Commonwealth of Virginia

REGULATIONS

CANNABIS CONTROL AUTHORITY

VIRGINIA Cannabis Control Authority

Title of Regulations: 3 VAC 10-10 et seq.

Statutory Authority: §§ 4.1-604, 4.1-605, 4.1-606 and Chapter 16

of Title 4.1 of the *Code of Virginia*

Effective Date: January 01, 2024

Cannabis Control Authority

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Preface

AGENCY SUMMARY

The Virginia Cannabis Control Authority ("CCA" or "Authority") is responsible for the regulation of legal cannabis in the Commonwealth. Code of Virginia, Title 4.1, Subtitle II, Chapter 6. This mission includes regulatory oversight and administration of the Commonwealth's existing medical cannabis program (effective January 1, 2024) and potential regulation of any future adult-use retail market created by the General Assembly.

The Authority is an independent political subdivision of the Commonwealth, exclusive of the legislative, executive, or judicial branches of state government. A five-person Board of Directors guides and is ultimately responsible for the governance of the Authority. A Chief Executive Officer manages the day-to-day work of the CCA. The Governor appoints and the General Assembly confirms both the board and the CEO. A career, nonpolitical staff of employees reports to the CEO and, via the CEO, to the board. Code of Virginia, Title 4.1, Subtitle II, Chapter 6.

The CCA is advised by the Cannabis Public Health Advisory Council ("Advisory Council"), a 21-member advisory group comprised of health experts. The Governor and General Assembly appoint members of the Advisory Council and the Secretary of Health and Human Resources chairs the group. The Advisory Council's responsibilities include assessing and monitoring public health issues, trends, and impacts related to cannabis. It also must approve in advance certain public health-related regulations the CCA intends to issue. CCA staff support the work of the Advisory Council, establishing agendas for its meetings, providing the research and analysis necessary for the council's operations, and liaising with the Office of the Secretary of Health and Human Resources. Code of Virginia, Title 4.1, Subtitle II, Chapter 6.

In addition to its rulemaking and regulatory enforcement roles on legal cannabis matters, the CCA also is responsible for creating and disseminating guidance and other resources on how to engage with cannabis legally and safely. The CCA's public health and safety responsibilities also include development and implementation of a safe driving campaign that highlights the dangers of drug-impaired driving.

The Authority operates under the supervision of the Secretary of Public Safety and Homeland Security. The CCA can be contacted at rules@cca.virginia.gov, and it is located at 333 East Franklin Street, Richmond, Virginia 23219.

3VAC10-10. Public Participation Guidelines

Part I. Purpose and Definitions

3VAC10-10-10. Purpose.

The purpose of this chapter is to promote public involvement in the development, amendment or repeal of the regulations of the Virginia Cannabis Control Authority. This chapter does not apply to regulations, guidelines, or other documents exempted or excluded from the provisions of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).

3VAC10-10-20. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Administrative Process Act" means Chapter 40 (§ 2.2-4000 et seq.) of Title 2.2 of the Code of Virginia.

"Agency" means the Virginia Cannabis Control Authority, which is the unit of state government empowered by the agency's basic law to make regulations or decide cases. Actions specified in this chapter may be fulfilled by state employees as delegated by the agency.

"Basic law" means provisions in the Code of Virginia that delineate the basic authority and responsibilities of an agency.

"Commonwealth Calendar" means the electronic calendar for official government meetings open to the public as required by § 2.2-3707 C of the Freedom of Information Act.

"Negotiated rulemaking panel" or "NRP" means an ad hoc advisory panel of interested parties established by an agency to consider issues that are controversial with the assistance of a facilitator or mediator, for the purpose of reaching a consensus in the development of a proposed regulatory action.

"Notification list" means a list used to notify persons pursuant to this chapter. Such a list may include an electronic list maintained through the Virginia Regulatory Town Hall or other list maintained by the agency.

"Open meeting" means any scheduled gathering of a unit of state government empowered by an agency's basic law to make regulations or decide cases, which is related to promulgating, amending or repealing a regulation.

"Person" means any individual, corporation, partnership, association, cooperative, limited liability company, trust, joint venture, government, political subdivision, or any other legal or commercial entity and any successor, representative, agent, agency, or instrumentality thereof.

"Public hearing" means a scheduled time at which members or staff of the agency will meet for the purpose of receiving public comment on a regulatory action.

"Regulation" means any statement of general application having the force of law, affecting the rights or conduct of any person, adopted by the agency in accordance with the authority conferred on it by applicable laws.

"Regulatory action" means the promulgation, amendment, or repeal of a regulation by the agency.

"Regulatory advisory panel" or "RAP" means a standing or ad hoc advisory panel of interested parties established by the agency for the purpose of assisting in regulatory actions.

"Town Hall" means the Virginia Regulatory Town Hall, the website operated by the Virginia Department of Planning and Budget at www.townhall.virginia.gov, which has online public comment forums, displays information about regulatory meetings and regulatory actions under consideration in Virginia, and sends this information to registered public users.

"Virginia Register" means the Virginia Register of Regulations, the publication that provides official legal notice of new, amended and repealed regulations of state agencies, which is published under the provisions of Article 6 (§ 2.2-4031 et seq.) of the Administrative Process Act.

Part II. Notification of Interested Person

3VAC10-10-30. Notification list.

A. The agency shall maintain a list of persons who have requested to be notified of regulatory actions being pursued by the agency.

B. Any person may request to be placed on a notification list by registering as a public user on the Town Hall or by making a request to the agency. Any person who requests to be placed on a notification list shall elect to be notified either by electronic means or through a postal carrier.

C. The agency may maintain additional lists for persons who have requested to be informed of specific regulatory issues, proposals, or actions.

D. When electronic mail is returned as undeliverable on multiple occasions at least 24 hours apart, that person may be deleted from the list. A single undeliverable message is insufficient cause to delete the person from the list.

E. When mail delivered by a postal carrier is returned as undeliverable on multiple occasions, that person may be deleted from the list.

F. The agency may periodically request those persons on the notification list to indicate their desire to either continue to be notified electronically, receive documents through a postal carrier, or be deleted from the list.

3VAC10-10-40. Information to be sent to persons on the notification list.

A. To persons electing to receive electronic notification or notification through a postal carrier as described in 3VAC5-11-30, the agency shall send the following information:

1. A notice of intended regulatory action (NOIRA).

2. A notice of the comment period on a proposed, a reproposed, or a fast-track regulation and hyperlinks to, or instructions on how to obtain, a copy of the regulation and any supporting documents.

3. A notice soliciting comment on a final regulation when the regulatory process has been extended pursuant to § 2.2-4007.06 or 2.2-4013 C of the Code of Virginia.

B. The failure of any person to receive any notice or copies of any documents shall not affect the validity of any regulation or regulatory action.

Part III. Public Participation Procedures

3VAC10-10-50. Public comment.

A. In considering any nonemergency, nonexempt regulatory action, the agency shall afford interested persons an opportunity to submit data, views, and arguments, either orally or in writing, to the agency. Such opportunity to comment shall include an online public comment forum on the Town Hall.

1. To any requesting person, the agency shall provide copies of the statement of basis, purpose, substance, and issues; the economic impact analysis of the proposed or fast-track regulatory action; and the agency's response to public comments received.

2. The agency may begin crafting a regulatory action prior to or during any opportunities it provides to the public to submit comments.

B. The agency shall accept public comments in writing after the publication of a regulatory action in the Virginia Register as follows:

1. For a minimum of 30 calendar days following the publication of the notice of intended regulatory action (NOIRA).

2. For a minimum of 60 calendar days following the publication of a proposed regulation.

3. For a minimum of 30 calendar days following the publication of a reproposed regulation.

4. For a minimum of 30 calendar days following the publication of a final adopted regulation.

5. For a minimum of 30 calendar days following the publication of a fast-track regulation.

6. For a minimum of 21 calendar days following the publication of a notice of periodic review.

7. Not later than 21 calendar days following the publication of a petition for rulemaking.

C. The agency may determine if any of the comment periods listed in subsection B of this section shall be extended.

D. If the Governor finds that one or more changes with substantial impact have been made to a proposed regulation, he may require the agency to provide an additional 30 calendar days to solicit additional public comment on the changes in accordance with § 2.2-4013 C of the Code of Virginia.

E. The agency shall send a draft of the agency's summary description of public comment to all public commenters on the proposed regulation at least five days before final adoption of the regulation pursuant to § 2.2-4012 E of the Code of Virginia.

3VAC10-10-60. Petition for rulemaking.

A. As provided in § 2.2-4007 of the Code of Virginia, any person may petition the agency to consider a regulatory action.

B. A petition shall include but is not limited to the following information:

1. The petitioner's name and contact information;

2. The substance and purpose of the rulemaking that is requested, including reference to any applicable Virginia Administrative Code sections; and

3. Reference to the legal authority of the agency to take the action requested.

C. The agency shall receive, consider and respond to a petition pursuant to § 2.2-4007 and shall have the sole authority to dispose of the petition.

D. The petition shall be posted on the Town Hall and published in the Virginia Register.

E. Nothing in this chapter shall prohibit the agency from receiving information or from proceeding on its own motion for rulemaking.

3VAC10-10-70. Appointment of regulatory advisory panel.

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

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

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

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

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

3VAC10-10-80. Appointment of negotiated rulemaking panel.

A. The agency may appoint a negotiated rulemaking panel (NRP) if a regulatory action is expected to be controversial.

B. An NRP that has been appointed by the agency may be dissolved by the agency when:

1. There is no longer controversy associated with the development of the regulation;

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

3. The agency determines that resolution of a controversy is unlikely.

3VAC10-10-90. Meetings.

Notice of any open meeting, including meetings of a RAP or NRP, shall be posted on the Virginia Regulatory Town Hall and Commonwealth Calendar at least seven working days prior to the date of the meeting. The exception to this requirement is any meeting held in accordance with § 2.2-3707 D of the Code of Virginia allowing for contemporaneous notice to be provided to participants and the public.

3VAC10-10-100. Public hearings on regulations.

A. The agency shall indicate in its notice of intended regulatory action whether it plans to hold a public hearing following the publication of the proposed stage of the regulatory action.

B. The agency may conduct one or more public hearings during the comment period following the publication of a proposed regulatory action.

C. An agency is required to hold a public hearing following the publication of the proposed regulatory action when:

1. The agency's basic law requires the agency to hold a public hearing;

2. The Governor directs the agency to hold a public hearing; or

3. The agency receives requests for a public hearing from at least 25 persons during the public comment period following the publication of the notice of intended regulatory action.

D. Notice of any public hearing shall be posted on the Town Hall and Commonwealth Calendar at least seven working days prior to the date of the hearing. The agency shall also notify those persons who requested a hearing under subdivision C 3 of this section.

3VAC10-10-110. Periodic review of regulations.

A. The agency shall conduct a periodic review of its regulations consistent with:

1. An executive order issued by the Governor pursuant to § 2.2-4017 of the Administrative Process Act to receive comment on all existing regulations as to their effectiveness, efficiency, necessity, clarity, and cost of compliance; and

2. The requirements in § 2.2-4007.1 of the Administrative Process Act regarding regulatory flexibility for small businesses.

B. A periodic review may be conducted separately or in conjunction with other regulatory actions.

C. Notice of a periodic review shall be posted on the Town Hall and published in the Virginia Register.

3VAC10-20. Definitions and General Provisions

3VAC10-20-10. Definitions.

In addition to words and terms defined in § 4.1-600 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 products reasonably necessary to ensure an uninterrupted availability of supply for a 90-day period for patients with a valid, unexpired written certification issued by a practitioner for the use of cannabis products.

