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Virginia Code Commission

http://register.dls.virginia.gov

### THE VIRGINIA REGISTER INFORMATION PAGE

THE VIRGINIA REGISTER OF REGULATIONS is an official state publication issued every other week throughout the year. Indexes are published quarterly, and are cumulative for the year. The Virginia Register has several functions. The new and amended sections of regulations, both as proposed and as finally adopted, are required by law to be published in the Virginia Register. In addition, the Virginia Register is a source of other information about state government, including petitions for rulemaking, emergency regulations, executive orders issued by the Governor, and notices of public hearings on regulations.

#### ADOPTION, AMENDMENT, AND REPEAL OF REGULATIONS

Unless exempted by law, an agency wishing to adopt, amend, or repeal regulations must follow the procedures in the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia). Typically, this includes first publishing in the *Virginia Register* a notice of intended regulatory action; a basis, purpose, substance and issues statement; an economic impact analysis prepared by the Department of Planning and Budget; the agency's response to the economic impact analysis; a summary; a notice giving the public an opportunity to comment on the proposal; and the text of the proposed regulation.

Following publication of the proposed regulation in the *Virginia Register*, the promulgating agency receives public comments for a minimum of 60 days. The Governor reviews the proposed regulation to determine if it is necessary to protect the public health, safety, and welfare, and if it is clearly written and easily understandable. If the Governor chooses to comment on the proposed regulation, his comments must be transmitted to the agency and the Registrar of Regulations no later than 15 days following the completion of the 60-day public comment period. The Governor's comments, if any, will be published in the *Virginia Register*. Not less than 15 days following the completion of the 60-day public comment period, the agency may adopt the proposed regulation.

The Joint Commission on Administrative Rules or the appropriate standing committee of each house of the General Assembly may meet during the promulgation or final adoption process and file an objection with the Registrar and the promulgating agency. The objection will be published in the *Virginia Register*. Within 21 days after receipt by the agency of a legislative objection, the agency shall file a response with the Registrar, the objecting legislative body, and the Governor.

When final action is taken, the agency again publishes the text of the regulation as adopted, highlighting all changes made to the proposed regulation and explaining any substantial changes made since publication of the proposal. A 30-day final adoption period begins upon final publication in the *Virginia Register*.

The Governor may review the final regulation during this time and, if he objects, forward his objection to the Registrar and the agency. In addition to or in lieu of filing a formal objection, the Governor may suspend the effective date of a portion or all of a regulation until the end of the next regular General Assembly session by issuing a directive signed by a majority of the members of the appropriate legislative body and the Governor. The Governor's objection or suspension of the regulation, or both, will be published in the *Virginia Register*.

If the Governor finds that the final regulation contains changes made after publication of the proposed regulation that have substantial impact, he may require the agency to provide an additional 30-day public comment period on the changes. Notice of the additional public comment period required by the Governor will be published in the *Virginia Register*. Pursuant to § 2.2-4007.06 of the Code of Virginia, any person may request that the agency solicit additional public comment on certain changes made after publication of the proposed regulation. The agency shall suspend the regulatory process for 30 days upon such request from 25 or more individuals, unless the agency determines that the changes have minor or inconsequen111tial impact.

A regulation becomes effective at the conclusion of the 30-day final adoption period, or at any other later date specified by the promulgating agency, unless (i) a legislative objection has been filed, in which event the regulation, unless withdrawn, becomes effective on the date specified, which shall be after the expiration of the 21-day objection period; (ii) the Governor exercises his

authority to require the agency to provide for additional public comment, in which event the regulation, unless withdrawn, becomes effective on the date specified, which shall be after the expiration of the period for which the Governor has provided for additional public comment; (iii) the Governor and the General Assembly exercise their authority to suspend the effective date of a regulation until the end of the next regular legislative session; or (iv) the agency suspends the regulatory process, in which event the regulation, unless withdrawn, becomes effective on the date specified, which shall be after the expiration of the 30-day public comment period and no earlier than 15 days from publication of the readopted action.

A regulatory action may be withdrawn by the promulgating agency at any time before the regulation becomes final.

#### FAST-TRACK RULEMAKING PROCESS

Section 2.2-4012.1 of the Code of Virginia provides an alternative to the standard process set forth in the Administrative Process Act for regulations deemed by the Governor to be noncontroversial. To use this process, the Governor's concurrence is required and advance notice must be provided to certain legislative committees. Fast-track regulations become effective on the date noted in the regulatory action if fewer than 10 persons object to using the process in accordance with § 2.2-4012.1.

#### EMERGENCY REGULATIONS

Pursuant to § 2.2-4011 of the Code of Virginia, an agency may adopt emergency regulations if necessitated by an emergency situation or when Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or fewer from its enactment. In either situation, approval of the Governor is required. The emergency regulation is effective upon its filing with the Registrar of Regulations, unless a later date is specified per § 2.2-4012 of the Code of Virginia. Emergency regulations are limited to no more than 18 months in duration; however, may be extended for six months under the circumstances noted in § 2.2-4011 D. Emergency regulations are published as soon as possible in the *Virginia Register* and are on the Register of Regulations website at <a href="https://register.dls.virginia.gov">https://register.dls.virginia.gov</a>.

During the time the emergency regulation is in effect, the agency may proceed with the adoption of permanent regulations in accordance with the Administrative Process Act. If the agency chooses not to adopt the regulations, the emergency status ends when the prescribed time limit expires.

#### STATEMENT

The foregoing constitutes a generalized statement of the procedures to be followed. For specific statutory language, it is suggested that Article 2 (§ 2.2-4006 et seq.) of Chapter 40 of Title 2.2 of the Code of Virginia be examined carefully.

#### CITATION TO THE VIRGINIA REGISTER

The *Virginia Register* is cited by volume, issue, page number, and date. **34:8 VA.R. 763-832 December 11, 2017,** refers to Volume 34, Issue 8, pages 763 through 832 of the *Virginia Register* issued on December 11, 2017.

The Virginia Register of Regulations is published pursuant to Article 6 (§ 2.2-4031 et seq.) of Chapter 40 of Title 2.2 of the Code of Virginia.

Members of the Virginia Code Commission: Marcus B. Simon, Chair; Russet W. Perry, Vice Chair; Katrina E. Callsen; Nicole Cheuk; Richard E. Gardiner; Ryan T. McDougle; Michael Mullin; Christopher R. Nolen; Steven Popps; Charles S. Sharp; Malfourd W. Trumbo; Amigo R. Wade.

<u>Staff of the Virginia Register:</u> **Holly Trice**, Registrar of Regulations; **Anne Bloomsburg**, Assistant Registrar; **Nikki Clemons**, Managing Editor; **Erin Comerford**, Regulations Analyst

### **PUBLICATION SCHEDULE AND DEADLINES**

This schedule is available on the Virginia Register of Regulations website (http://register.dls.virginia.gov).

#### March 2025 through March 2026

Volume: Issue	Material Submitted By Noon*	Will Be Published On
41:15	February 19, 2025	March 10, 2025
41:16	March 5, 2025	March 24, 2025
41:17	March 19, 2025	April 7, 2025
41:18	April 2, 2025	April 21, 2025
41:19	April 16, 2025	May 5, 2025
41:20	April 30, 2025	May 19, 2025
41:21	May 14, 2025	June 2, 2025
41:22	May 28, 2025	June 16, 2025
41:23	June 11, 2025	June 30, 2025
41:24	June 25, 2025	July 14, 2025
41:25	July 9, 2025	July 28, 2025
41:26	July 23, 2025	August 11, 2025
42:1	August 6, 2025	August 25, 2025
42:2	August 20, 2025	September 8, 2025
42:3	September 3, 2025	September 22, 2025
42:4	September 17, 2025	October 6, 2025
42:5	October 1, 2025	October 20, 2025
42:6	October 15, 2025	November 3, 2025
42:7	October 29, 2025	November 17, 2025
42:8	November 10, 2025 (Monday)	December 1, 2025
42:9	November 24, 2025 (Monday)	December 15, 2025
42:10	December 9, 2025	December 29, 2025
42:11	December 22, 2025 (Monday)	January 12, 2026
42:12	January 6, 2026 (Tuesday)	January 26, 2026
42:13	January 21, 2026	February 9, 2026
42:14	February 4, 2026	February 23, 2026
42:15	February 18, 2026	March 9, 2026
42:16	March 4, 2026	March 23, 2026

<sup>\*</sup>Filing deadlines are Wednesdays unless otherwise specified.

