include any disciplinary action taken by any state on the permit, the registration, or an associated license;

i. Any business and marketing plans related to the operation of the pharmaceutical processor or the sale of cannabidiol oil or THC-A oil;

j. Text and graphic materials showing the exterior appearance of the proposed pharmaceutical processor;

k. A blueprint of the proposed pharmaceutical processor, which shall show and identify the square footage of each area of the facility, to include the location of all safes or vaults used to store the Cannabis plants and oils and the location of all areas that may contain Cannabis

plants, cannabidiol oil, or THC-A oil, showing the placement of walls, partitions, counters, and all areas of ingress and egress;

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

m. 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; and

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

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

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

C. In the event the board determines that there are no qualified applicants to award conditional approval for a pharmaceutical processor permit in a health service area, the board may republish, in accordance with 18VAC110-60-100, a notice of open applications for pharmaceutical processor permits.

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

Part V
Operation of a Pharmaceutical Processor

18VAC110-60-220. Pharmaceutical processor prohibitions.

A. No pharmaceutical processor shall:

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

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

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

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

B. 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.

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

D. A pharmaceutical processor shall not [~~market or~~] advertise cannabidiol oil or THC-A oil products, except it may post the following information on websites:

1. Name and location of the processor;

2. Contact information for the processor;

3. Hours and days the pharmaceutical processor is open for dispensing cannabidiol oil or THC-A oil products;

4. Laboratory results; and

5. Directions to the processor facility.

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

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

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

1. An employee shall escort and monitor such a visitor at all times the visitor is in the pharmaceutical processor.

2. A visitor shall visibly display the visitor identification badge at all times the visitor is in the pharmaceutical processor and shall return the visitor identification badge to a pharmaceutical processor employee upon exiting the pharmaceutical processor.

3. All visitors shall log in and out. The pharmaceutical processor shall maintain the visitor log, which shall include the date, time, and purpose of the visit, and 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 to obtain a waiver from the board, the processor shall provide written notice to the board as soon as practicable after the onset of the emergency. Such notice shall include the name and company affiliation of the visitor, the purpose of the visit, and the date and time of the visit. A pharmaceutical processor shall monitor the visitor and maintain a log of such visit as required by this subsection.

H. No cannabidiol oil or THC-A oil shall be sold, dispensed, or distributed via a delivery service or any other manner outside of a pharmaceutical processor, except that a registered parent or legal guardian may deliver cannabidiol oil or THC-A oil to the registered patient [or in accordance with 18VAC110-60-310 A].

I. Notwithstanding the requirements of subsection [~~E~~ F] of this section, 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.

18VAC110-60-240. Security requirements.

A. A pharmaceutical processor shall initially cultivate only the number of Cannabis plants necessary to produce cannabidiol oil or THC-A oil for the number of patients anticipated within the first [~~three~~ nine] months of operation. Thereafter, the processor shall:

1. Not maintain more than [~~four~~ 12] Cannabis plants per patient at any given time based on dispensing data from the previous [~~30~~ 90] days;

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

3. Maintain all Cannabis plants, seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil in a secure area or location accessible only by the minimum number of authorized employees essential for efficient operation;

4. Store all cut parts of Cannabis plants, extracts, cannabidiol oil, or THC-A oil in an approved safe or approved vault within the pharmaceutical processor and shall not sell cannabidiol oil or THC-A oil products when the pharmaceutical processor is closed;

5. Keep all approved safes, approved vaults, or any other approved equipment or areas used for the production, cultivation, harvesting, processing, manufacturing, or storage of cannabidiol oil or THC-A oil securely locked or protected from entry, except for the actual time required to remove or replace the Cannabis, seeds, parts of plants, extracts, cannabidiol oil, or THC-A oil;

6. Keep all locks and security equipment in good working order;

7. Restrict access to keys or codes to all safes, approved vaults, or other approved equipment or areas to pharmacists practicing at the pharmaceutical processor; and

8. Not allow keys to be left in the locks or accessible to nonpharmacists.

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

1. The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device;

2. The device shall be monitored in accordance with accepted industry standards, maintained in operating order, have an auxiliary source of power, and be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational;

3. The device shall fully protect the entire processor facility and shall be capable of detecting breaking by any means when activated;

4. The device shall include a duress alarm, a panic alarm, and automatic voice dialer; and

5. Access to the alarm system for the pharmaceutical processor shall be restricted to the pharmacists working at the pharmaceutical processor and the system shall be activated whenever the pharmaceutical processor is closed for business.

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

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

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

4. The processor 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 is aware of a pending criminal, civil, or administrative investigation or legal proceeding for which a recording may contain relevant information, it shall retain an unaltered copy of the recording until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the pharmaceutical processor PIC that it is not necessary to retain the recording.

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

E. A pharmaceutical processor shall limit access to surveillance areas to persons 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 shall make available a current list of authorized employees and security system service employees who have access to the surveillance room to the processor. The pharmaceutical processor shall keep all onsite surveillance rooms locked and shall not use such rooms for any other function.

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

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

[18VAC110-60-285. Registration of products.

A. A pharmaceutical processor shall assign a brand name to each product of cannabidiol oil or THC-A oil. The pharmaceutical processor shall register each brand name with the board, on a form prescribed by the board, prior to any dispensing and 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. Cannabidiols (CBD);

4. Cannabidiolic acid (CBDA); and

5. Any other active ingredient that constitutes at least 1.0% of the batch used in the product.

B. A pharmaceutical processor shall not label two 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 in subsection A of this section within a range of 97% to 103%.