"Batch" means a quantity of (i) cannabis oil from a production lot or (ii) harvested botanical cannabis product that is identified by a batch number or other unique identifier.

"Board" means the Board of Directors of the Cannabis Control Authority.

"Cannabis cultivation facility" means a location at which the board has authorized a pharmaceutical processor to cultivate cannabis plants pursuant to § 4.1-1602 of the Code of Virginia and the requirements of 3VAC10-30-250.

"Certification" means a written statement, consistent with requirements of § 4.1-1601 of the Code of Virginia, issued by a practitioner for the use of cannabis products for treatment of or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use.

"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 product is sold to a patient, parent, legal guardian, or registered agent 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.

"Medical cannabis advertising" means the act of providing consideration for the publication, dissemination, solicitation, or circulation of visual, oral, or written communication through any means to directly induce any

person to patronize a particular pharmaceutical processor or cannabis dispensing facility or to purchase particular approved cannabis products. Advertising includes marketing.

“Medical cannabis facility” means a pharmaceutical processor, cannabis dispensing facility, or cannabis cultivation facility.

"On duty" means that a pharmacist, the responsible party, or a person who is qualified to provide supervision in accordance with 3VAC10-30-160 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 products received, dispensed, or otherwise distributed by a cannabis dispensing facility.

"PIC" means the pharmacist-in-charge whose name is on the pharmaceutical processor or cannabis dispensing facility application for a permit that has been issued and who shall have oversight of the processor's dispensing area or cannabis dispensing facility.

"Production" or "produce" means the manufacture, planting, preparation, cultivation, growing, harvesting, propagation, conversion, or processing of marijuana for the creation of usable cannabis, botanical cannabis, or a cannabis product derived thereof, (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 who has received from a practitioner, as defined in § 4.1-1600 of the Code of Virginia, a written certification for the use of cannabis products for treatment of or to alleviate the symptoms of any diagnosed condition or disease.

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

"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.

"Responsible party" means the person designated on the pharmaceutical processor application who shall have oversight of the cultivation and production areas of the pharmaceutical processor.

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

3VAC10-20-20. 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 by a qualifying patient, parent, legal guardian, or registered agent. (Registration is voluntary.)

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. Initial registration or annual renewal of a registered agent	$25
6. Replacement of registration for a qualifying patient, parent, legal guardian, or registered agent whose original registration certificate has been lost, stolen, or destroyed.	$25

C. Pharmaceutical processor permit.

1. Application.	$18,000
2. Initial permit.	$165,000
3. Annual renewal of permit.	$132,000
4. Change of name of processor.	$200
5. Change of PIC or responsible party or any other information provided on the permit application.	$200
6. Change of ownership not requiring a criminal background check.	$200
7. Change of ownership requiring a criminal background check.	$500
8. Any acquisition, expansion, remodel, or change of location requiring an inspection.	$5,000
9. Reinspection fee.	$5,000
10. Registration of each cannabis product.	$50

D. Cannabis dispensing facility permit.

1. Application.	$5,000
2. Initial permit.	$80,000
3. Annual renewal of permit.	$64,000

4. Change of name of dispensing facility.	$200
5. Change of PIC or any other information provided on the permit application.	$200
6. Change of ownership not requiring a criminal background check.	$200
7. Change of ownership requiring a criminal background check.	$500
8. Any acquisition, expansion, remodel, or change of location requiring an inspection.	$5,000
9. Reinspection fee.	$5,000

E. Cannabis cultivation facility permit.

1. Application.	$5,000
2. Initial permit.	$80,000
3. Annual renewal of permit.	$64,000
4. Change of PIC or any other information provided on the permit application.	$200
5. Change of ownership not requiring a criminal background check.	$200
6. Change of ownership requiring a criminal background check.	$500
7. Any acquisition, expansion, remodel, or change of location requiring an inspection.	$5,000
8. Reinspection fee.	$5,000

F. The handling fee for returned check or dishonored credit card or debit card shall be $50.

3VAC10-30. Applications, Licenses, Permits, and Registrations

3VAC10-30-100. Requirements for practitioner issuing a certification.

A. Prior to issuing a certification for cannabis products for any diagnosed condition or disease, the practitioner shall meet the requirements of § 4.1-1601 of the Code of Virginia.

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;

2. Diagnose the patient;

3. Be of the opinion that the potential benefits of cannabis products would likely outweigh the health risks of such use to the qualifying patient;

4. Authorize on the written certification the use of botanical cannabis for a minor patient if the practitioner determines such use is consistent with the standard of care to dispense botanical cannabis to a minor. If not specifically included on the initial written certification, authorization for botanical cannabis may be communicated verbally or in writing to the pharmacist at the time of dispensing;

5. Explain proper administration and the potential risks and benefits of the cannabis product to the qualifying patient and, if the qualifying patient lacks legal capacity, to a parent or legal guardian prior to issuing the written certification;

6. Be available or ensure that another practitioner, as defined in § 4.1-1600 of the Code of Virginia, is available to provide follow-up care and treatment to the qualifying patient, including physical examinations, to determine the efficacy of cannabis products for treating the 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 cannabis products;

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

9. Access or direct the practitioner's delegate to access the Virginia Prescription Monitoring Program of the Department of Health Professions for the purpose of determining which, if any, covered substances have been dispensed to the patient.

C. The practitioner shall use his professional judgment to determine the manner and frequency of patient care and evaluation, which may include the use of telemedicine, provided that the use of telemedicine:

1. Includes the delivery of patient care through real-time interactive audio-visual technology;

2. Conforms to the standard of care expected for in-person care; and

3. Transmits information in a manner that protects patient confidentiality.

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 cannabis products to the patient, parent, or guardian, as applicable, and shall also securely transmit such instructions to the permitted pharmaceutical processor.

F. 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.

3VAC10-30-110. 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 products;

2. Offer a discount or any other thing of value to a qualifying patient, parent, guardian, or registered agent based on the patient's agreement or decision to use a particular pharmaceutical processor or cannabis product;

3. Examine a qualifying patient for purposes of diagnosing the condition or disease at a location where cannabis products are 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 products, 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 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 other than those approved by the U.S. Food and Drug Administration.

3VAC10-30-120. Registration of a patient, parent, legal guardian, or registered agent.

A. A qualifying patient, or a parent or legal guardian of a minor or vulnerable adult, for whom a practitioner has issued a certification may voluntarily request registration in accordance with this section. For issuance of a registration, the following items shall be submitted:

1. A copy of the certification issued by a 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 patient, or the patient's parent or legal guardian, may choose a registered agent to receive cannabis products on behalf of the patient. An individual may serve as a registered agent for no more than two patients. For a voluntary registration application to be approved, the following shall be submitted:

1. The name, address, and birthdate of each patient for whom the individual intends to act as a registered agent;

2. A copy of the written certification, issued to the patient, for the use of cannabis products for treatment of or to alleviate the symptoms of any diagnosed condition or disease;

3. Proof of identity in the form of a copy of a government-issued identification card;

4. Payment of the applicable fee; and

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

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

3VAC10-30-130. Denial of a patient, parent, legal guardian, or registered agent registration application.

A. The board may deny an application or renewal of the registration of a registered agent, or the voluntary registration or renewal of a 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 registration request denied, or registered agent status denied, suspended, or revoked by the board in the previous six months;

5. Has presented a certification issued by a practitioner who is not authorized to certify patients for cannabis products; 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 patient, parent, legal guardian, or registered agent 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.

3VAC10-30-140. Reporting requirements for practitioners, patients, parents, legal guardians, or registered agents.

A. A practitioner shall report to the board, on a form prescribed by the board, the death of a patient or a change in status of a patient for whom the practitioner has issued a certification if such change affects the patient's continued eligibility to use cannabis products or the practitioner's inability to continue treating the patient. A practitioner shall report such death, change of status, or inability to continue treatment not more than 15 days after the practitioner becomes aware of such fact.

B. A patient, parent, or legal guardian who has been issued a registration shall notify the board of any change in the information provided to the board not later than 15 days after such change. The patient, parent, or legal guardian shall report changes that include a change in name, address, contact information, medical status of the patient, or change of the certifying practitioner. The patient, parent, or legal guardian shall report such changes on a form prescribed by the board.

C. A registered agent who has been issued a registration shall notify the board of any change in the information provided to the board not later than 15 days after such change, to include a change in the identifying information of the patient for whom he is serving as a registered agent.

D. If a patient, parent, legal guardian, or registered agent notifies the board of any change that results in information on the registration of the patient, parent, legal guardian, or registered agent being inaccurate, the board shall issue a replacement registration. Upon receipt of a new registration, the qualifying patient, parent, legal guardian, or registered agent shall destroy in a nonrecoverable manner the registration that was replaced.

E. If a patient, parent, legal guardian, or registered agent becomes aware of the loss, theft, or destruction of the registration of such patient, parent, legal guardian, or registered agent, the registrant shall notify the board not

later than five business days after becoming aware of the loss, theft, or destruction, and submit the fee for a replacement registration. The board shall issue a replacement registration upon receiving the applicable fee, provided the applicant continues to satisfy the requirements of law and regulation.

3VAC10-30-150. Invalidation of the voluntary registration of a patient, parent, legal guardian, or registered agent.

The board may invalidate the voluntary registration of a patient, parent, legal guardian, or registered agent 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 voluntarily registered patient, parent, legal guardian, or registered agent provided false, misleading, or incorrect information to the board;

3. The voluntarily registered patient is no longer a resident of Virginia or is no longer temporarily residing in Virginia;

4. The voluntarily registered patient, parent, legal guardian, or registered agent obtained more than a 90-day supply of cannabis products in a 90-day period;

5. The voluntarily registered patient, parent, legal guardian, or registered agent sold or improperly provided cannabis products to any person, including another registered agent;

6. The voluntarily registered patient, parent, legal guardian, or registered agent permitted another person to use the registration of the voluntarily registered patient, parent, legal guardian, or registered agent, except as required for a registered agent to act on behalf of a patient;

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

8. The registration of the voluntarily registered patient, parent, legal guardian, or registered agent was lost, stolen, or destroyed, and the voluntarily registered patient, parent, legal guardian, or registered agent 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 voluntarily registered patient, parent, legal guardian, or registered agent failed to notify the board of a change in registration information or notified the board of such change more than 15 days after the change; or

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

3VAC10-30-160. Medical cannabis facility employee licenses and registrations.

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

B. A pharmacist with a current, unrestricted license issued by the Board of Pharmacy shall provide personal supervision on the premises of the dispensing area of the pharmaceutical processor or of a cannabis dispensing facility at all times during its hours of operation, unless all cannabis products are contained in a vault or other similar container to which only the pharmacist has access controls.

C. The person who is designated as the responsible party for a pharmaceutical processor shall practice at the location of the address on the pharmaceutical processor application, shall have oversight of the cultivation and production areas, and shall possess:

1. A current, unrestricted license as a pharmacist issued by the Board of Pharmacy;

2. A degree in chemistry, pharmacology, or a field related to the cultivation of plants;

3. A certification recognized by the board; or

4. At least two years of verifiable experience cultivating plants or extracting chemicals from plants.

D. A person who holds a current, unrestricted registration as a pharmacy technician pursuant to § 54.1-3321 of the Code of Virginia 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 cannabis product or patient information;

3. The removal of the cannabis product to be dispensed from inventory;

4. The measuring of the cannabis product to be dispensed;

5. The packaging and labeling of the cannabis product to be dispensed and the repackaging thereof;

6. The packaging and labeling of bulk cannabis oil, botanical cannabis, and usable cannabis intended to be wholesale distributed pursuant to 3VAC10-40-100;

7. The stocking or loading of devices used in the dispensing process;

8. The selling of the cannabis product to the patient, parent, legal guardian or registered agent; and

9. The performance of any other task restricted to pharmacy technicians by the board of pharmacy's regulations.

E. 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 of Pharmacy may perform duties associated with the cultivation and extraction as authorized by the pharmaceutical processor, and duties associated with the dispensing of the products as authorized by the PIC or as otherwise authorized in law.