### PETITIONS FOR RULEMAKING

# TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

#### **BOARD OF COUNSELING**

#### **Agency Decision**

<u>Title of Regulation:</u> **18VAC115-20. Regulations Governing the Practice of Professional Counseling.** 

Statutory Authority: §§ 54.1-2400 and 54.1-3505 of the Code of Virginia.

Name of Petitioner: Marva Michelle Baskerville.

<u>Nature of Petitioner's Request:</u> The petitioner requests that the Board of Counseling revise 18VAC115-20-70 to establish a pathway for licensed substance abuse treatment providers (LSATPs) to become licensed professional counselors (LPCs). A similar pathway exists for LPCs to become LSATPs without an examination under 18VAC115-60-90 C.

Agency Decision: Request denied.

Statement of Reason for Decision: At its January 24, 2025, meeting, the Board of Counseling voted to deny the petition for rulemaking as the board feels LSATPs and LPCs are different professional tracks with distinct educational requirements. The board concluded that, as a result, a distinct pathway for LSATPs to become LPCs is not viable.

Agency Contact: Jaime Hoyle, Executive Director, Board of Counseling, 9960 Mayland Drive, Suite 300, Henrico, VA 23233, telephone (804) 367-4406, or email jaime.hoyle@dhp.virginia.gov.

VA.R. Doc. No. PFR25-29; Filed October 16, 2024, 4:06 p.m.

#### **Agency Decision**

<u>Title of Regulation:</u> **18VAC115-20. Regulations Governing the Practice of Professional Counseling.** 

Statutory Authority: §§ 54.1-2400 and 54.1-3505 of the Code of Virginia.

Name of Petitioner: James Honeycutt.

Nature of Petitioner's Request: The petitioner requests that the Board of Counseling amend 18VAC115-20-52 C 3 and 18VAC115-50-60 C 3 to allow previous clinical experience obtained by a licensed professional counselor or licensed marriage and family therapist who is also a licensed psychologist, licensed clinical social worker, or psychiatrist to satisfy the requirements for two years of post-licensure clinical experience.

Agency Decision: Request denied.

<u>Statement of Reason for Decision:</u> At its January 24, 2025, meeting, the Board of Counseling voted to deny the petition for

rulemaking as the board feels the current standards of supervision are sufficient.

Agency Contact: Jaime Hoyle, Executive Director, Board of Counseling, 9960 Mayland Drive, Suite 300, Henrico, VA 23233, telephone (804) 367-4406, or email jaime.hoyle@dhp.virginia.gov.

VA.R. Doc. No. PFR25-27; Filed August 26, 2024, 8:42 a.m.

#### **Agency Decision**

<u>Title of Regulation:</u> **18VAC115-20. Regulations Governing the Practice of Professional Counseling.** 

<u>Statutory Authority:</u> §§ 54.1-2400 and 54.1-3505 of the Code of Virginia.

Name of Petitioner: Jenna Pagano.

Nature of Petitioner's Request: The petitioner requests that the Board of Counseling amend 18VAC115-20-40 and 18VAC115-20-51 to create a pathway for licensed marriage and family therapists to obtain licensure as a professional counselor similar to the pathway provided for licensed professional counselors to obtain licensure as a marriage and family therapist.

Agency Decision: Request denied.

Statement of Reason for Decision: At its January 24, 2025, meeting, the Board of Counseling voted to deny the petition for rulemaking as the board feels current regulations are sufficient for individuals who hold a licensed marriage and family therapist license to obtain licensed professional counselor credentials.

Agency Contact: Jaime Hoyle, Executive Director, Board of Counseling, 9960 Mayland Drive, Suite 300, Henrico, VA 23233, telephone (804) 367-4406, or email jaime.hoyle@dhp.virginia.gov.

VA.R. Doc. No. PFR25-28; Filed September 24, 2024, 3:15 p.m.

#### **Agency Decision**

<u>Title of Regulation:</u> **18VAC115-20. Regulations Governing the Practice of Professional Counseling.** 

Statutory Authority: §§ 54.1-2400 and 54.1-3505 of the Code of Virginia.

Name of Petitioner: Jenna Pagano.

Nature of Petitioner's Request: The petitioner requests that the Board of Counseling amend 18VAC115-20-40 to exempt licensed marriage and family counselors from passing the National Clinical Mental Health Counselor Examination or National Counselor Examination to apply for licensure as a professional counselor and accept passage of the National Marriage and Family Therapy Examination for those applicants.

### Petitions for Rulemaking

Agency Decision: Request denied.

Statement of Reason for Decision: At its January 24, 2025, meeting, the Board of Counseling voted to deny the petition for rulemaking. The board feels there is not sufficient information on the equivalence of the licensed marriage and family therapist exam to the currently accepted exams by the board for licensure as a licensed professional counselor.

Agency Contact: Jaime Hoyle, Executive Director, Board of Counseling, 9960 Mayland Drive, Suite 300, Henrico, VA 23233, telephone (804) 367-4406, or email jaime.hoyle@dhp.virginia.gov.

VA.R. Doc. No. PFR25-30; Filed September 24, 2024, 3:09 p.m.

#### **Agency Decision**

<u>Title of Regulation:</u> **18VAC115-20. Regulations Governing the Practice of Professional Counseling.** 

Statutory Authority: §§ 54.1-2400 and 54.1-3505 of the Code of Virginia.

Name of Petitioner: Sharon Watson.

Nature of Petitioner's Request: The petitioner requests that the Board of Counseling amend 18VAC115-20-52 C 2 and 18VAC115-50-60 C 3 to require that supervisors complete two hours of continuing education in residency and supervision requirements and related supervisory ethical issues as part of required annual continuing education for licensed professional counselors and licensed marriage and family therapists.

Agency Decision: Request denied.

Statement of Reason for Decision: At its January 24, 2025, meeting, the Board of Counseling voted to deny the petition for rulemaking and send the issue to the regulatory committee. While the board supported the idea of the petition, the board preferred that the regulatory committee look at the issue to identify all potential changes that would need to be made.

Agency Contact: Jaime Hoyle, Executive Director, Board of Counseling, 9960 Mayland Drive, Suite 300, Henrico, VA 23233, telephone (804) 367-4406, or email jaime.hoyle@dhp.virginia.gov.

VA.R. Doc. No. PFR25-26; Filed August 12, 2024, 7:34 a.m.

#### PERIODIC REVIEWS AND SMALL BUSINESS IMPACT REVIEWS

# TITLE 24. TRANSPORTATION AND MOTOR VEHICLES

#### **COMMONWEALTH TRANSPORTATION BOARD**

#### Report of Findings

Pursuant to §§ 2.2-4007.1 and 2.2-4017 of the Code of Virginia, the Commonwealth Transportation Board conducted a periodic review and a small business impact review of **24VAC30-540**, **Conveyance of Land and Disposal of Improvements**, and determined that this regulation should be retained as is. The board is publishing its report of findings dated February 3, 2025, to support this decision.

The regulation sets forth policy and procedures for the Commissioner of Highways to recommend transfer or conveyance of residue and surplus land acquired in contemplation of a highway construction project based upon highest and best use. The regulation is necessary for the protection of public health, safety, and welfare and is clearly written and easily understandable. The Virginia Department of Transportation (VDOT) recommends retaining the regulation as is. The regulation helps to ensure that VDOT resources are used effectively, and it articulates policy and protocol for the transfer or conveyance of residue and surplus land with an emphasis on highest and best use.

A periodic review of this regulation was last performed in 2020. This regulation continues to be needed as it helps ensure effective use of highway resources by setting forth the policy and procedures for the conveyance of land no longer needed by VDOT. Typically, the original landowner is offered right of first refusal, with exceptions to that policy clearly articulated in the regulation. The regulation also emphasizes the importance of conveying surplus VDOT right-of-way based on highest and best use. VDOT is not aware of any undue burden placed on small business due to the regulation. VDOT has received no complaints concerning the regulation, and the regulation is not overly complex. The regulation is consistent with federal and state law.

<u>Contact Information:</u> JoAnne P. Maxwell, Agency Regulatory Coordinator, Governance and Legislative Affairs Division, Department of Transportation, 1401 East Broad Street, Richmond, VA 23219, telephone (804) 786-1830, or email joanne.maxwell@vdot.virginia.gov.