C. The board shall not register any brand name that:

1. Is identical to, or confusingly similar to, the name of an existing commercially available 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 marijuana, cannabidiol oil, or THC-A oil for recreational purposes;

6. May encourage the use of cannabidiol oil or THC-A oil for a disease or condition other than the disease or condition the practitioner intended to treat;

7. Is customarily associated with persons younger than 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.]

18VAC110-60-290. Labeling of batch of cannabidiol oil or THC-A oil products.

[~~A.~~] Cannabidiol oil or THC-A oil produced [~~for dispensing~~ as a batch] shall not be adulterated and shall be:

1. Processed, packaged, and labeled according to the Food and Drug Administration's Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements," 21 CFR Part 111; and

2. Labeled with [~~the results of an active ingredient analysis, a microbiological contaminants analysis, a mycotoxin analysis, a heavy metal analysis, and a pesticide chemical residue analysis that have been completed on a batch basis by a laboratory~~:

a. The name and address of the pharmaceutical processor;

b. The brand name of the cannabidiol oil or THC-A oil product that was registered with the board pursuant to 18VAC110-20-285;

c. A unique serial number that will match the product with the pharmaceutical processor batch and lot number so as to facilitate any warnings or recalls the board or pharmaceutical processor deem appropriate;

d. The date of final testing and packaging;

e. The expiration date;

f. The quantity of cannabidiol oil or THC-A oil contained therein;

g. A terpenes profile and a list of all active ingredients, including:

(1) Tetrahydrocannabinol (THC);

(2) Tetrahydrocannabinol acid (THCA);

(3) Cannabidiol (CBD);

(4) Cannabidiolic acid (CBDA); and

(5) Any other active ingredient that constitute at least 1.0% of the batch used in the product; and

h. A pass or fail rating based on the laboratory's microbiological, mycotoxins, and heavy metals and chemical residue analysis].

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

~~1. Tetrahydrocannabinol (THC);~~

~~2. Tetrahydrocannabinol acid (THC-A); and~~

~~3. Cannabidiol (CBD).~~

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

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

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

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

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

~~4. Is obscene or indecent;~~

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

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

~~7. Is customarily associated with persons younger than the age of 18 years; or~~

~~8. Is related to the benefits, safety, or efficacy of the cannabidiol oil or THC-A oil product unless supported by substantial evidence or substantial clinical data.~~

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

~~1. The name of the cannabidiol oil or THC-A oil;~~

~~2. A unique serial number that will match the product with a pharmaceutical processor batch and lot number so as to facilitate any warnings or recalls the board or pharmaceutical processor deem appropriate;~~

~~3. The date of final testing and packaging;~~

~~4. An appropriate expiration date, not to exceed six months;~~

~~5. The quantity of cannabidiol oil or THC-A oil contained therein;~~

~~6. A terpenes profile and a list of all active ingredients, including:~~

~~a. Tetrahydrocannabinol (THC);~~

~~b. Tetrahydrocannabinol acid (THC-A); and~~

~~c. Cannabidiol (CBD); and~~

~~7. A pass or fail rating based on the laboratory's microbiological, mycotoxins, heavy metals, and chemical residue analysis.~~

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

18VAC110-60-295. Labeling of dispensed cannabidiol oil or THC-A oil.

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

1. The brand name of the cannabidiol oil or THC-A oil that was registered with the board pursuant to 18VAC110-20-285;

2. A serial number as assigned by the pharmaceutical processor;

3. The date of dispensing the cannabidiol oil or THC-A oil;

4. An appropriate expiration date, not to exceed six months;

5. The quantity of cannabidiol oil or THC-A oil contained therein;

6. A terpenes profile and a list of all active ingredients, including:

a. Tetrahydrocannabinol (THC);

b. Tetrahydrocannabinol acid (THC-A); and

c. Cannabidiol (CBD);

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

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

9. The name of the certifying practitioner;

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

11. Name and address of the pharmaceutical processor; and

12. Any cautionary statement as may be required by statute or regulation.

B. No person except a pharmacist or pharmacist technician under the direct supervision of a pharmacist at the pharmaceutical processor shall alter, deface, or remove any label so affixed.

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

18VAC110-60-310. Dispensing of cannabidiol oil or THC-A oil.

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

[~~A pharmacist or pharmacy technician shall require the presentation of a current registration for the patient and parent or legal guardian, if applicable, current written certification and current valid photographic identification issued to a registered patient, parent, or legal~~

~~guardian, prior to selling oil to such registered patient, parent, or legal guardian.~~ 1. Prior to the initial dispensing of oil pursuant to each written certification, the pharmacist or pharmacy technician at the location of the pharmaceutical processor shall view a current photo identification of the patient, parent, or legal guardian.] The pharmacist or pharmacy technician shall verify in the prescription monitoring program 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 cannabidiol oil or THC-A oil to the registered patient.

[2. The pharmacist or pharmacy technician shall make and maintain for two 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 processor.]

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

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 which contains:

1. A serial number assigned to the dispensing of the oil;

2. The name or kind of cannabidiol oil or THC-A oil and its strength;

3. The serial number assigned to the oil during production;

4. The date of dispensing the cannabidiol oil or THC-A oil;

5. The quantity of cannabidiol oil or THC-A oil dispensed, which cannot exceed [~~20~~ 60] fluid ounces;

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

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

8. Such directions for use as may be included in the practitioner's written certification or otherwise provided by the practitioner;

9. The name or initials of the dispensing pharmacist;

10. Name, address, and telephone number of the pharmaceutical processor;

11. Any cautionary statement as may be necessary; and

12. A prominently printed expiration date based on the pharmaceutical processor's recommended conditions of use and storage that can be read and understood by the ordinary individual.

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

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

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

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

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

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