F. A pharmaceutical processor may employ individuals with less than two years of experience to perform cultivation-related duties under the supervision of an individual who has received a degree in a field related to the cultivation of plants or a certification recognized by the board or who has at least two years of experience cultivating plants.

G. A pharmaceutical processor may employ individuals with less than two years of experience to perform 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. At no time shall the dispensing area of a pharmaceutical processor operate or be accessed without a pharmacist on duty. At no time shall the cultivation and production area operate or be accessed without an employee on duty who satisfies the requirements for providing direct supervision for the activities in the respective areas.

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

J. 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 medical cannabis facility unless such license or registration has been reinstated and is current and unrestricted.

3VAC10-30-200. Publication of notice for submission of applications.

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

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

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

3VAC10-30-210. Application process for pharmaceutical processor permits.

A. The application process for permits shall occur in three stages: submission of initial application, award of conditional approval, and grant 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 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 cannabis products pursuant to §§ 4.1-1602 and 4.1-1603 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 cannabis products;

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 the applicant;

g. Information about any previous or current involvement in the medical cannabis industry;

h. Whether the applicant has ever applied for a permit or registration related to medical cannabis 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 cannabis products;

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

k. A blueprint of the proposed pharmaceutical processor that shall show and identify (i) the square footage of each area of the facility; (ii) the location of all safes or vaults used to store the cannabis plants and products; (iii) the location of all areas that may contain cannabis plants or cannabis products; (iv) the placement of walls, partitions, and counters; and (v) 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 cannabis products 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 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 3VAC10-30-200, a notice of open applications for pharmaceutical processor permits.

D. No person who has been convicted of a felony under the Code of Virginia or another jurisdiction within the last five years shall have a 5.0% or greater ownership, be employed by, or act as an agent of a pharmaceutical processor.

3VAC10-30-220. Conditional approval.

A. Following the deadline for receipt of applications, the board shall evaluate each complete and timely submitted application and may grant conditional approval on a competitive basis based on compliance with requirements set forth in 3VAC10-30-210.

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

1. The results of the criminal background checks required in 3VAC10-30-210 B 3 or any history of disciplinary action imposed by a state or federal regulatory agency;

2. The location for the proposed pharmaceutical processor, which shall not be within 1,000 feet of a school or daycare;

3. The applicant's ability to maintain adequate control against the diversion, theft, and loss of the cannabis, to include the seeds, any parts or extracts of the cannabis plants or the cannabis products;

4. The applicant's ability to maintain the knowledge, understanding, judgment, procedures, security controls, and ethics to ensure optimal safety and accuracy in the dispensing and sale of cannabis products;

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

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

C. The board may disqualify any applicant who:

1. Submits an incomplete, false, inaccurate, or misleading application;

2. Fails to submit an application by the published deadline;

3. Fails to pay all applicable fees; or

4. Fails to comply with all requirements for a pharmaceutical processor.

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

E. If granted conditional approval, an applicant shall have one year from date of notification to complete all requirements for issuance of a permit, to include employment of a PIC, responsible party, and other personnel necessary for operation of a pharmaceutical processor, construction or remodeling of a facility, installation of equipment, and securing local zoning approval.

3VAC10-30-230. Granting of a pharmaceutical processor permit.

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

1. Designation of a PIC and responsible party;

2. Evidence of criminal background checks for all employees and delivery agents of the pharmaceutical processor to ensure compliance with § 4.1-1602 of the Code of Virginia;

3. Evidence of utilization of an electronic tracking system; and

4. A satisfactory inspection of the facility conducted by agents of the board.

B. The board shall not award a permit until the pharmaceutical processor has corrected any deficiency identified by inspectors and, if warranted, the facility has been satisfactorily reinspected.

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

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

E. A pharmaceutical processor shall be deemed to have commenced operation if cannabis plants are under cultivation by the processor in accordance with the approved application.

F. In the event a permit is rescinded pursuant to this section, the board may award a pharmaceutical processor permit by selecting from among the qualified applicants who applied for the pharmaceutical processor permit subject to rescission. If no other qualified applicant who applied for such pharmaceutical processor permit satisfied the criteria for awarding a permit, the board shall publish in accordance with this section a notice of open applications for a pharmaceutical processor permit.

G. Once the permit is issued, a processor may begin cultivation of cannabis, and the responsible party or a person who is qualified to provide supervision in accordance with 3VAC10-30-160 shall be present during hours of operation to ensure the safety, security, and integrity of the cannabis. Once cannabis has been placed in the dispensing area of the pharmaceutical processor, a pharmacist shall be present during hours of operation to ensure the safety, security, and integrity of the cannabis. The responsible party shall ensure security measures are adequate to protect the cannabis in the cultivation and production area from diversion at all times, and the PIC shall have concurrent responsibility for preventing diversion from the dispensing area. If there is a change in the designated opening date, the pharmaceutical processor shall notify the board office, and a pharmacist or the responsible party shall continue to be on site on a daily basis.

3VAC10-30-240. Application for and granting of a permit for a cannabis dispensing facility.

A. Pursuant to § 4.1-1602 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 products that have 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 5.0% 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 products; and

5. Information necessary for the board to conduct a criminal background check on the facilities' owners with 5.0% or greater ownership.

C. Prior to issuing the permit, an agent of the board shall perform an inspection of the facility. 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 a felony under the laws of the Commonwealth or another jurisdiction within the last five years shall be employed by or act as an agent of a 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 products from a pharmaceutical processor.

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

3VAC10-30-245. Denial of a cannabis dispensing facility permit application.

A. The board may deny an application for a cannabis dispensing facility permit 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 permit, 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.

3VAC10-30-250. Application for and granting of authorization for a cannabis cultivation facility.

A. Pursuant to § 4.1-1602 of the Code of Virginia, the board may authorize a pharmaceutical processor to establish one cannabis cultivation facility. The cannabis cultivation facility shall be located within the same health service area as the pharmaceutical processor.

B. A separate application and fee for a cannabis cultivation facility 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 5.0% or greater ownership;

3. Details regarding the applicant's plans for security to maintain adequate control against the diversion, theft, or loss of cannabis; and

4. Information necessary for the board to conduct a criminal background check on the facilities' owners with 5.0% or greater ownership.

C. Prior to authorizing a cannabis cultivation facility, an agent of the board shall perform an inspection of the facility. If inspectors identify any deficiency, the board shall not authorize a cannabis cultivation facility until the pharmaceutical processor has corrected any deficiency identified and the facility has been satisfactorily reinspected, if warranted.

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

E. A cannabis cultivation 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 a felony under the laws of the Commonwealth or another jurisdiction within the last five years shall be employed by or act as an agent of a cannabis cultivation facility.

G. If the cannabis cultivation facility is not operational within 180 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 cultivation facility shall be deemed to have commenced operation if cannabis plants are under cultivation by the processor in accordance with the approved application.

I. Once the board has authorized a cannabis cultivation facility, a pharmaceutical processor may begin cultivation of cannabis, and the responsible party or a person who is qualified to provide supervision in accordance with 3VAC10-30-160 shall be present during hours of operation to ensure the safety, security, and integrity of the cannabis.

3VAC10-30-255. Denial of a cannabis cultivation facility permit application.

A. The board may deny an application for a cannabis cultivation facility permit 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 cultivation facility.

B. If the board denies an application of cannabis cultivation facility permit, 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.

3VAC10-30-260. Notification of changes by medical cannabis facility.

A. Unless otherwise provided in law or regulation, the PIC or the responsible party designated on the application of the medical cannabis facility shall provide any notification or information that is required from a medical cannabis facility with respect to its designated areas of oversight.

B. Prior to making any change to the medical cannabis facility name, the medical cannabis 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 medical cannabis facility, change the location of a medical cannabis facility, make structural changes to an existing medical cannabis facility, or make changes to a previously approved security system shall submit an application to the board and pay the required fee.

1. An authorized agent of the board shall inspect any proposed location or structural changes prior to issuance of a permit.

2. Cannabis, industrial hemp extracts, or cannabis products shall not be moved to a new location until an authorized agent of the board grants approval.

3VAC10-40. Regulated Operations.

Part I. General Provisions

3VAC10-40-10. General Provisions.

A. A pharmaceutical processor or cannabis dispensing facility shall only sell cannabis products in a child-resistant, secure, and light-resistant container. Upon a written request from the patient, parent, legal guardian, or registered agent, the product 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 products to patients or parents or legal guardians of patients who are minors or vulnerable adults, or to a registered agent. A pharmacy technician who meets the requirements of 3VAC10-30-160 C may assist, under the direct supervision of a pharmacist, in the dispensing and selling of cannabis products.

C. The PIC, pharmacist, responsible party, or person who is qualified to provide supervision in accordance with 3VAC10-30-160 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 patient, parent, legal guardian, registered agent, or a companion of the patient, in which case such person shall not be permitted behind the service counter or in other areas where cannabis plants, extracts, or cannabis products are stored.

D. A pharmacist, pharmacy technician, or an employee of the pharmaceutical processor or cannabis dispensing facility who has routine access to confidential patient data and who has signed a patient data confidentiality agreement with the processor or dispensing facility may determine eligibility for access to the processor or facility by verifying through a verification source recognized by the board that the registration of the patient, parent, legal guardian, or registered agent is current.

E. 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.

F. While inside the pharmaceutical processor or cannabis dispensing facility, all 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.

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

H. A pharmaceutical processor or cannabis dispensing facility that closes the dispensing area during its normal hours of operation shall implement procedures to notify patients, parents, legal guardians, and registered agents 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 cultivation, production, or dispensing area of the pharmaceutical processor or if a 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.

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

J. The medical cannabis facility shall establish, implement, and adhere to a written alcohol-free, drug-free, and smoke-free workplace policy that shall be available to the board or the board's agent upon request.

3VAC10-40-20. Facility Prohibitions.

A. No pharmaceutical processor shall:

1. Cultivate cannabis plants or produce or dispense cannabis products 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 products, to any other facility except for wholesale distribution pursuant to 3VAC10-40-100;

3. Produce or manufacture cannabis products for use outside of Virginia; or

4. Provide cannabis products samples.

B. No cannabis dispensing facility shall:

1. Dispense cannabis products 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 products to any other facility, except for wholesale distribution pursuant to 3VAC10-40-100; or

3. Provide cannabis product samples.

C. No cannabis cultivation facility shall:

1. Sell, deliver, transport, or distribute cannabis to any other facility, except for the pharmaceutical processor that established the cannabis cultivation facility;

2. Produce, manufacture, or dispense cannabis products; or

3. Provide cannabis samples.

D. When a pharmacist is not on the premises and directly supervising the activity within the dispensing area of the pharmaceutical processor or a cannabis dispensing facility:

1. The dispensing area shall not be open or in operation;

2. No person shall be in the dispensing area; and

3. The dispensing area shall be closed and properly secured.

E. Employee access to secured areas designated for cultivation and production, as authorized by the responsible party pursuant to § 4.1-1602 of the Code of Virginia, is permissible when a pharmacist is not on the premises.

F. No pharmaceutical processor or cannabis dispensing facility shall sell anything other than cannabis products except for devices for administration of dispensed products or hemp-based CBD products.

G. Except as provided in subsections H and I of this section, no person other than a medical cannabis facility employee, a patient, parent, legal guardian, registered agent, or a companion of a patient shall be allowed on the premises of a processor or facility.