### **REGULATIONS**

For information concerning the different types of regulations, see the Information Page.

#### Symbol Key

Roman type indicates existing text of regulations. Underscored language indicates proposed new text.

Language that has been stricken indicates proposed text for deletion. Brackets are used in final regulations to indicate changes from the proposed regulation.

# TITLE 3. ALCOHOLIC BEVERAGE AND CANNABIS CONTROL

#### **VIRGINIA CANNABIS CONTROL AUTHORITY**

#### **Final Regulation**

REGISTRAR'S NOTICE: The Board of Directors of the Virginia Cannabis Control Authority is claiming an exemption from the Administrative Process Act in accordance with § 4.1-1602 of the Code of Virginia, which exempts adoption of regulations if prior to adoption, the board publishes a notice of opportunity to comment in the Virginia Register of Regulations and posts the action on the Virginia Regulatory Town Hall. Such notice of opportunity to comment shall contain (i) a summary of the proposed regulation; (ii) the text of the proposed regulation; and (iii) the name, address, and telephone number of the agency contact person responsible for receiving public comments. Such notice shall be made at least 60 days in advance of the last date prescribed in such notice for submittals of public comment.

<u>Titles of Regulations:</u> **3VAC10-20. Medical Cannabis Program Fees (amending 3VAC10-20-10).** 

3VAC10-30. Applications, Licenses, Permits, and Registrations (amending 3VAC10-30-10, 3VAC10-30-30, 3VAC10-30-40, 3VAC10-30-50, 3VAC10-30-70, 3VAC10-30-100, 3VAC10-30-110, 3VAC10-30-120, 3VAC10-30-130, 3VAC10-30-140, 3VAC10-30-160).

Statutory Authority: §§ 4.1-601, 4.1-604, and 4.1-606 of the Code of Virginia.

Effective Date: February 10, 2025.

Agency Contact: Jake Shuford, Legislative and Regulatory Manager, Virginia Cannabis Control Authority, 333 East Franklin Street, Richmond, VA 23219, telephone (804) 873-9038, or email jake.shuford@cca.virginia.gov.

#### Summary:

Pursuant to Chapter 812 of the 2023 Acts of Assembly and Chapter 732 of the 2024 Acts of Assembly, the amendments update the application procedures for pharmaceutical processor permits to reflect updated business standards and practices, specify when pharmaceutical processor operations commence, and add requirements for additional cultivation facilities. Amendments also update definitions and clarify other regulatory requirements.

#### 3VAC10-20-10. Definitions.

In addition to words and terms defined in the Cannabis Control Act (§ 4.1-600 et seq. 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:

"Board" means the Board of Directors of the Virginia 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 3VAC10-30-160.

"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.

"Medical cannabis facility" means a pharmaceutical processor, cannabis dispensing facility, or cannabis cultivation 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 an individual who resides within the geographical boundaries of the Commonwealth. 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.

#### 3VAC10-30-10. Definitions.

In addition to words and terms defined in the Cannabis Control Act (§ 4.1-600 et seq. 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 either included on a valid, unexpired written certification issued by a practitioner for the use of cannabis products or established by a pharmacist during initial consultation.

# "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 3VAC10-30-160.

"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.

# "Daycare" means a "child day center" or "family day home" as defined in § 22.1-289.02 of the Code of Virginia.

"Electronic tracking system" means an electronic radiofrequency 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.

"Material owner" means (i) for a publicly traded entity, voting rights that entitle a person to individually elect or appoint one or more of the members of the board of directors or other governing board or the ownership or beneficial holding of

5.0% or more of the securities of the publicly traded entity and (ii) for a privately held entity, the ownership of any security or beneficial interest in the entity.

"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 3VAC10-30-90 is on the premises at the address of the permitted pharmaceutical processor and is available as needed.

"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 an individual who resides within the geographical boundaries of the Commonwealth. 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.

"School" means (i) any public school from kindergarten through grade 12 operated under the authority of any locality within the Commonwealth, (ii) any private or religious school that offers instruction at any level or grade from kindergarten through grade 12, and (iii) any private or religious nursery

school or preschool or any private or religious childcare center required to be licensed by the Commonwealth.

"Temporary residency" means a person 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.

### 3VAC10-30-30. 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 diagnose the patient, which or confirm another medical provider's diagnosis. This shall include an examination of the patient and the patient's medical history, prescription history, and current medical condition;
- 2. Diagnose Develop a treatment plan for 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 the practitioner's 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.
- G. If the authority determines that a practitioner has violated, attempted to violate, solicited any person to violate, or consented to any violation of this chapter, the authority may restrict that practitioner's ability to issue written certifications for patients in the future or report information to the applicable licensing board.

#### **3VAC10-30-40.** Prohibited practices for practitioners.

- A. A practitioner who issues certifications shall not:
- 1. Directly or indirectly accept, solicit, or receive anything of value from any person associated with a pharmaceutical processor or provider of paraphernalia, excluding information on products or educational materials on the benefits and risks of cannabis 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 <u>medical</u> 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 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.

# 3VAC10-30-50. 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 in a manner 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 birth date 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.

# **3VAC10-30-70.** Reporting requirements for practitioners, patients, parents, legal guardians, or registered agents.

- A. A practitioner shall report to the board, in a manner 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 in a manner 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 including a change in the identifying information of the patient for whom the registered agent 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.

# 3VAC10-30-100. Publication of notice for submission of open applications.

- A. The board When there is an available pharmaceutical processor permit, the authority shall publish a notice of open applications for pharmaceutical processor permits.
  - <u>1.</u> Such notice shall include information on how to obtain and complete an application, the required fees, the criteria for issuance of a permit, and the deadline for receipt of applications.
  - 2. The criteria set forth in the notice of open applications shall include the following:
    - a. Any history of disciplinary action imposed by a state or federal regulatory agency;
    - b. The applicant's ability to maintain adequate control against the diversion, theft, and loss of the cannabis, including the seeds, any parts, or extracts of the cannabis plants or the cannabis products;
    - c. 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; and
    - d. The extent to which the applicant or any of the applicant's pharmaceutical processor material owners have a financial interest in another license, permit, registrant, or applicant.
- B. The board shall have the right to amend the notice of open applications prior to the deadline for submitting to submit 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.

# 3VAC10-30-110. Application process for pharmaceutical processor permits Initial application and award of conditional approval.

- A. The application process for permits shall occur in the following three stages: submission of initial application, award of conditional approval, and grant of a pharmaceutical processor permit.
- B. A. Submission of initial application.

- 1. A pharmaceutical processor permit applicant shall submit the required application fee and <u>all requested application</u> materials <u>with the following information and</u> <u>documentation</u>, including:
  - 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 where the applicant intends to operate the pharmaceutical processor permit; and
  - 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 eriminal 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. An applicant may only submit one application for a pharmaceutical processor permit in response to any notice of open applications issued by the authority unless the applicant meets the following criteria:
  - a. Each application identifies a separate and distinct physical address where the applicant intends to operate a pharmaceutical processor permit; and
  - b. Each application contains documentation of separate and distinct capital to support the operations of the proposed pharmaceutical processor.
- 3. 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 authority 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.
- B. Identification of qualified applicants. [ 1. ] Following the deadline for receipt of applications, the authority shall identify qualified applicants by evaluating each complete and timely submitted application based on compliance with requirements set forth in notice of open applications.
  - [ <u>a. 1.</u> ] When circumstances warrant, the authority may verify information contained in an application and accompanying documentation in order to assess the applicant's ability to operate a pharmaceutical processor.
  - [ b. 2. ] The authority shall disqualify any applicant who:
    - [ (1) a. ] Fails to submit an application by the published deadline;
    - [ (2) b. ] Fails to pay all applicable fees;
    - [ (3) c. ] Fails to timely notify the board of any changes or corrected information; or
    - [ (4) d. ] Fails to cooperate with any authority inquiries or investigations related to an application or accompanying documentation.
- C. Award of conditional approval.
- 1. 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.

- 2. In the event the authority determines there is more than one qualified applicant, the authority may hold a lottery or similar process to select the applicant to award conditional approval for a pharmaceutical processor.
- <u>3.</u> 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 3VAC10-30-100, 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.