H. Laboratory staff may enter a pharmaceutical processor or cannabis cultivation facility for the sole purpose of identifying and collecting cannabis or cannabis products samples to conduct laboratory tests.

I. A medical cannabis facility may submit a written request for entry by other persons to the board or the board's authorized representative.

J. All persons who the board, or the board's representative, has authorized in writing to enter the medical cannabis facility shall obtain a visitor identification badge from a medical cannabis facility employee prior to entering the processor or facility.

1. An employee shall escort and monitor an authorized visitor at all times the visitor is in the medical cannabis facility.

2. The visitor identification badge shall remain visible at all times the visitor is in the medical cannabis facility and the visitor shall return the visitor identification badge to an employee upon exiting the medical cannabis facility.

3. All visitors shall log in and out. The medical cannabis facility shall maintain the visitor log that shall include the date, time, and purpose of the visit and be available to the board.

4. If an emergency requires the presence of a visitor and makes it impractical for the medical cannabis facility to obtain prior authorization from the board, the medical cannabis 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 medical cannabis facility shall monitor the visitor and maintain a log of such visit as required by this subsection.

K. No cannabis products shall be sold, dispensed, or distributed via a delivery service or any other manner outside of a pharmaceutical processor or cannabis dispensing facility; however, a parent, legal guardian, or registered agent or an agent of the processor or cannabis dispensing facility may deliver cannabis products to the patient or in accordance with 3VAC10-50-130 A.

L. Notwithstanding the requirements of subsection G 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 medical cannabis facility if necessary to perform their governmental duties.

Part II. Cannabis Production, Distribution, and Inventory

3VAC10-40-100. Wholesale distribution of cannabis products, bulk cannabis oil, botanical cannabis, and usable cannabis.

A. Cannabis oil, cannabis products, botanical cannabis, and usable cannabis from a batch that have passed the tests required in 3VAC10-60-20(G) and 3VAC10-60-20(H) and are packaged and labeled for sale with an appropriate expiration date in accordance with 3VAC10-60-20 may be wholesale distributed between pharmaceutical processors, between a pharmaceutical processor and a cannabis dispensing facility, and between cannabis dispensing facilities.

B. Bulk cannabis oil, botanical cannabis, and usable cannabis that have not been packaged for sale and have not passed the tests required in 3VAC10-60-20(G) and 3VAC10-60-20(H) and do not bear an appropriate expiration date may be wholesale distributed between pharmaceutical processors. Prior to distribution, the bulk cannabis oil, botanical cannabis and usable cannabis shall be labeled in compliance with 3VAC10-70-20.

C. A pharmaceutical processor or cannabis dispensing facility engaged in wholesale distribution of cannabis products shall create a record of the transaction that shows (i) the date of distribution, (ii) the names and addresses of the processor or cannabis dispensing facility distributing the product and the processor or cannabis dispensing facility receiving the product, (iii) the kind and quantity of product being distributed, and (iv) the batch and lot identifying information to include harvest date, testing date, processing or manufacturing date, and expiration date. The record of the transaction shall be maintained by the distributing pharmaceutical processor or cannabis dispensing facility 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 processor or facility for three years in compliance with 3VAC10-40-500.

D. A pharmaceutical processor engaged in wholesale distribution of bulk cannabis oil, botanical cannabis, and usable cannabis shall create a record of the transaction.

1. The record of the transaction shall show (i) the date of distribution, (ii) the names and addresses of the processor distributing the bulk cannabis oil, botanical cannabis, and usable cannabis and the processor receiving the bulk cannabis oil, botanical cannabis, and usable cannabis, (iii) the quantity or weight of the cannabis oil, botanical cannabis, or usable cannabis in each container; (iv) the quantity of each type of container being distributed; (v) the identification of the contents of each container, including a brief description of the type or form of cannabis oil, botanical cannabis, or usable cannabis and the strain name, as appropriate; (vi) the lot or batch number or unique identifier so as to facilitate any warnings or recalls the board or pharmaceutical processor deem appropriate, and; (vii) the dates of harvest and packaging.

2. 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 receiving the product in its records of receipt.

3. Such records shall be maintained by each processor for three years in compliance with 3VAC10-40-500.

E. A pharmaceutical processor or cannabis dispensing facility engaged in the wholesale distribution of cannabis 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 patients, parents, legal guardians, registered agents, practitioners who have certified qualifying patients, or an agent of the board.

F. A pharmaceutical processor or cannabis dispensing facility engaged in the wholesale distribution of cannabis products and pharmaceutical processors engaged in the wholesale distribution of bulk cannabis oil, botanical cannabis, and usable cannabis shall store and handle the items and maintain policies and procedures that include a process for executing or responding to mandatory and voluntary recalls in a manner that complies with 3VAC10-40-510.

G. If a pharmaceutical processor or cannabis dispensing facility participating in wholesale distribution uses an electronic system for the storage and retrieval of records related to distribution, the pharmaceutical processor shall use a system that is compliant with 3VAC10-40-500.

3VAC10-40-200. Inventory Requirements.

A. Each medical cannabis 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 products, at the facility. If a facility commences business with no cannabis or cannabis products on hand, the pharmacist or responsible party shall record this fact as the initial inventory.

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 products, that shall enable the facility to detect any diversion, theft, or loss in a timely manner.

B. For all inventories conducted by a medical cannabis facility:

1. The responsible party shall ensure all required inventories are performed in the cultivation and production areas, and the PIC shall ensure all required inventories are performed in the dispensing area.

2. The inventory shall be conducted by a pharmacist, pharmacy technician, responsible party, or person authorized by the responsible party who provides supervision of cultivation or production-related activities.

3. The inventories shall include, at a minimum, the date of the inventory, a summary of the inventory findings, and the name, signature, and title of the person who conducted the inventory.

C. Upon commencing business, each pharmaceutical processor shall conduct a weekly inventory of all cannabis plants, including the seeds, parts of plants, and cannabis products in stock, that shall comply with the requirements of subsection B of this section.

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

E. Upon commencing business, each cannabis cultivation facility shall conduct a weekly inventory of all cannabis plants, including the seeds and parts of plants, in stock that shall comply with the requirements of subsection B of this section.

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

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

H. 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.

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

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

Part III. Personnel and Security

3VAC10-40-300. Employee Training.

A. All employees of a medical cannabis facility shall complete training prior to the employee commencing work at the medical cannabis 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 products;

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 products.

B. The PIC and the responsible party shall assure the continued competency of all employees, in the respective areas for which they have oversight, 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.

C. The PIC and the responsible party shall be responsible for maintaining a written record documenting the initial and continuing training of all their respective 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 or the responsible party.

D. When a change of PIC or responsible party for the medical cannabis facility occurs, the new PIC or responsible party shall review the training record and sign it, indicating that the new PIC or responsible party understands its contents.

E. A medical cannabis facility shall maintain the record documenting the employee training and make it available in accordance with regulations.

3VAC10-40-310. Pharmacy technicians; ratio; supervision and responsibility.

A. The ratio of pharmacy technicians to pharmacists on duty in the areas of a pharmaceutical processor designated for production or dispensing or in a cannabis dispensing facility shall not exceed 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 products 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 production of cannabis products 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 patient, a patient's parent, legal guardian, or registered agent regarding (i) cannabis products or other drugs either before or after cannabis products have been dispensed or (ii) any medical information contained in a patient medication record;

2. Consult with the practitioner who certified the patient, or the practitioner's agent, regarding a patient or any medical information pertaining to the patient's cannabis product 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 product should be substituted for the cannabis product or formulation recommended by the practitioner or requested by the patient or parent or legal guardian; or

5. Communicate with a practitioner who certified a patient, or the practitioner's agent, to obtain a clarification on a qualifying patient's written certification or instructions.

3VAC10-40-320. Responsibilities of the responsible party.

A. A person may only serve as the responsible party for one pharmaceutical processor or cannabis cultivation facility at any one time. The responsible party shall be employed full time in a managerial position at the location of the pharmaceutical processor or cannabis cultivation facility and shall be actively engaged in daily operations of the processor during normal hours of operation.

B. The responsible party shall be aware of and knowledgeable about all policies and procedures pertaining to the operations of the pharmaceutical processor or cannabis cultivation facility.

C. The responsible party shall ensure compliance with all security measures to protect the cannabis within the cultivation and production areas from diversion at all times and ensure that cultivation and production is performed in a safe and compliant manner and free of adulteration and misbranding.

D. The responsible party shall be responsible for ensuring that:

1. All employees practicing in the cultivation and production areas are properly trained;

2. All record retention requirements are met;

3. All requirements are met for the physical security of the cannabis, to include the seeds, any parts or extracts of the cannabis plants and the cannabis products within the cultivation and production area; and

4. Any other required filings or notifications regarding the cultivation and production areas are made on behalf of the processor as set forth in regulation.

E. When the responsible party ceases practice at a pharmaceutical processor or cannabis cultivation facility or no longer wishes to be designated as the responsible party, the responsible party shall immediately return the

pharmaceutical processor permit to the board indicating the effective date on which he ceased to be the responsible party.

F. The outgoing responsible party shall have the opportunity to take a complete and accurate inventory of all cannabis, to include plants, extracts, or cannabis products on hand in the cultivation and production areas, on the date he ceases to be the responsible party unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed.

G. A responsible party who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the responsible party. If the responsible party 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 responsible party 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 responsible party.

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

3VAC10-40-330. Responsibilities of the PIC.

A. The PIC of a pharmaceutical processor shall not serve as PIC of any other medical cannabis 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 in the dispensing area of the pharmaceutical processor or in a 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 or cannabis dispensing facility shall be responsible for ensuring that:

1. Pharmacy technicians are registered and properly trained;

2. All record retention requirements pertaining to the dispensing area met;

3. All requirements for the physical security of the cannabis products are met;

4. The pharmaceutical processor or cannabis dispensing facility has appropriate pharmaceutical reference materials to ensure that cannabis products 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 patients, parents, legal guardians, or registered agents:

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 products offered by the pharmaceutical processor or cannabis dispensing facility; and

6. Any other required filings or notifications are made on behalf of the dispensing area of the pharmaceutical processor or the 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 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 products on hand in the dispensing area of the pharmaceutical processor or the dispensing facility 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.

3VAC10-40-340. Security requirements.

A. A pharmaceutical processor shall initially cultivate only the number of cannabis plants necessary to produce cannabis products for the number of patients anticipated within the first nine months of operation. Thereafter, the processor shall not maintain cannabis product in excess of the quantity required for normal, efficient operation.

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

C. A medical cannabis facility shall properly secure cannabis plants, seeds, parts of plants, extracts, and cannabis products. To secure these items a medical cannabis facility shall:

1. Maintain all cannabis plants, seeds, parts of plants, extracts, and cannabis products in a secure area or location accessible only by the minimum number of authorized employees essential for efficient operation;

2. Store all cut parts of cannabis plants, extracts, or cannabis products in an approved safe or approved vault within the medical cannabis facility and not sell cannabis products when the regulated cannabis facility is closed;

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 products 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 products;

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

5. Restrict access to keys or codes to all safes, approved vaults, or other approved equipment or areas in the dispensing area to pharmacists practicing at the pharmaceutical processor or cannabis dispensing facility;

6. Restrict access to keys or codes to all safes, approved vaults, or other approved equipment or areas in the cultivation and production areas to the responsible party and to those authorized by the responsible party. The responsible party shall authorize access to pharmacists practicing in the processor or persons supervising cultivation-related or production-related activities at the processor; and

7. Not allow keys to be left in the locks or otherwise accessible to persons not authorized by the PIC or responsible party.

D. The PIC or responsible party may designate employees, other than a pharmacist or person supervising cultivation-related or production-related activities at the processor, to have the ability to unlock a secured area to gain entrance to perform required job duties, but only during hours of operation of the processor or dispensing facility. At no time shall these employees have access to the security system.

E. The regulated cannabis facility shall have an adequate security system to prevent and detect diversion, theft, or loss of cannabis seeds, plants, extracts, or cannabis products. A failure notification system 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 operation of the system shall meet accepted alarm industry standards, subject to the following conditions:

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

2. The system 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 system shall fully protect the entire processor or facility and shall be capable of detecting any failure in the system when activated;

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

5. Access to the alarm system for the dispensing area of 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 cannabis dispensing facility is closed for business.

6. Access to the alarm system in a cannabis cultivation facility or areas of a pharmaceutical processor that are designated for cultivation and production shall be restricted to the responsible party and to those authorized by the responsible party who shall be the pharmacists practicing at the pharmaceutical processor or person supervising cultivation-related or production-related activities.

F. A medical cannabis facility shall keep the outside perimeter of the premises well lit.

G. A medical cannabis facility shall have video cameras in all areas that may contain cannabis plants, seeds, parts of plants, extracts, or cannabis products and at all points of entry and exit, which shall be appropriate for the normal lighting conditions of the area under surveillance.

1. The medical cannabis facility shall direct cameras at all approved safes, approved vaults, dispensing areas, or cannabis products sales areas, and any other area where cannabis plants, seeds, extracts, or cannabis products are being produced, harvested, manufactured, stored, or handled. At entry and exit points, the medical cannabis 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 medical cannabis 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 medical cannabis facility shall erase all recordings prior to disposal or sale of the facility; and

4. The medical cannabis 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 medical cannabis facility is aware of a pending criminal, civil, or administrative investigation or legal proceeding for which a recording may contain relevant information, the medical cannabis 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 medical cannabis facility PIC or responsible party that it is not necessary to retain the recording.

H. The medical cannabis 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. The pharmaceutical processor or cannabis dispensing facility shall keep all onsite surveillance rooms locked and shall not use such rooms for any other function.

I. A medical cannabis 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 medical cannabis facility shall make available a current list of authorized employees and security system service employees who have access to the surveillance room of the processor or facility.

J. If diversion, theft, or loss of cannabis plants, seeds, parts of plants, extracts, or cannabis products has occurred from a medical cannabis facility, the board may require additional safeguards to ensure the security of the products.

3VAC10-40-350. Reportable events.

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

B. A pharmacist, responsible party, or medical cannabis 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 registered cannabis product names of cannabis product diverted, stolen, lost, destroyed, or damaged and confirmation that the local law-enforcement authorities were notified. A pharmacist, responsible party, or medical cannabis facility shall make such notice no later than 24 hours after discovery of the event.

C. A pharmacist, responsible party, or medical cannabis 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, responsible party, pharmaceutical processor, or cannabis dispensing facility shall immediately notify the board of an employee convicted of a felony.

Part IV. Advertising

3VAC10-40-400. General Provisions.

A. A medical cannabis facility may engage in marketing activities related to products, the medical cannabis program, the pharmaceutical processor company, and related communications, except those marketing activities that:

1. Include false or misleading statements;

2. Promote excessive consumption;

3. Depict a person younger than 21 years of age consuming cannabis;

4. Include any image designed or likely to appeal to minors, specifically including cartoons, toys, animals, children, or any other likeness to images, character, or phrases that are popularly used to advertise to children;

5. Depict products or product packaging or labeling that bears reasonable resemblance to any product legally available for consumption as a candy or that promotes cannabis consumption; or

6. Contain any seal, flag, crest, coat of arms, or other insignia that is likely to mislead patients or the general public to believe that the cannabis product has been endorsed, made, or used by the Commonwealth of Virginia or any of its representatives except where specifically authorized.

3VAC10-40-410. Prohibited Practices.

A. A medical cannabis facility shall not advertise (i) through any means unless at least 85% of the audience is reasonably expected to be 18 years of age or older, as determined by reliable, up-to-date audience composition data or (ii) on television or the radio at any time outside of regular school hours for elementary and secondary schools.

B. Advertising shall not:

1. Be misleading, deceptive, or false or contain any health-related statement that is untrue in any particular manner or tends to create a misleading impression as to the effects on health of cannabis consumption;

2. Contain a statement, design, illustration, picture, or representation that:

a. Encourages or represents the recreational use of cannabis;

b. Targets or is attractive to persons younger than 18 years of age, including a cartoon character, a mascot, or any other depiction or image that is commonly used to market products to minors;

c. Displays the use of cannabis, including the consumption, smoking, or vaping of cannabis;

d. Encourages or promotes cannabis for use as an intoxicant; or

e. Is obscene or indecent.

3. Display cannabis or cannabis product pricing except as allowed in 3VAC10-40-400.

4. Display cannabis products or images of products where the advertisement is visible to members of the public from any street, sidewalk, park, or other public place; and

5. Include coupons, giveaways of free cannabis products, or distribution of merchandise that displays anything other than the facility name and contact information.

C. No outdoor cannabis product advertising shall be placed within 1,000 feet of (i) a school or daycare; (ii) a public or private playground or similar recreational or child-centered facility; or (iii) a substance use disorder treatment facility.

D. Signs placed on the property of a medical cannabis facility shall not:

1. Display imagery of cannabis or the use of cannabis or utilize long luminous gas-discharge tubes that contain rarefied neon or other gases;

2. Draw undue attention to the facility but may be designed to assist patients, parents, legal guardians, and registered agents to find the medical cannabis facility; or

3. Be illuminated during non-business hours.

E. A medical cannabis facility shall not advertise at any sporting event or use any billboard advertisements.

F. No cannabis product advertising shall be on or in a public transit vehicle, public transit shelter, bus stop, taxi stand, transportation waiting area, train station, airport, or any similar transit-related location.

3VAC10-40-420. Permitted Practices.

A. A medical cannabis facility may list its business in public phone books, business directories, search engines, or other places where it is reasonable for a business to maintain an informational presence of its existence and a description of the nature of the business. A medical cannabis facility shall not engage in the use of pop-up digital advertisements.

B. A medical cannabis facility may display the following information on its website or social media site:

1. Name and location of the medical cannabis facility;

2. Contact information for the medical cannabis facility;

3. Hours and days the pharmaceutical processor or cannabis dispensing facility is open for dispensing cannabis products;

4. Laboratory results;

5. Product information and pricing;

6. Directions to the medical cannabis facility; and

7. Educational materials regarding the use of cannabis products that are supported by substantial, current clinical evidence or data.

C. Medical cannabis facilities may provide communication and engagement for educational purposes with health care practitioners, patients, parents, legal guardians, registered agents, and the general public, including the dissemination of information permitted by 3VAC10-40-400 and educational materials.

3VAC10-40-430. Advertising Requirements.

A. Advertising must accurately and legibly identify the medical cannabis facility responsible for its content and include a statement that cannabis products are for use by patients only. Any advertisement for cannabis products that is related to the benefits, safety, or efficacy, including therapeutic or medical claims, shall:

1. Be supported by substantial, current clinical evidence or data; and

2. Include information on side effects or risks associated with the use of cannabis.

B. Any website or social media site owned, managed, or operated by a medical cannabis facility shall employ a neutral age-screening mechanism that verifies that the user is at least 18 years of age, including by using an age-gate, age-screen, or age verification mechanism.

C. All outdoor signage must comply with local or state requirements.

Part V. Records, Storage, and Administration

3VAC10-40-500. Recordkeeping requirements.

A. If a medical cannabis facility uses an electronic system for the storage and retrieval of patient information or other records related to cultivating, producing, and dispensing cannabis products, 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 safeguarding against erasures and unauthorized changes in data after the information has been entered and verified by the pharmacist or responsible party; 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 inventory, laboratory results, and dispensing shall be maintained for a period of three years and shall be made available to the board upon request.

3VAC10-40-510. Storage and handling requirements.

A. A medical cannabis facility shall:

1. Have storage areas that provide adequate lighting, ventilation, sanitation, space, equipment, and security conditions for the cultivation of cannabis and the production and dispensing of cannabis products;

2. Have storage areas with temperature and humidity maintained in the following ranges:

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

3. Store cannabis plants, seeds, parts of plants, extracts, including cannabis products, that are outdated, damaged, deteriorated, misbranded, adulterated, or whose containers or packaging have been opened or breached, in a separate quarantined storage area until such cannabis plants, seeds, parts of plants, extracts, or cannabis products are destroyed;

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

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

B. A medical cannabis facility shall compartmentalize all areas in the facility based on function and shall restrict access between compartments.

C. The pharmaceutical processor or cannabis cultivation facility 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 products. These shall include policies and procedures that:

1. Restrict movement between compartments;

2. Provide for different colored identification cards for 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 employees working in an area containing cannabis plants, seeds, and extracts, including cannabis oil and cannabis products; and

4. Document the chain of custody of all cannabis plants, parts of plants, seeds, extracts, and cannabis products.

D. 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 products, including a requirement for pocketless clothing for all facility employees working in an area containing cannabis products.

E. The PIC and/or responsible party of a medical cannabis 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 cannabis products, 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. Medical cannabis facilities shall include in their written policies and procedures a process for:

1. Handling mandatory and voluntary recalls of cannabis products and bulk cannabis oil, botanical cannabis, and usable cannabis distributed or received via wholesale distribution. 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 products from the market or (ii) promote public health and safety by replacing existing cannabis products 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 products, is segregated from all other cannabis, seeds, parts of plants, extracts, and cannabis products and destroyed. This procedure shall provide for written documentation of the cannabis, including seeds, parts of plants, extracts, and cannabis product disposition; and

4. Ensuring the oldest stock of cannabis, including seeds, parts of plants, extracts, and cannabis products are used first. The procedure may permit deviation from this requirement if such deviation is temporary and appropriate.

F. The pharmaceutical processor or cannabis cultivation facility shall store all cannabis, including seeds, parts of plants, extracts, and cannabis products, 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 products 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, responsible party, or other person authorized by the responsible party to supervise cultivation and production at the pharmaceutical processor or cannabis cultivation facility shall securely lock the processing area or tanks, vessels, bins, or bulk containers containing cannabis, including the seeds, parts of plants, extracts, and cannabis products, inside an area or building that affords adequate security.

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

3VAC10-40-520. Medical cannabis facility closings; going out of business; change of ownership.

A. At least 30 days prior to the date a medical cannabis 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 medical cannabis facility.

B. The proposed disposition of all cannabis, industrial hemp extracts, cannabis products, dispensing records, patient information records, and other required records, as applicable, shall be reported to the board. If the cannabis, cannabis products, and records are to be transferred to another medical cannabis facility located in Virginia, 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, cannabis products, and records are being transferred and the date of transfer.

C. The board may approve exceptions to the public notice requirement due to exigent circumstances including sudden closing due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, or other emergency circumstances. If the medical cannabis 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, responsible party, 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 medical cannabis 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 of § 4.1-1602 of the Code of Virginia.

3VAC10-50. Cannabis Products

Part I. General Provisions

3VAC10-50-10. Definitions.

"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 product:

1. Variation from the intended product to be dispensed, including:

a. Incorrect product;

b. Incorrect product 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 a cannabis product to the incorrect patient.

4. An act or omission relating to the dispensing of cannabis product that results in, or may reasonably be expected to result in, injury to or death of a patient or results in any detrimental change to the medical treatment for the patient.

Part II. Cultivation, Production, and Dispensing of Cannabis Products

3VAC10-50-100. Cultivation and production of cannabis products.