#### 3VAC10-30-120. Conditional approval.

- A. Following the deadline for receipt of applications, the board shall evaluate each complete and timely submitted application and may grant award of conditional approval on a competitive basis based on compliance with requirements set forth in 3VAC10-30-110, the selected applicant shall submit information necessary for the board to conduct a criminal background check on the selected applicant's material owners. No person who has been convicted of a felony under the Code of Virginia or another jurisdiction within the last five years shall be a material owner of, be employed by, or act as an agent of a pharmaceutical processor.
- 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 30 110 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.

- B. Upon request of the authority, the selected applicant shall provide additional information or documents.
- C. The board may disqualify any revoke conditional approval if the authority determines the selected applicant who:
  - 1. Submits an incomplete, false, inaccurate, or misleading application information or documentation;
  - 2. Fails to submit an application by the published deadline cooperate in any investigation conducted by the authority;
  - 3. Fails to pay all applicable fees; or secure property to operate the proposed pharmaceutical processor at a location that is more than 1,000 feet from a school or daycare;
  - 4. <u>Is in violation of § 4.1-1602 K of the Code of Virginia based on the results of criminal background checks of the selected applicant's material owners; or</u>
  - <u>5.</u> 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. D. 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 including 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.
- E. In the event conditional approval is rescinded pursuant to this section, the board may award conditional approval for a pharmaceutical processor permit by selecting from among the qualified applicants who applied for the pharmaceutical processor permit or publishing a new notice of open applications.

# 3VAC10-30-130. 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 including:
  - 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.
- <u>D.</u> A pharmaceutical processor permit shall not be issued to any person to operate from a private dwelling or residence.
- D. E. 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. F. 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 or the processor has received cannabis products from another pharmaceutical processor holding a permit issued by the board.
- G. Once the pharmaceutical processor has commenced operation, it shall inform the authority of its normal hours of operation.
- F. H. In the event a permit is rescinded pursuant to this section, the board may award <u>conditional approval for</u> 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 <u>in</u> accordance with 3VAC10-30-100.
- G. I. Once the board issues a permit is issued, a processor may begin <del>cultivation of</del> cultivating cannabis, and <del>the</del> receiving cannabis through wholesale distribution. The responsible party or a person who is qualified to provide supervision in accordance with 3VAC10-30-90 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.

# 3VAC10-30-140. 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 <u>material</u> 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 facility <u>material</u> 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.

# **3VAC10-30-160.** 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. 2. 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.
  - 3. The distance of the proposed additional cannabis cultivation location from the pharmaceutical processor;
  - 4. Details regarding access to a secure transportation network between the proposed additional cannabis cultivation location and the pharmaceutical processor;
  - 5. The economic viability of the additional cannabis cultivation at the proposed location; and
  - <u>6. Any demonstrated demand for additional cannabis</u> cultivation.
- 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 authorization 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 authorization is issued, the board shall rescind the authorization 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 this section shall be present during hours of operation to ensure the safety, security, and integrity of the cannabis.

VA.R. Doc. No. R25-8122; Filed January 31, 2025, 1:55 p.m.

#### **Final Regulation**

REGISTRAR'S NOTICE: The Board of Directors of the Virginia Cannabis Control Authority is claiming an exemption from the Administrative Process Act in accordance with § 4.1-1602 of the Code of Virginia, which exempts adoption of regulations if prior to adoption, the board publishes a notice of opportunity to comment in the Virginia Register of Regulations and posts the action on the Virginia Regulatory Town Hall. Such notice of opportunity to comment shall contain (i) a summary of the proposed regulation; (ii) the text of the proposed regulation; and (iii) the name, address, and telephone number of the agency contact person responsible for receiving public comments. Such notice shall be made at least 60 days in advance of the last date prescribed in such notice for submittals of public comment.

<u>Title of Regulation:</u> 3VAC10-40. Regulated Operations (amending 3VAC10-40-10 through 3VAC10-40-60, 3VAC10-40-100, 3VAC10-40-120 through 3VAC10-40-170, 3VAC10-40-190, 3VAC10-40-210; adding 3VAC10-40-230 through 3VAC10-40-280).

Statutory Authority: §§ 4.1-601, 4.1-604, and 4.1-606 of the Code of Virginia.

Effective Date: February 10, 2025.

Agency Contact: Jake Shuford, Legislative and Regulatory Manager, Virginia Cannabis Control Authority, 333 East Franklin Street, Richmond, VA 23219, telephone (804) 873-9038, or email jake.shuford@cca.virginia.gov.

#### Summary:

The amendments (i) add definitions; (ii) prohibit permittees from endorsing practitioners; (iii) codify the current practice of permittees using electronic tracking; and (iv) establish public health and safety standards for the transportation and delivery of medical cannabis, including vehicle inspections, global positioning system (GPS) tracking, and incident and accident protocols. Changes to the proposed regulation clarify the distance requirements

for outdoor cannabis product advertising located near real property of a school or daycare, a public or private playground or similar recreational or child-centered facility, or a substance use disorder treatment facility.

#### 3VAC10-40-10. Definitions.

In addition to words and terms defined in the Cannabis Control Act (§ 4.1-600 et seq. 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:

"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 3VAC10-30-160.

"Cannabis product 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.

"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.

"Cartoon" means any drawing, sketch, computer-generated illustration, or other depiction of an object, person, animal, creature, or any similar caricature that meets any of the following criteria:

- 1. The use of comically exaggerated features;
- 2. The attribution of human characteristics to animals, plants, or other objects;
- 3. The attribution of animal, plant, or other object characteristics to humans; or
- 4. The attribution of unnatural or extra-human abilities.
- "Companion" means a person who provides fellowship and protection for an elderly person or person with an illness, injury, or disability who requires assistance with self-care.

"Endorse" means declaring public approval, support, or recommendation of a practitioner, including sharing information online and hosting or facilitating events that would promote a particular practitioner's services above others.

Patient education events are permissible provided the event (i) is clearly focused on patient education and (ii) offers information about multiple practitioners without favor or emphasis on a particular practitioner.

"Immediate container" means a container that is in direct contact with cannabis or a cannabis product or, if a wrapper is in direct contact with the cannabis or the cannabis product, with the wrapper.

"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 3VAC10-30-90 is on the premises at the address of the permitted pharmaceutical processor and is available as needed.

<u>"Package" or "packaging" means any inner or outer container or covering.</u>

"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.

"Registered cannabis product" means cannabis flower, concentrated cannabis, cannabis extracts, and products that are infused with cannabis or an extract thereof intended for use or consumption by humans and approved by the board.

"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.

"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.

#### 3VAC10-40-20. 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- $30-90 \in \underline{D}$  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 3VAC10-30-90 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. I. 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.

#### 3VAC10-40-30. 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 3VAC10-40-50;
- 3. Produce or manufacture cannabis products for use outside of Virginia; or
- 4. Provide cannabis products samples;
- 5. Endorse or promote a practitioner; or
- <u>6. Provide anything of value, directly or indirectly, to a practitioner.</u>
- 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 3VAC10-40-50; 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;
  - No person shall be in the dispensing area unless all cannabis products are contained in a vault or other similar container to which only the pharmacist has access controls;
  - 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. An employee of a business that is contracted by a pharmaceutical processor may be allowed on the premises of the processor to perform the employee's duties (e.g. security, cleaning, electrical, plumbing) without requesting board authorization. The pharmaceutical processor should apply the requirements for visitor access found in subsection K of this section to the contracted employee.
- K. 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.
- L. 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 3VAC10-50-80 A.
- M. 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 such individual's governmental duties.

#### 3VAC10-40-40. Reserved Electronic tracking.

- A. A pharmaceutical processor must implement and maintain an electronic tracking system as prescribed by the authority.
- B. A pharmaceutical processor shall identify, monitor, and track all cannabis through a unique identifier assigned at seed acquisition or plant propagation.
- C. A pharmaceutical processor shall maintain a record of all cannabis through cultivation and processing until transferred, distributed to qualifying patients, parents, legal guardians, or registered agents, or otherwise disposed of according to 3VAC10-50-110.

#### Part II

Cannabis Production, Wholesale Distribution, and Inventory

3VAC10-40-50. 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 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 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 3VAC10-70-30.
- 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, including 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 3VAC10-40-200.
- 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 3VAC10-40-200.
- 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 3VAC10-40-210.
- 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 3VAC10-40-200.