A. No cannabis products shall have had pesticide chemicals or petroleum-based solvents, except for hydrocarbon-based solvents described herein, used during the cultivation, extraction, production, or manufacturing process, except that the board may authorize the use of pesticide chemicals for purposes of addressing an infestation that could result in a catastrophic loss of cannabis crops.

B. Cultivation methods for cannabis plants, extraction methods used to produce the cannabis products, and the manufacturing of cannabis products shall be performed in a manner deemed safe and effective based on current standards or scientific literature.

1. The cultivation, extraction, production, and manufacturing of cannabis products may include the use of hydrocarbon-based solvents as described in 3VAC10-50-110.
2. The cultivation, extraction, production, and manufacturing of cannabis products may include any other generally accepted technology, provided that:
    a. The pharmaceutical processor complies with any applicable requirements contained in 3VAC10-50-110 regarding flammable solvents as defined in that section;
    b. The pharmaceutical processor complies with any licensing, permitting, and general safety laws or regulations of any state or federal agency that governs the technology and the use of such technology; and
    c. The pharmaceutical processor maintains sole responsibility for any adverse outcomes or violations of state or federal laws or regulations caused by such use.

C. Any cannabis plant, seed, parts of plant, extract, or cannabis products not in compliance with this section shall be deemed adulterated.

D. A pharmaceutical processor may acquire industrial hemp extract, including isolates and distillates, for the purpose of formulating such extracts into allowable dosages of cannabis products provided:

1. The pharmaceutical processor acquires the extracts from industrial hemp extract processed in Virginia and in compliance with state or federal law from a registered industrial hemp dealer or processor;

2. The extracts from industrial hemp acquired by a pharmaceutical processor is subject to the same third-party testing requirements applicable to cannabis plant extract as verified by testing performed by a laboratory located in Virginia and in compliance with state law; and

3. The industrial hemp dealer or processor provides such third-party testing results to the pharmaceutical processor before extracts from industrial hemp are acquired.

E. A pharmaceutical processor acquiring industrial hemp extract shall ensure receipt of a record of the transaction that shows the date of distribution, the names and addresses of the registered industrial hemp dealer or processor distributing the product and the pharmaceutical processor receiving the product, and the kind and quantity of product being distributed. The record of the transaction shall be maintained by the pharmaceutical processor with its records of receipt. Such records shall be maintained by each pharmaceutical processor for three years.

F. A pharmaceutical processor shall maintain policies and procedures for the proper storage and handling of industrial hemp extracts, to include a process for executing or responding to mandatory and voluntary recalls in a manner that complies with 3VAC10-40-510.

G. No cannabis oil intended to be vaporized or inhaled shall contain vitamin E acetate.

3VAC10-50-110. Use of hydrocarbon-based solvents or other flammable solvents.

A. The following words and phrases used in this section have the following meaning:

1. "Closed-loop system" means machinery in which volatile hydrocarbon substances are self-contained without the loss or escape of those substances.
2. "Flammable solvent" means a liquid that has a flash point below 100 degrees Fahrenheit. Flammable solvents include, but are not limited to, hydrocarbon-based solvents.
3. "Hydrocarbon-based solvent" means a type of solvent composed of hydrogen and carbon compounds, such as N-butane, isobutene, propane, or any isomer or combination thereof.

B. Hydrocarbon-based solvents may be used in the cultivation, extraction, production, or manufacturing of cannabis products provided that:

1. A pharmaceutical processor complies with all requirements in this section.
2. A pharmaceutical processor using hydrocarbon-based solvents shall comply with all regulations regarding use of hydrocarbon-based solvents in general industrial use as promulgated by the Occupational Safety and Health Administration and published in 29 C.F.R. § 1910 or any subsequent regulation governing such use, including, but not limited to, regulations governing:
    a. ventilation requirements;
    b. air contaminants; and
    c. hazard communication.
3. A pharmaceutical processor using hydrocarbon-based solvents shall comply with any requirements issued by the Virginia Department of Labor and Industry regarding use of hydrocarbon-based solvents.

4. A pharmaceutical processor using hydrocarbon-based solvents shall comply with any requirements issued by the Virginia Department of Environmental Quality regarding use of hydrocarbon-based solvents promulgated.
5. A pharmaceutical processor using hydrocarbon-based solvents maintains sole responsibility for any adverse outcomes or violations of state or federal laws or regulations caused by such use.
6. A pharmaceutical processor using hydrocarbon-based solvents shall ensure that all equipment, counters, and surfaces used in the cultivation, extraction, production, or manufacturing of cannabis products are food-grade and do not react adversely with any hydrocarbon solvent used. All counters and surface areas shall be constructed in a manner that reduces the potential development of microbials, molds, and fungi and can be easily cleaned.
7. A pharmaceutical processor using hydrocarbon-based solvents shall ensure that any room in which hydrocarbon-based solvents will be used contains an emergency eye-wash station.
8. A pharmaceutical processor using hydrocarbon-based solvents shall ensure that a professional grade, closed-loop extraction system capable of recovering solvent is used in the cultivation, extraction, production, or manufacturing of cannabis products.
    a. Closed-loop extraction systems must be commercially manufactured and bear a permanently affixed and visible serial number.
    b. A pharmaceutical processor using a closed-loop extraction system must obtain certification from a licensed engineer that certifies that the system was commercially manufactured, is safe for its intended use, and built to codes of recognized and generally accepted good engineering practices, such as: (i) the American Society of Mechanical Engineers ("ASME"); (ii) American National Standards Institute ("ANSI"); (iii) Underwriters Laboratories ("UL"); or (iv) the American Society for Testing and Materials ("ASTM").
    c. The certification must contain the signature and stamp of a professional engineer and include the serial number of the extraction unit certified.
9. A pharmaceutical processor using hydrocarbon-based solvents shall obtain a safety data sheet for each hydrocarbon-based solvent used and store such data sheet on the premises. All such records shall be subject to inspection by the board.
10. A pharmaceutical processor using hydrocarbon-based solvents shall develop standard operating procedures, good manufacturing practices, and a training plan prior to using such solvents. Standard operating procedures shall specifically address:
    a. Safe and proper handling and use of hydrocarbon-based solvents;
    b. Safe and proper operation of machinery and equipment;
    c. Adequate cleaning and maintenance of machinery and equipment;

d. Incident reporting for any instances where the operator does not follow the stated standard operating procedures which identifies: (i) the operator's name, (ii) the date and time of the incident, (iii) the supervising employees to which the incident report will be sent, and (iv) an incident summary which includes whether any cannabis products or other substances escaped from the closed-loop system, the amount of escaped material, whether the material was destroyed, and how the incident was resolved; and

e. Safe and proper disposal of waste created during processes using hydrocarbon-based solvents.

11. A pharmaceutical processor using hydrocarbon-based solvents shall ensure that any person using such solvents in a closed-loop system:

    a. Is fully trained on how to use the system;

    b. Has direct access to applicable material safety data sheets; and

    c. Handles and stores the solvents safely.

C. If a pharmaceutical processor intends to use a flammable solvent, then a designated industrial hygienist or professional engineer that is not an employee of the pharmaceutical processor must:

1. Establish a maximum amount of flammable solvents and other flammable materials that may be stored within the pharmaceutical processor facility in accordance with applicable laws and regulations;

2. Determine what type of electrical equipment must be installed within the room or rooms in which flammable solvents are to be stored in accordance with applicable laws and regulations;

3. Determine whether a gas monitoring system must be installed within the room in which flammable solvents are to be used or stored, and, if required, the system's specifications in accordance with applicable laws and regulations;

4. Determine whether a fire suppression system must be installed within the room in which the flammable solvents are to be used or stored, and, if required, the system's specifications in accordance with applicable laws and regulations; and

5. Determine whether a fume vent hood or exhaust system must be installed within the room or rooms in which a flammable solvent will be used, and, if required, the system's specifications in accordance with applicable laws and regulations.

D. If a pharmaceutical processor makes a material change to its use of flammable solvents in any part of the manufacturing process, a designated industrial hygienist or professional engineer that is not an employee of the pharmaceutical processor must re-certify the standard operating procedures for use of flammable solvents determined under subsection (C).

E. A pharmaceutical processor shall maintain copies of all reports generated by or received from the designated industrial hygienist or professional engineer for inspection by the board.

F. A pharmaceutical processor shall not store more flammable solvents onsite which exceeds the maximum amount allowable as identified by the designated industrial hygienist or professional engineer.

G. A pharmaceutical processor shall ensure that all appropriate safety and sanitary equipment, including personal protective equipment, is provided to, and appropriately used by, each employee handling a flammable solvent.

H. The board shall approve chemicals for use as hydrocarbon or other flammable solvents in the cultivation, extraction, production, or manufacturing of cannabis products based on availability of testing for residual material of individual solvents.

3VAC10-50-120. Registration of products.

A. A pharmaceutical processor shall assign a product name to each product of cannabis. The pharmaceutical processor shall register each cannabis product name with the board on a form prescribed by the board prior to any dispensing and shall associate each registered cannabis product name with a specific laboratory test that includes the total cannabidiol (CBD) and total tetrahydrocannabinol (THC), a terpenes profile, and a list of all active ingredients, including:

1. Tetrahydrocannabinol (THC);

2. Tetrahydrocannabinol acid (THC-A);

3. Cannabidiols (CBD); and

4. Cannabidiolic acid (CBDA).

For botanical cannabis products, only the total cannabidiol (CBD) and total tetrahydrocannabinol (THC) are required.

B. A pharmaceutical processor shall not label two products with the same registered cannabis product name unless the laboratory test results for each product indicate that the level of each listed active ingredient varies by no more than 15 percent. However, in cases where (i) the total tetrahydrocannabinol (THC) concentration is less than 5 milligrams per dose, the concentration of THC shall be within 0.5 milligrams per dose and (ii) the total cannabidiol (CBD) concentration is less than 5 milligrams per dose, the concentration of total CBD shall be within 0.5 milligrams per dose.

C. The board shall not register any cannabis product 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 registered cannabis product name of a previously approved cannabis oil product;

4. Is obscene or indecent;

5. May encourage the use of marijuana or cannabis products for recreational purposes;

6. May encourage the use of cannabis products 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 cannabis product unless supported by substantial evidence or substantial clinical data.

3VAC10-50-130. Dispensing of cannabis products.

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

1. Prior to the initial dispensing of cannabis products pursuant to each written certification, the pharmacist or pharmacy technician at the location of the pharmaceutical processor or cannabis dispensing facility shall view in person or by audiovisual means a current photo identification of the patient, parent, legal guardian, or registered agent. 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 any registrations, if applicable, are current, the written certification has not expired, and the date and quantity of the last dispensing of cannabis products to the patient.

2. A pharmacist or pharmacy technician employed by the pharmaceutical processor or cannabis dispensing facility shall make a paper or electronic copy of the current written certification that provides an exact image of the document that is clearly legible and shall maintain it on site or by electronic means for two years. The pharmaceutical processor and cannabis dispensing facility shall also provide an electronic copy of the written certification to the board.

3. Prior to any subsequent dispensing, the pharmacist or pharmacy technician shall verify that the written certification on file has not expired. An employee or delivery agent shall view a current photo identification and current registration of the patient, parent, legal guardian, or registered agent 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 patient's 90-day supply of cannabis product. The pharmacist may dispense the remaining portion of the 90-day supply of cannabis products at any time except that no patient, parent, legal guardian, or registered agent shall receive more than a 90-day supply of cannabis products for a patient in a 90-day period from any pharmaceutical processor or cannabis dispensing facility. A pharmaceutical processor or cannabis dispensing facility may dispense more than one cannabis product to a patient at one time. However, no more than four ounces of botanical cannabis shall be dispensed for each 30-day period for which

botanical cannabis is dispensed. In determining the appropriate amount of cannabis product to be dispensed to a patient, a pharmacist shall consider all cannabis products dispensed and adjust the amount dispensed accordingly.

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 cannabis product that contains:

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

2. The cannabis product name that was registered with the board pursuant to 3VAC10-50-120 and its strength;

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

4. The date of dispensing the cannabis product;

5. The quantity of cannabis products 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);

For botanical cannabis products, only the total cannabidiol (CBD) and total tetrahydrocannabinol (THC) are required;

7. A pass rating based on the laboratory's microbiological, mycotoxins, heavy metals, residual solvents, pesticide chemical residue analysis, and for botanical cannabis, the water activity and moisture content analysis;

8. The name of the patient;

9. The name 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. For botanical cannabis, the amount recommended by the practitioner or dispensing pharmacist;

12. The name or initials of the dispensing pharmacist;

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

14. Any necessary cautionary statement;

15. A prominently printed expiration date based on stability testing; and

16. 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. The label shall be exempt from containing the items listed in subdivisions C 6, C 7, and C 15 if the items are included on the batch label as required in 3VAC10-70-10 and are clearly visible to the patient.

E. A pharmaceutical processor shall not label cannabis 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.

F. The cannabis products shall be dispensed in child-resistant packaging, except as provided in 3VAC10-40-10 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).

G. 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.

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

I. A pharmacist shall document a patient's self-assessment of the effects of cannabis products in treating the patient's diagnosed condition or disease or the symptoms thereof.

J. If the authorization for botanical cannabis for a minor is communicated verbally or in writing to the pharmacist at the time of dispensing, the pharmacist shall also document such authorization. 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.

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

3VAC10-50-140. 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.

B. A pharmaceutical processor or cannabis dispensing facility shall distribute the written policies and procedures to all employees and shall make the written policies and procedures readily available on the premises of the pharmaceutical processor or cannabis dispensing facility.

C. 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, the patient's registered agent, 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.

D. 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 patient, parent, legal guardian, or registered agent, 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.

E. 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.

3VAC10-50-150. Product samples.

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.

3VAC10-50-160. Disposal of cannabis products.

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 products, as applicable. Green waste includes cannabis plants seeds and parts of plants. Green waste shall be weighed, ground, and combined with a minimum of 51% non-cannabis waste to render the mixture inactive and unrecognizable. Once rendered unrecognizable, green waste shall be considered agricultural waste and may be disposed of accordingly.

B. The destruction and disposal of green waste, extracts, and cannabis products, as applicable, shall be witnessed by a pharmacist or the responsible party of the medical cannabis facility and shall be conducted under video surveillance. The persons destroying and disposing of the green waste, extracts, or cannabis products shall maintain and make available a separate record of each occurrence of destruction and disposal indicating:

1. The date and time of destruction and disposal;

2. The manner of destruction and disposal;

3. The name and quantity of cannabis product and green waste destroyed and disposed of; and

4. The signatures of the persons destroying and disposing of the green waste, extracts, or cannabis products.

C. Disposal of green waste may be by incineration, inert composting, or any other means of disposal or destruction.

D. A pharmaceutical processor may sell or otherwise distribute inert composted green waste.

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

3VAC10-50-170. Disposal of chemical, dangerous, and hazardous waste.

A. Disposal of chemical, dangerous, and hazardous waste must be conducted in a manner consistent with federal, state, and local statutes and regulations. This includes, but is not limited to, any waste product soaked in a flammable solvent.

1. Any waste that may be hazardous must be treated as hazardous waste in regard to storage, labeling, and disposal.
2. The pharmaceutical processor can, alternatively, test waste that may be hazardous for elemental impurities content.
    a. When tested for elemental impurities content, materials that meet the definition of hazardous waste, as defined by the Resource Conservation and Recovery Act ("RCRA") or other applicable federal, state, or local statutes and regulations, must be treated as hazardous waste. Such materials must be properly labeled, contained, stored, and disposed of in accordance with the Environmental Protection Agency, RCRA, and other applicable regulations for hazardous waste.
    b. Materials that contain elemental impurities concentrations less than the allowable concentration limits specified in RCRA and are not designated hazardous waste by other applicable federal, state, or local statutes and regulations, may be disposed of in accordance with 3VAC10-50-160.

3VAC10-60. Testing

3VAC10-60-10. Definitions.

"ISO/IEC 17025" means the general requirements specified by the joint technical committee of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) for the competence of testing and calibration laboratories.

3VAC10-60-20. Laboratory requirements.

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

1. Is independent from all other persons involved in the cannabis 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 products; 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 nonaccredited 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 24 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 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 of cannabis oil is required to achieve a representative sample for analysis.

C. A pharmaceutical processor or cannabis cultivation facility shall make a sample available from each harvest batch of botanical cannabis product to (i) test for microbiological contaminants, mycotoxins, heavy metals, pesticide chemical reside, water activity, and moisture content and (ii) conduct an active ingredient analysis and terpenes profile. In determining the minimum sample size for testing from each batch of botanical cannabis, the certified testing laboratory may determine the minimum sample size. The sample must be representative of the entire batch to include selection from various points in the batch lot and be of sufficient sample size to allow for analysis of all required tests.

D. From the time that a batch of cannabis product has been sampled for 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.

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

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

G. A sample of cannabis oil product shall pass the microbiological, mycotoxin, heavy metal, or residual solvent test based on the standards set forth in this subsection, the batch may be remediated with further processing.

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.

H. A sample of botanical cannabis product shall pass the microbiological, mycotoxin, heavy metal, water activity, or moisture content test based on the standards set forth in this subsection.

1. For purposes of the microbiological test, a botanical cannabis sample shall be deemed to have passed if it satisfies the standards set forth in the most current American Herbal Pharmacopoeia Cannabis Inflorescence Standards of Identity, Analysis, and Quality Control.

2. For purposes of the mycotoxin test, a sample of botanical cannabis 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 botanical cannabis 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 botanical cannabis 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 botanical cannabis shall be tested for:

a. Total tetrahydrocannabinol (THC); and

b. Total cannabidiol (CBD).

6. For the purposes of water activity and moisture content for botanical cannabis, the botanical cannabis shall be deemed to have passed if the water activity rate does not exceed 0.65Aw and the moisture content does not exceed 15%.

I. If a sample of cannabis product passes the required tests listed in subsections G and H of this section, 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, except stability testing shall not be required for cannabis products if an expiration date of six months or less from the date of the cannabis product registration approval is signed.

J. 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 required tests listed in subsections G and H of this section 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.

K. Each medical cannabis facility shall have such laboratory results available upon request to patients, parents, legal guardians, registered agents, practitioners who have certified qualifying patients, the board, or an agent of the board.

3VAC10-60-30. Remediation.

A. If a sample of cannabis oil product does not pass the microbiological, mycotoxin, heavy metal, or residual solvent test based on the standards set forth in 3VAC10-60-20 G, the batch may be remediated with further processing. After further processing, the batch shall be retested for microbiological, mycotoxin, heavy metal, pesticide chemical residue, and residual solvent, and an active ingredient analysis and terpenes profile shall be conducted.

B. A cannabis oil product that does not pass the pesticide chemical residue test cannot be remediated.

C. If a sample of botanical cannabis product does not pass the microbiological, mycotoxin, heavy metal, water activity, or moisture content test based on the standards set forth in 3VAC10-60-20 H, the batch may be remediated.

1. Once remediated, the batch shall be retested for microbiological, mycotoxin, heavy metal, pesticide chemical residue, water activity, and moisture content, and an active ingredient analysis and terpenes profile shall be conducted.

2. If the botanical cannabis batch fails retesting, it shall be considered usable cannabis and may be processed into cannabis oil, unless the failure is related to pesticide requirements, in which case the batch shall not be considered usable cannabis and shall not be processed into cannabis oil.

3. Any batch processed into cannabis oil shall comply with all testing standards set forth in 3VAC10-60-20 G.

D. A botanical cannabis product that does not pass the pesticide chemical residue test cannot be remediated.

3VAC10-70. Labeling and Packaging

3VAC10-70-10. Labeling of batch of cannabis products.

A. Cannabis products produced as a batch shall not be adulterated.

B. Cannabis products produced as a batch shall be:

1. Processed, packaged, and labeled according to the U.S. 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:

a. The name and address of the pharmaceutical processor;

b. The cannabis product name that was registered with the board pursuant to 18VAC110-20-285;

c. A unique serial number that matches the product with the pharmaceutical processor batch and lot number, including the cultivator and manufacturer if produced from bulk cannabis oil, botanical cannabis, or usable cannabis obtained through distribution from another pharmaceutical processor, so as to facilitate any warnings or recalls the board or pharmaceutical processor deem appropriate;

d. The date of testing and packaging;

e. For products produced from bulk cannabis oil, botanical cannabis, or usable cannabis obtained through distribution from another pharmaceutical processor, the name and address of the testing laboratory;

f. The expiration date, which shall be six months or less from the date of the cannabis product registration approval, unless supported by stability testing;

g. The quantity of cannabis products contained in the batch;

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

(1) Tetrahydrocannabinol (THC);

(2) Tetrahydrocannabinol acid (THC-A);

(3) Cannabidiol (CBD); and

(4) Cannabidiolic acid (CBDA).

For botanical cannabis products, only the total cannabidiol (CBD) and total tetrahydrocannabinol (THC) are required;

i. For cannabis oil products, pass or fail rating based on the laboratory's microbiological, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue analysis; and

j. For botanical cannabis products, a pass or fail rating based on the laboratory's microbiological, mycotoxins, heavy metals, pesticide chemical residue analysis, water activity, and moisture content.

3VAC10-70-20. Labeling of Bulk Cannabis Oil, Botanical Cannabis, and Usable Cannabis.

A. Bulk cannabis oil, botanical cannabis, and usable cannabis shall not be adulterated.

B. Bulk cannabis oil, botanical cannabis, and usable cannabis produced for wholesale distribution shall be:

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

2. Packaged in a tamper-evident container, and;

3. Labeled with:

a. the name and addresses of the pharmaceutical processor distributing the product and the pharmaceutical processor receiving the product;

b. the quantity or weight of the cannabis oil, botanical cannabis, or usable cannabis in the container;

c. identification of the contents of the container, including a brief description of the type or form of cannabis oil, botanical cannabis, or usable cannabis and the strain name, as appropriate;

d. the prominent statement “Not Packaged for Final Sale”;

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

f. the dates of harvest and packaging.

C. Cannabis products produced from bulk cannabis oil, botanical cannabis, and usable cannabis shall comply with all laboratory testing and labeling requirements prior to dispensing.

3VAC10-80. Enforcement and Dispute Resolution

Part I. Enforcement

3VAC10-80-10. Grounds for action against a pharmaceutical processor permit or a 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 products 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 products, 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, the written certification of a qualifying patient, parent, or legal guardian, the registration of a qualifying patient, parent, legal guardian, or registered agent that has voluntarily registered with the board;

6. Failure to cooperate or give information to the board on any matter arising out of conduct at a pharmaceutical processor or cannabis dispensing facility; 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.

a. Good cause includes exigent circumstances that necessitate the closing of the facility.

b. Good cause shall not include a voluntary closing of the pharmaceutical processor or cannabis dispensing facility.

Part II. Dispute Resolution

3VAC10-80-100. Definitions.

"Chairman" means the Chairman of the Board or his designee.

"Conciliation" means a process in which a neutral facilitates settlement by clarifying issues and serving as an intermediary for negotiations in a manner that is generally more informal and less structured than mediation.