#### 3VAC10-40-60. Inventory requirements.

- A. Each Upon commencing operation, each medical cannabis facility prior to commencing business shall: 1. Conduct 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. Each medical cannabis facility shall establish ongoing inventory controls and procedures to conduct 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.
- <u>C.</u> 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.
- $\underline{C}$ .  $\underline{D}$ . Upon commencing <u>business</u> <u>operation</u>, 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  $\underline{B}$   $\underline{C}$  of this section.
- D. E. Upon commencing business operation, 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. F. Upon commencing business operation, 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 C of this section.
- F. G. 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. H. 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. I. 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.
- <u>H. J.</u> Inventory records shall be maintained for three years from the date the inventory was taken.
- $\pm \underline{K}$ . 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.

#### 3VAC10-40-100. 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 including 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 ensure 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.

#### 3VAC10-40-120. 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 including 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 this chapter.
- 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 notify the board indicating and indicate the effective date on which the responsible party ceased or will cease 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. F. A responsible party who is absent from practice a pharmaceutical processor or cannabis cultivation facility 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, the responsible party 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 in a manner provided by the board. G. If the responsible party resigns or otherwise ceases employment, the

pharmaceutical processor or cannabis cultivation facility shall submit a change of responsible party application designating the new responsible party within 14 days of the former responsible party's resignation or termination date. It shall be unlawful for a pharmaceutical processor to operate without a new permit responsible party designated past the 14-day deadline unless the board receives a request for an extension prior to the deadline. The chair of the board, or the chair's designee, authority may grant an extension for up to an additional 14 days for good cause shown.

#### 3VAC10-40-130. 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 <u>are</u> 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 this chapter.
- D. When the PIC ceases practice at a pharmaceutical processor or cannabis dispensing facility or no longer wishes to be designated as PIC, the PIC shall immediately return the permit to the board indicating the effective date on which the PIC 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 the PIC 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. E. 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, the PIC 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 F. If the PIC resigns or otherwise ceases employment, the pharmaceutical processor or cannabis dispensing facility shall submit a change of PIC application within 14 days of the PIC's resignation or termination date. It shall be unlawful for a pharmaceutical processor or cannabis dispensing facility to operate without a new permit PIC designated past the 14-day deadline unless the board receives a request for an extension prior to the deadline. The executive director for the board authority may grant an extension for up to an additional 14 days for good cause shown.

#### 3VAC10-40-140. 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;
- 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; and
- 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.

#### 3VAC10-40-150. Reportable events.

- A. Upon A medical cannabis facility shall immediately notify appropriate law-enforcement authorities and the board upon becoming aware of (i) diversion any of the following:
  - 1. Diversion, theft, loss, or discrepancies identified during inventory;
  - (ii) unauthorized <u>2. Unauthorized</u> destruction of any cannabis products; or
  - (iii) any 3. 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; or
  - 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. In addition to the notice required by subsection C of this section, the medical cannabis facility shall provide written notification to the board no later than 10 business days that details the circumstances of the event and identifies corrective measures taken, if any.
- <u>E.</u> A pharmacist, responsible party, pharmaceutical processor, or cannabis dispensing facility shall immediately notify the board of an employee convicted of a felony.
- F. A medical cannabis facility shall immediately notify the board upon becoming aware or having reasonable suspicion of a violation of any provision of 3VAC10-30-30 or 3VAC10-30-40.

#### 3VAC10-40-160. General provisions.

- 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, <u>fruit</u>, 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.

#### 3VAC10-40-170. 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. 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 or
- 2. 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 1,000 500 [linear] feet [on the same side of the road, and parallel to such road, measured from the nearest edge of the sign face upon which the advertisement is placed to the nearest edge of a building or structure located on the real property ] 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. [ However, (a) if there is no building or structure on a playground or similar recreational facility, the measurement shall be from the nearest edge of the sign face upon which the advertisement is placed to the property line of such playground or similar recreational facility and (b) if a public or private school providing grade K through 12 education is located across the road from a sign, the measurement shall be from the nearest edge of the sign face upon which the advertisement is placed to the nearest edge of a building or structure located on such real property across the road. ]
- 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; or
  - 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 nonbusiness 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.
- G. No advertising shall be conducted through the marketing of free promotional items, including gifts and "free" or "donated" cannabis.

#### 3VAC10-40-190. 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.
- <u>B.</u> 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. C. 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. D. All outdoor signage must comply with local or state requirements.

Part V
Records, Storage, and Administration Transportation

#### 3VAC10-40-210. 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	<del>50% 75%</del>
Nursery phase	<del>65 - 85° F</del>	<del>50% - 75%</del>
Vegetation phase	65 85° F	<del>50% 75%</del>
Flower/harvest phase	65 85° F	<del>40% 75%</del>
Drying/extraction rooms	<75° F	40% 75%

- 3. 2. 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. 3. Be maintained in a clean, sanitary, and orderly condition; and
- 5. 4. 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 the employees 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. 3. 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 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 <u>labor</u> 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:
  - <u>1. Store</u> 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 2. 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 3. Return such items to their secure location immediately after completion of the production, transfer, or analysis process or at the end of the scheduled business day.
- <u>G.</u> 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. H. 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.

# <u>3VAC10-40-230.</u> Cannabis delivery and transportation general requirements.

- A. Prior to transporting medical cannabis to another medical cannabis facility or offering cannabis delivery to patients, a medical cannabis facility shall submit the following items to the authority:
  - 1. A list of the employees authorized to transport or deliver cannabis, along with a copy of each authorized employee's valid driver license; and
  - 2. For each transport or delivery vehicle:
    - a. License plate number, vehicle identification number, make, and model;
    - b. An attestation that the vehicle is properly registered and insured:
    - c. A description of the locked, safe, and secure storage compartments in the vehicle; and
    - d. A description of the security system, form of secure communication, global positioning system (GPS) monitoring device, and any other equipment or system required pursuant to 3VAC10-40-240.
- B. A medical cannabis facility shall provide written notice to the authority, along with the documentation required in subsection A of this section, in the event the facility adds or removes a transport or delivery vehicle or an authorized employee.
- C. No medical cannabis facility shall advertise, offer, or commence delivery or transport operations prior to receiving written approval from the authority.

#### 3VAC10-40-240. Vehicle security.

- A. All transport or delivery vehicles shall be properly registered with the Commonwealth and be insured in the Commonwealth. Medical cannabis facilities shall maintain registration and insurance documents and provide the documents to the authority and law-enforcement officials upon request.
- B. A transport or delivery vehicle shall bear no marking or outward appearance, including brand or company names, that would indicate to a reasonable person that the vehicle is used to transport cannabis.
- C. At all times during the transportation of cannabis, a transport or delivery vehicle shall be equipped with the following functioning features:
  - 1. Heating and air conditioning systems sufficient for maintaining appropriate temperatures for the storage of cannabis during transport in accordance with recommendations provided by the originating medical cannabis facility to protect the quality and integrity of the cannabis;

- 2. A locked, safe, and secure storage compartment where cannabis will be stored during transport that [ is ] (i) [ is ] a secured part of the vehicle, (ii) [ is ] not easily removed, and (iii) [ ensures cannabis is ] not visible from the outside of the vehicle;
- 3. A global positioning system (GPS) monitoring device that is secured to the vehicle in a manner not easily removed and able to remain powered on when the transport vehicle is not running, the information from which shall be maintained in accordance with 3VAC10-40-260;
- 4. A secure form of communication between the transporting agent and the transporting facility, and any originating facility if required by 3VAC10-40-260 G, at all times during the transportation of cannabis. Secure forms of communication shall include a two-way digital or analog radio, cellular telephone, and satellite telephone, taking into consideration the functionality of the communication device within the geographic area of the transport; and
- 5. An adequate vehicle security system to prevent adulteration, diversion, theft, and loss of cannabis, including an audible alarm system.
- D. Access to transport vehicle security equipment and records shall be limited to (i) persons [ that who ] are essential to security operations, (ii) law-enforcement agencies, (iii) security system service employees, (iv) the authority, and (v) other persons approved by the authority. A transporting facility shall maintain a current list of all individuals [ that who ] have access to any transport vehicle security equipment and records.
- E. The authority may inspect a transport or delivery vehicle as well as its equipment, including security systems, forms of secure communication, and GPS monitoring devices at any time without prior notice. If the authority determines that the transport or delivery vehicle does not satisfy the requirements of this section, or that such transport or delivery vehicle requires additional security measures to address public health and safety concerns, the medical cannabis facility shall not use the transport vehicle until such time as it receives a satisfactory inspection from the authority.