"Dispute resolution," "dispute resolution procedure," or "dispute resolution proceeding" means any structured process in which a neutral assists disputants in reaching a voluntary settlement by means of dispute resolution techniques such as mediation, conciliation, early neutral evaluation, nonjudicial settlement conferences, or any other proceeding leading to a voluntary settlement conducted consistent with the requirements of this chapter. The term includes the orientation session.

"Dispute resolution program" means a program that offers dispute resolution services to the public that is run by the Commonwealth or any private for-profit or not-for-profit (including nonprofit) organization, political subdivision, or public corporation, or a combination of these.

"Dispute resolution services" includes the screening and intake of disputants, conducting dispute resolution proceedings, drafting agreements, and providing information or referral services.

"Mediation" means a process in which a mediator facilitates communication between the parties and, without deciding the issues or imposing a solution on the parties, enables them to understand and to reach a mutually agreeable resolution to their dispute.

"Mediator" means a neutral who is an impartial third party selected by agreement of the parties to a controversy to assist them in mediation. As used in this chapter, this word may refer to a single person or to two or more people.

"Neutral" means a person who is trained or experienced in conducting dispute resolution proceedings and in providing dispute resolution services. As used in this chapter, this word may refer to a single person or to two or more people.

"Orientation session" means a preliminary meeting during which the dispute resolution proceeding is explained to the parties and the parties and the neutral assess the case and decide whether to continue with a dispute resolution proceeding or adjudication.

"Party" means an interested person who has chosen to be and who is eligible to be a disputant in a dispute resolution proceeding. An interested person is eligible if he (i) has attended a public meeting or public hearing on the permit or regulation in dispute and is therefore named in the public record, (ii) is the applicant for the permit in dispute, or (iii) is the agency.

"Person" means an individual, a corporation, a partnership, an association, a government body, a municipal corporation, or any other legal entity.

"Virginia Cannabis Control Act" means Subtitle II (§ 4.1-600 et seq.) of Title 4.1 of the Code of Virginia.

3VAC10-80-110. Applicability.

A. The provisions of this chapter, unless specified otherwise, shall apply in the administration of all regulations of the board to the extent the administration of a regulation is not covered by a specific regulation of the board. In cases where the provisions of this chapter conflict with another regulation of the board, the provisions of the other regulation shall apply.

B. No provision of this chapter shall limit the power of the board to take appropriate action as necessary to carry out its duties under the Virginia Waste Management Act.

C. By the adoption of this chapter, the board confers upon the Chief Executive Officer or his designee the administrative, enforcement, and decision-making authority articulated in this chapter.

D. Nothing in this chapter shall create or alter any right, action, or cause of action, or be interpreted or applied in a manner inconsistent with the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia), with applicable federal law, or with any applicable requirement for the Commonwealth to obtain or maintain federal delegation or approval of any regulatory program.

E. For a permit in dispute, dispute resolution may not be initiated after the final permit is issued. For a regulation in dispute, dispute resolution may not be initiated after the final regulation is adopted.

3VAC10-80-120. Purpose and Scope.

A. Dispute resolution shall be used to resolve only those disputes that reveal significant issues of disagreement among parties and may be used unless the board decides that it is not in the public interest to do so.

B. The decision to employ dispute resolution is in the board's sole discretion and is not subject to judicial review.

C. The outcome of any dispute resolution procedure shall not be binding upon the board but may be considered by the board in issuing a permit or promulgating a regulation.

D. Dispute resolution may be used to resolve a dispute relating to the promulgation, amendment, or repeal of a regulation that is subject to the public participation process prescribed in Article 2 (§ 2.2-4006 et seq. of the Code of Virginia) of the Administrative Process Act.

E. Dispute resolution may be used to resolve a dispute involving any process relating to the issuance of a permit. Dispute resolution may be used in this case only with the consent and participation of the permit applicant and may be terminated at any time at the request of the permit applicant.

3VAC10-80-130. Costs.

A. Compensation of the neutral and any other associated common costs, such as rental fees, shall be the responsibility of the parties. Compensation of each party's counsel and other individual costs shall be the responsibility of that party alone, unless the parties agree otherwise.

B. An agreement regarding compensation and other associated costs shall be reached between the neutral and the parties before the dispute resolution procedure commences and shall be memorialized in writing.

C. In the absence of an agreement to the contrary, all costs shall be paid by the parties in equal shares.

3VAC10-80-140. Attendance.

A. All parties shall attend all sessions of the dispute resolution procedure. Any party who fails to attend any session shall be conclusively deemed to have dropped out of the dispute resolution procedure. A party may satisfy the attendance requirement by sending a representative familiar with the facts of the case. This representative shall have the authority to negotiate and to recommend settlement to the party that he represents.

B. Any party may have the assistance of an attorney or other representative during any session of the dispute resolution procedure.

C. Persons who are not parties or representatives of parties may attend dispute resolution sessions only with the permission of all parties and with the consent of the neutral.

3VAC10-80-150. Confidentiality.

A. The provisions of § 8.01-576.10 of the Code of Virginia concerning the confidentiality of dispute resolution shall govern all dispute resolution proceedings held pursuant to this chapter except when the board uses or relies on information obtained in the course of such proceeding in issuing a permit or promulgating a regulation.

B. The use of attorney work product in dispute resolution shall not result in a waiver of the attorney work product privilege.

3VAC10-80-160. Standards for and authority of neutral.

A. A neutral participating in a dispute resolution procedure pursuant to this chapter shall comply with all provisions of this section.

B. A neutral acting as a mediator shall adhere to the Judicial Council of Virginia's Standards of Ethics and Professional Responsibility for Certified Mediators, effective July 1, 2011, and the standards and duty provisions of § 8.01-581.24 of the Code of Virginia. A neutral conducting a non-mediation dispute resolution proceeding shall adhere to the requirements of § 8.01-576.9 of the Code of Virginia.

C. If a complaint is made to the chairman that a neutral has failed to comply with all the provisions of the applicable regulations, laws, and Judicial Council Standards during a dispute resolution proceeding, the

chairman shall notify the neutral of the complaint and shall give the neutral 10 business days to respond in writing. If the chairman deems the response unsatisfactory, or if no response is made by the deadline, the chairman shall remove the neutral from the ongoing dispute resolution process. The parties to the terminated dispute resolution procedure shall decide whether to continue in the same dispute resolution procedure with a new neutral, to begin a new dispute resolution procedure, or to forego further dispute resolution.

D. The recommendation of a neutral is not a case decision as defined in § 2.2-4001 of the Administrative Process Act and therefore may not be appealed.

3VAC10-80-170. Resumes of neutrals and descriptions of dispute resolution programs.

The agency may maintain a file containing the resumes of neutrals and descriptions of dispute resolution programs. The file shall contain a disclaimer stating, "Inclusion of a resume or dispute resolution program description in this file does not constitute an endorsement of a neutral or a dispute resolution program, nor should negative implications be drawn from the fact that a neutral's resume or a dispute resolution program description is not included in this file. Parties are not obligated to choose a neutral or dispute resolution program from those whose resumes and descriptions are maintained in this file."

3VAC10-80-180. Enforcement of written settlement agreement.

The board may incorporate the terms of the written settlement agreement into decisions pertinent to the case.

3VAC10-80-190. Referral of disputes to dispute resolution.

A. The board may refer disputes to dispute resolution.

B. A party other than the board may request dispute resolution by applying to the chairman.

1. The application shall contain the following:

a. A request for dispute resolution, specifying mediation or another dispute resolution procedure;

b. The names, postal addresses, telephone numbers, email addresses, or other appropriate communication addresses or numbers of all known parties to the dispute and of their attorneys, if known; and

c. A statement of issues and a summary of the basis for the dispute.

2. Filing an application constitutes consent to referral of the dispute to the dispute resolution process.

3. Filing an application shall not stay any proceeding and shall have no effect on any procedural or substantive right of any party to the dispute.

4. If the chairman has decided that mediation is appropriate, the provisions of 3VAC10-80-200 through 3VAC10-80-220 shall apply.

5. If the chairman has decided that a dispute resolution proceeding other than mediation is appropriate, the chairman shall specify what that proceeding is.

The appointment of the neutral for this proceeding shall follow the procedure for the appointment of a mediator as specified in 3VAC10-80-200. The parties and the neutral shall determine the appropriate procedures for conducting this dispute resolution proceeding.

3VAC10-80-200. Appointment of mediator.

A. If the chairman has decided that mediation is appropriate, any party may nominate a mediator.

B. If all parties agree with the nomination, the chairman shall appoint that person the mediator for the case and shall notify the parties accordingly.

C. If all parties do not agree with the nomination, the following procedure shall apply:

1. By a date specified by the chairman, each party shall name up to three mediators who would be acceptable to that party. These mediators may or may not have resumes on file with the agency.

2. The chairman shall compile a list of the names submitted and send it to the parties.

3. Upon receipt of the list, each party may strike two names and return the list to the chairman within 14 business days following the date on which the list was mailed.

4. On the next business day after the 14-day period expires or as soon as practicable thereafter, the chairman shall appoint a mediator from the remaining list of names and shall notify the parties accordingly.

D. Once the mediator is appointed, the chairman shall send the mediator an acceptance form to sign and return. The acceptance form shall require the mediator to append his signature to the following statements:

1. That the mediator agrees to abide by the applicable dispute resolution and mediation statutes, regulations, and ethical standards;

2. That the mediator agrees to attempt to complete the mediation within 60 business days from the date of his appointment; and

3. That the mediator foresees no potential conflict of interest in agreeing to mediate the case. A determination of conflict of interest shall be made by the chairman or board on a case-by-case basis.

3VAC10-80-210. Orientation session.

A. Once the mediator has been appointed, the board shall issue a referral to the mediator and the parties. This referral shall include a list of the information that the board, in its preliminary judgment, expects to use in making its final decision regarding the case. This list shall contain the caveat that the board may require other information as yet unspecified at some point in the future. All parties shall attend one orientation session with the mediator unless excused pursuant to subsection B of this section.

B. The board shall excuse a party from participation in the orientation session if, within 14 business days after issuance of the order of referral, a statement signed by the party is filed with the board. This statement shall declare that the mediation process has been explained to the party and that the party does not wish to participate in the orientation session.

C. The orientation session shall be conducted at any place within the Commonwealth of Virginia, at any time, and on any date convenient to the mediator and the parties.

D. At least seven business days before the orientation session, each party shall provide the mediator with a statement outlining his perspective on the facts and issues of the case. At the discretion of the mediator, these statements may be mutually exchanged by the parties.

E. During the orientation session, the parties, assisted by the mediator, shall determine the manner in which the issues in dispute shall be framed and addressed. In the absence of agreement by the parties, the mediator shall make this determination.

3VAC10-80-220. Continuation, termination, and resolution of mediation.

A. Following the orientation session, mediation shall proceed in any manner agreed on by the parties and the mediator in conformance with the provisions of 3VAC10-80-130 through 3VAC10-80-150.

B. Mediation may be terminated through written notice by the permit applicant or the chairman at any time before settlement is reached.

C. Mediation shall continue if a party other than the permit applicant or the chairman chooses to opt out of mediation following the orientation session. A party who chooses to opt out of mediation at any time following the orientation session or who, through nonattendance, is conclusively deemed to have dropped out of the dispute resolution procedure shall not be bound by any written settlement agreement resulting from the mediation but shall be bound by the cost provisions of 3VAC10-80-130 and the confidentiality provisions of 3VAC10-80-150.

D. If the mediation is terminated before settlement is reached, the parties shall resume the same status as before mediation and may proceed with the formal adjudication as if mediation had not taken place. The board shall not refer the case to mediation a second time.

E. If the mediation results in settlement, a written settlement agreement shall be signed and dated by each party or by that party's authorized representative.