#### 3VAC10-40-250. Manifests.

- A. Prior to transporting cannabis between medical cannabis facilities or from a medical cannabis facility to a testing laboratory:
  - 1. The originating facility shall prepare a transport manifest on a form and in a manner prescribed by the authority, itemizing all cannabis to be transported. A separate copy of the transport manifest shall be provided to the transporting employee to accompany the itemized cannabis at all times during transport.

- 2. The originating facility shall securely transmit a copy of the transport manifest to the receiving facility at least 24 hours prior to transport.
- 3. An authorized transportation employee shall review the transport manifest prepared by the originating facility and confirm that it accurately describes the type and quantity of cannabis in the transport vehicle to be transported by the transporting employee, in the aggregate and for each delivery.
- B. Prior to delivering cannabis to a qualifying patient, parent, legal guardian, or registered agent:
  - 1. The pharmaceutical processor or cannabis dispensing facility shall prepare a delivery manifest on a form and in a manner prescribed by the authority, itemizing all cannabis to be delivered. A separate copy of the delivery manifest shall be provided to the delivery employee to accompany the itemized cannabis at all times during transport.
  - 2. The delivery employee shall review the delivery manifest prepared by the medical cannabis facility and confirm that it includes sufficient identifying information for each patient, parent, legal guardian, or registered agent, including name and day and month of birth.
- C. No transport vehicle shall carry any cannabis for which a manifest has not been provided, and all cannabis shall be packaged in sealed, labeled, and tamper-resistant packaging at all times.

#### 3VAC10-40-260. Transportation of cannabis.

- A. A transporting employee shall remain with the transport vehicle at all times that the vehicle contains cannabis, provided that if there is only one transporting employee, the transporting employee may leave the vehicle, which shall be securely locked, only for:
  - 1. Delivering or transferring cannabis to a qualifying patient, parent, legal guardian, registered agent, or medical cannabis facility;
  - 2. Meals, when the transport lasts more than three hours round trip;
  - 3. Rest periods required by law;
  - 4. Refueling; or
  - 5. Exigent circumstances, including collisions, traffic stops, mechanical breakdowns, weather emergencies, or medical emergencies.
- B. A transporting employee shall carry transportation credentials at all times during the transportation of cannabis and display such credentials to the appropriate persons at the originating facility prior to each instance of transportation of cannabis, and to any law-enforcement official or authorized authority representative upon request. For purposes of this section, "transportation credentials" shall mean the

- transporting employee's valid driver's license, a copy of the medical cannabis facility's permit, and all transport or delivery manifests for cannabis contained in the transport vehicle.
- C. A transporting facility shall inspect and test all security systems, secure communications, and global positioning system (GPS) monitoring devices of each transport vehicle at least once per day of use, prior to the transport vehicle's first departure. The individual conducting the inspection on behalf of the transporting facility shall create a signed record of the inspection that includes (i) the name of the individual, (ii) the vehicle identification number of the transport vehicle, (iii) the date of inspection, and (iv) the status of all inspected systems, equipment, and devices. The transporting facility shall maintain all inspection records.
- D. No transport vehicle shall transport cannabis unless every security system, form of secure communication, and GPS monitoring device is in good working order and functioning properly.
- E. If any security system, form of secure communication, or GPS monitoring device fails during the transportation of cannabis, the transporting employee shall immediately notify the transporting facility and all impacted originating facilities of the specific failure and return directly to the transporting facility or originating facility. Such transport vehicle shall not resume transportation of cannabis until all systems resume full functioning capacity.
- F. The transporting facility shall create a confidential delivery schedule within 24 hours of the transport and only provide the transporting employee with a copy of such confidential delivery schedule immediately prior to departure.
- G. A transporting employee shall communicate with the transporting facility upon arriving at and departing from each scheduled delivery location.
- H. A transporting employee shall strictly adhere to the delivery schedule provided by the transporting facility and not make any unscheduled stops. In the case of an emergency unscheduled stop, the transport vehicle shall remain securely locked, and the transporting employee shall verbally communicate with the transporting facility, describing the reason for the emergency unscheduled stop, the location and the duration of the emergency unscheduled stop, any activities of the transporting employee, and the identities and activities of any persons interacting with the transport vehicle or the transporting employee. The transporting facility shall maintain a record of any communications related to an unscheduled stop.
- I. For a period of not less than 90 days, a transporting facility shall maintain a record of the GPS information of each of its transport vehicles for the entire duration of any transportation of cannabis and make such information available to the authority upon request. A transporting facility may contract with the GPS provider or similar service provider to conduct

GPS monitoring, provided that any such third-party GPS monitor shall comply with all applicable state and federal laws regarding patient confidentiality.

- J. A transporting employee shall return any undeliverable cannabis to the respective originating facility directly after the last scheduled delivery.
- K. No cannabis shall be stored in a transport vehicle after the facility's hours of operation, and in no event longer than 24 hours, unless the vehicle is contained within an enclosed, secure part of the facility.

L. A transporting facility shall report to the authority and local law enforcement any transport vehicle accidents, transport vehicle theft, cannabis diversion, loss, or adulteration, and any other event deemed by the authority to be a reportable event in connection with the transportation of cannabis within 24 hours of such event being discovered.

# <u>3VAC10-40-270.</u> Delivery to qualifying patients, parents, legal guardians, and registered agents.

- A. Medical cannabis facilities offering delivery shall require each qualifying patient, parent, legal guardian, or registered agent [ that who ] purchases cannabis for delivery to provide the medical cannabis facility with the full legal name, date of birth, address, email address, and telephone number of the qualifying patient and, if applicable, the legal name, date of birth, and address of the parent, legal guardian, or registered agent.
- B. For each delivery of cannabis to a qualifying patient, parent, legal guardian, or registered agent, a transporting employee shall confirm from a valid driver's license or other valid, government-issued photographic identification that the identity of the individual accepting the cannabis delivery is the same as the individual [ that who ] ordered the cannabis and confirm the qualifying patient's registration number.
- C. If the identity, age, or registration of the individual accepting the cannabis delivery remains in question after presentation of the required documentation, the transporting employee shall (i) immediately alert the originating facility and (ii) return the cannabis to the originating facility directly after the last scheduled delivery.
- D. Medical cannabis may only be delivered to a residence in Virginia. "Residence" means a dwelling such as a house, apartment, nursing home, or retirement center. It does not include a dormitory, hotel, motel, bed and breakfast, or other commercial business.
- E. Medical cannabis may only be delivered between the hours of 6 a.m. and midnight.

# 3VAC10-40-280. Delivery and transportation incident notification.

A. A pharmaceutical processor transporting or delivering medical cannabis must report any traffic stop, breakdown, collision, or unscheduled stop lasting more than two hours to the authority with 24 hours.

B. An originating facility's authorized employees shall make a good faith effort to contact the authority if exigent circumstances require removal of cannabis or cannabis products from the vehicle prior to arrival at the destination listed on the transport manifest. Authorized employees shall make a good faith effort to protect the shipment from diversion.

VA.R. Doc. No. R25-8121; Filed January 31, 2025, 1:55 p.m.

#### **Final Regulation**

REGISTRAR'S NOTICE: The Board of Directors of the Virginia Cannabis Control Authority is claiming an exemption from the Administrative Process Act in accordance with § 4.1-1602 of the Code of Virginia, which exempts adoption of regulations if prior to adoption, the board publishes a notice of opportunity to comment in the Virginia Register of Regulations and posts the action on the Virginia Regulatory Town Hall. Such notice of opportunity to comment shall contain (i) a summary of the proposed regulation; (ii) the text of the proposed regulation; and (iii) the name, address, and telephone number of the agency contact person responsible for receiving public comments. Such notice shall be made at least 60 days in advance of the last date prescribed in such notice for submittals of public comment.

<u>Title of Regulation:</u> 3VAC10-50. Cannabis Products (amending 3VAC10-50-10, 3VAC10-50-50 through 3VAC10-50-80, 3VAC10-50-110).

Statutory Authority: §§ 4.1-601, 4.1-604, and 4.1-606 of the Code of Virginia.

Effective Date: February 10, 2025.

Agency Contact: Jake Shuford, Legislative and Regulatory Manager, Virginia Cannabis Control Authority, 333 East Franklin Street, Richmond, VA 23219, telephone (804) 873-9038, or email jake.shuford@cca.virginia.gov.

#### Summary:

The amendments (i) adopt a common practice in the industry of restricting non-cannabinoid additives that could increase the potency, toxicity, or addictive properties of cannabis to protect patients and the integrity of medicinal cannabis products; (ii) codify a list of previously approved chemicals for use in the cultivation, extraction, production, or manufacturing of cannabis products to avoid potential patient exposure to harmful chemicals; and (iii) ensure patients are offered the opportunity to consult with a pharmacist or pharmacy technician during the patient's initial visit to a dispensary. Other amendments relocate certain provisions within the medical cannabis program regulations and remove the redundant requirement for a pharmacist or pharmacy technician to physically witness certain actions that are required to be conducted under video surveillance.

#### 3VAC10-50-10. Definitions.

In addition to words and terms defined in the Cannabis Control Act (§ 4.1-600 et seq. 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 either included on a valid, unexpired written certification issued by a practitioner for the use of cannabis products or established by a pharmacist during initial consultation.

"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.

"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.

"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.

"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 3VAC10-30-90 is on the premises at the address of the permitted pharmaceutical processor and is available as needed.

"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.

"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.

# 3VAC10-50-50. 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 in this chapter, 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. No cannabis product shall contain any of the following:
- 1. Any regulated drug or controlled substance other than cannabis.

- 2. Non-cannabinoid additives that are psychotropic or would increase the potency, toxicity, or addictive properties of cannabis, including alcohol, caffeine, and nicotine. This prohibition shall not apply to the combination of cannabis with sugar or a product in which caffeine is naturally occurring, such as chocolate.
- <u>C.</u> 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 3VAC10-50-60.
  - 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 3VAC10-50-60 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. D. Any cannabis plant, seed, parts of plant, extract, or cannabis products not in compliance with this section shall be deemed adulterated.
- D. E. 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 are ] 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. F. 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.** <u>G.</u> A pharmaceutical processor shall maintain policies and procedures for the proper storage and handling of industrial hemp extracts, to include including a process for executing or responding to mandatory and voluntary recalls in a manner that complies with 3VAC10-40-210.
- G. H. No cannabis oil intended to be vaporized or inhaled shall contain vitamin E acetate.

# **3VAC10-50-60.** 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 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 CFR 1910 or any subsequent regulation governing such use, including 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 is built to codes of recognized and generally accepted good engineering practices, such as the following: (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 that identifies (i) the operator's name; (ii) the date and time of the incident; (iii) the supervising employees to which whom the incident report will be sent; and (iv) an incident summary that 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 who ] 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 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 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 who is not an employee of the pharmaceutical processor must recertify the standard operating procedures for use of flammable solvents determined under subsection C of this section.

- 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 that on site than 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. Approved chemicals include:
  - 1. Ethanol;
  - 2. Ethyl acetate;
  - 3. Ethyl ether;
  - 4. Heptane;
  - 5. Hexane;
  - 6. Pentane;
  - 7. 2-propanol (IPA);
  - 8. Butane; and
  - 9. Propane.

The board recognizes butane and propane as Class 3 solvents with a permissible daily exposure of 50 mg per day.

#### 3VAC10-50-70. 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 in a manner 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%. However, in cases where (i) the total tetrahydrocannabinol (THC) concentration is less than five 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 five 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 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 years of age; or
  - 8. Is related to the benefits, safety, or efficacy of the cannabis product unless supported by substantial evidence or substantial clinical data.

#### 3VAC10-50-80. 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:
    - a. Offer patients, parents, legal guardians, and registered agents the opportunity to consult with a pharmacist regarding the use of cannabis products, including 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;
  - <u>b. View</u> 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; and
- c. 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, is valid 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: according to 3VAC10-70-40.
  - 1. A serial number assigned to the dispensing of the product;
  - 2. The cannabis product name that was registered with the board pursuant to 3VAC10-50-70 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 of this section if the items are included on the batch label as required in 3VAC10 70 20 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 20 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. D. 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.
- <u>F. E.</u> 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. F. 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. G. 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.

#### 3VAC10-50-110. 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.

VA.R. Doc. No. R25-8120; Filed January 31, 2025, 1:56 p.m.

#### **Final Regulation**

REGISTRAR'S NOTICE: The Board of Directors of the Virginia Cannabis Control Authority is claiming an exemption from the Administrative Process Act in accordance with § 4.1-1602 of the Code of Virginia, which exempts adoption of regulations if prior to adoption, the board publishes a notice of opportunity to comment in the Virginia Register of Regulations and posts the action on the Virginia Regulatory Town Hall. Such notice of opportunity to comment shall contain (i) a summary of the proposed regulation; (ii) the text of the proposed regulation; and (iii) the name, address, and telephone number of the agency contact person responsible for receiving public comments. Such notice shall be made at least 60 days in advance of the last date prescribed in such notice for submittals of public comment.

# <u>Title of Regulation:</u> **3VAC10-60. Testing of Cannabis Products (amending 3VAC10-60-10, 3VAC10-60-20).**

Statutory Authority: §§ 4.1-601, 4.1-604, and 4.1-606 of the Code of Virginia.

Effective Date: February 10, 2025.

Agency Contact: Jake Shuford, Legislative and Regulatory Manager, Virginia Cannabis Control Authority, 333 East Franklin Street, Richmond, VA 23219, telephone (804) 873-9038, or email jake.shuford@cca.virginia.gov.

#### Summary:

The amendments (i) clarify and implement § 4.1-1602 D of the Code of Virginia, which addresses independent laboratory testing standards and requires certain cannabis products to be homogenized for laboratory testing; (ii) clarify the standards for microbiological, mycotoxin, and residual solvent testing standards by specifying the applicable part of a document incorporated by reference and, where possible, including standards in the regulation rather than referring to external documents; and (iii) pursuant to Chapter 732 of the 2024 Acts of Assembly, extend the expiration of cannabis products from six months to 12 months.

#### 3VAC10-60-10. Definitions.

In addition to words and terms defined in the Cannabis Control Act (§ 4.1-600 et seq. 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:

"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 3VAC10-30-160.

"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.

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

#### 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;
  - 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; and
- 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. Laboratories shall perform a visual inspection for homogeneity and reject heterogeneous samples.
- 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 residue, 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 The certified testing laboratory may determine the minimum sample size for testing from each batch. 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 <u>Table 1 of</u> 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: the sum of aflatoxins B1, B2, G1, and G2 and ochratoxin A is less than 20 parts per billion.

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 the sample contains 290 parts per million or less of hexane and 5,000 parts per million or less of the other solvents approved under 3VAC10-50-60 H.
- 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: the sum of aflatoxins B1, B2, G1, and G2 and ochratoxin A is less than 20 parts per billion.

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 shelf life for unopened products, except stability testing shall not be required for cannabis

products if an expiration date of six 12 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.

VA.R. Doc. No. R25-8119; Filed January 31, 2025, 1:56 p.m.

### Final Regulation

REGISTRAR'S NOTICE: The Board of Directors of the Virginia Cannabis Control Authority is claiming an exemption from the Administrative Process Act in accordance with § 4.1-1602 of the Code of Virginia, which exempts adoption of regulations if prior to adoption, the board publishes a notice of opportunity to comment in the Virginia Register of Regulations and posts the action on the Virginia Regulatory Town Hall. Such notice of opportunity to comment shall contain (i) a summary of the proposed regulation; (ii) the text of the proposed regulation; and (iii) the name, address, and telephone number of the agency contact person responsible for receiving public comments. Such notice shall be made at least 60 days in advance of the last date prescribed in such notice for submittals of public comment.

<u>Titles of Regulations:</u> 3VAC10-70. Labeling and Packaging (amending 3VAC10-70-10, 3VAC10-70-20, 3VAC10-70-30; adding 3VAC10-70-40, 3VAC10-70-50).

3VAC10-80. Enforcement (amending 3VAC10-80-10).

<u>Statutory Authority:</u> §§ 4.1-601, 4.1-604, and 4.1-606 of the Code of Virginia.

Effective Date: February 10, 2025.

Agency Contact: Jake Shuford, Legislative and Regulatory Manager, Virginia Cannabis Control Authority, 333 East Franklin Street, Richmond, VA 23219, telephone (804) 873-9038, or email jake.shuford@cca.virginia.gov.

## Summary:

The amendments (i) define "universal symbol" and require the symbol to be included on the package of cannabis products as is customary in other medical cannabis programs; (ii) increase product transparency for patients by adding or specifying labeling requirements such as product descriptions and use instructions, child and safety warnings, and information required on the immediate container; and (iii) pursuant to Chapter 732 of the 2024 Acts of Assembly, extend the expiration date of cannabis products from six months to 12 months. Changes to the proposed regulation include amending label requirements for botanical cannabis products and clarifying that no packaging shall be designed to be especially appealing to persons younger than 21 years of age.

#### 3VAC10-70-10. Definitions.

In addition to words and terms defined in the Cannabis Control Act (§ 4.1-600 et seq. 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:

"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.

"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.

"Universal symbol" means the image established by the authority and made available on the authority's website indicating that the package contains medical cannabis.

#### 3VAC10-70-20. Labeling of batch of cannabis products.

- A. Cannabis products produced as a batch shall not be adulterated Each container and layer of packaging containing cannabis shall prominently display the universal symbol.
- B. Cannabis products produced as a batch shall be:
- 1. Unadulterated;
- 2. 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. 3. Labeled with:
  - a. The name and address of the pharmaceutical processor;
  - b. The cannabis product name that was registered with the board pursuant to <del>18VAC110-20-285</del> § 4.1-1603.2 of the Code of Virginia;
  - c. A description of the product's purpose and instructions for use:

- d. Child and safety warnings, as approved by the authority, in a conspicuous font;
- e. 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. f. The date of testing and packaging;
- e. g. 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. h. The expiration date, which shall be six 12 months or less from the date of the cannabis product registration approval, unless supported by stability testing;
- g. i. The quantity of cannabis products contained in the batch:
- h. j. A terpenes profile and a list of all active and inactive ingredients, including:
- (1) Tetrahydrocannabinol (THC);
- (2) Tetrahydrocannabinol acid (THC-A);
- (3) Cannabidiol (CBD); and
- (4) Cannabidiolic acid (CBDA);
- i. [ k. For botanical cannabis products, list of only total cannabidiol (CBD) and total tetrahydrocannabinol (THC); ]
- j. [k.l.] 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
- k. [ <u>l. m.</u>] 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.
- C. If the immediate container is too small, then an outer layer of packaging shall include the requirements of subdivision B 3 of this section and the immediate container shall include:
  - 1. Pharmaceutical processor name, telephone number, and email or website;
  - 2. The cannabis product name that was registered with the board pursuant to § 4.1-1603.2 of the Code of Virginia;
  - 3. The serial number assigned to the product during production;
  - 4. A prominently printed expiration date;
  - 5. The quantity of cannabis products by weight, volume, or count and weight; and

- 6. A list of all active ingredients, including:
  - a. Tetrahydrocannabinol (THC);
  - b. Tetrahydrocannabinol acid (THC-A);
  - c. Cannabidiol (CBD); and
  - d. Cannabidiolic acid (CBDA).
- D. Labels may be accordion, expandable, extendable, or layered to permit labeling of containers of any manner of size or shape.
- <u>E. Cannabis vaporizer cartridges shall bear a universal symbol no smaller than one-quarter-inch wide by one-quarter-inch high that is engraved, printed, or affixed with a sticker.</u>
- F. No pharmaceutical processor shall 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.

# 3VAC10-70-30. 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 date of harvest and packaging and, for botanical cannabis, the date of harvest.
- 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.

### 3VAC10-70-40. Dispensing label requirements.

- A. The pharmacist or pharmacy technician under the direct supervision of the pharmacist shall affix a label, in a manner provided by the board, to each cannabis product, including:
  - 1. A serial number assigned to the dispensing of the product;
  - 2. The cannabis product name that was registered with the board pursuant to 3VAC10-50-70 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;
  - <u>6. A terpenes profile and a list of all active ingredients, including:</u>
    - a. Tetrahydrocannabinol (THC);
    - b. Tetrahydrocannabinol acid (THC-A);
    - c. Cannabidiol (CBD); and
    - d. Cannabidiolic acid (CBDA);
  - 7. A pass rating based on the laboratory's microbiological, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue analysis 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 provided by the practitioner, on the written certification or otherwise, or the dispensing pharmacist;
  - 11. For botanical cannabis, the amount recommended by the practitioner or dispensing pharmacist;
  - 12. The name or initials of the dispensing pharmacist;
  - 13. The name, address, and telephone number of the pharmaceutical processor or cannabis dispensing facility;
  - 14. Any necessary cautionary statement;
  - 15. A prominently printed expiration date; and
  - 16. The recommended conditions of use and storage from the pharmaceutical processor or cannabis dispensing facility that can be read and understood by the ordinary individual.
- B. The label shall be exempt from containing the items listed in subdivisions A 6, A 7, and A 15 of this section if the items are included on the batch label as required in 3VAC10-70-20 and are clearly visible to the patient.

C. 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.

### 3VAC10-70-50. Medical cannabis packaging requirements.

A. Packaging shall be child-resistant, except as provided in 3VAC10-40-20 A, tamper-resistant, and light-resistant based on the following standards:

- 1. 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). A pharmaceutical processor shall maintain a copy of the certificate showing that any packaging containing medical cannabis is child-resistant and complies with the requirements of 16 CFR 1700.15 and 16 CFR 1700.25;
- 2. A package shall be deemed tamper-resistant if it has one or more indicators or barriers to entry that would preclude its contents from being accessed or adulterated without indicating to a reasonable person that the package was breached; and
- 3. A package shall be deemed light-resistant if it is entirely and uniformly opaque and protects the whole of its contents from the effects of light.
- B. No packaging shall (i) bear any reasonable resemblance to a trademarked, characteristic, or product-specialized packaging of any commercially available candy, snack, baked good, or beverage or (ii) be [ visually similar to packaging used for any good that is marketed to an audience reasonably expected to be designed in any manner to be especially appealing to persons ] younger than 21 years of age.

#### 3VAC10-80-10. Definitions.

In addition to words and terms defined in the Cannabis Control Act (§ 4.1-600 et seq. 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:

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

"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.

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

"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.

VA.R. Doc. No. R25-8118; Filed January 31, 2025, 1:56 p.m.



# TITLE 4. CONSERVATION AND NATURAL RESOURCES

### MARINE RESOURCES COMMISSION

## Final Regulation

REGISTRAR'S NOTICE: The Marine Resources Commission is claiming an exemption from the Administrative Process Act in accordance with § 2.2-4006 A 11 of the Code of Virginia; however, the commission is required to publish the full text of final regulations.

<u>Title of Regulation:</u> 4VAC20-390. Wetlands Mitigation - Compensation Policy (amending 4VAC20-390-10, 4VAC20-390-20, 4VAC20-390-30, 4VAC20-390-50; adding 4VAC20-390-60; repealing 4VAC20-390-40).

Statutory Authority: §§ 28.2-103 and 28.2-1301 of the Code of Virginia.

Effective Date: February 1, 2025.

Agency Contact: Randy Owen, Chief of Habitat Management, Marine Resources Commission, 380 Fenwick Road, Fort Monroe, VA 23651, telephone (757) 247-2251, or email randy.owen@mrc.virginia.gov.

#### Summary:

Pursuant to Chapter 334 of the 2023 Acts of Assembly, the amendments provide for the generation of vegetated and unvegetated wetland credits from wetland creation, restoration, conversion, and enhancement activities, invasive species control, and the establishment of open water channels. The amendments require that the local wetlands board or the Marine Resources Commission select the compensatory mitigation option in the following order of preference: (i) use of an approved mitigation bank, (ii) use of an approved in-lieu fee program, (iii) permittee-responsible on-site and in-kind mitigation, or (iv) permittee-responsible mitigation through off-site or out-of-kind mitigation within the same watershed.

### 4VAC20-390-10. Definitions.

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

"Compensation" means actions taken which have the effect of substituting some form of wetland resource for those lost or significantly disturbed due to a permitted development

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activity; generally habitat creation or restoration. Compensation is a form of mitigation.

"Ad hoc in-lieu fees" means the payment of funds to a participating locality for the restoration, establishment, enhancement, or, in certain circumstances, preservation of wetlands resources to satisfy compensatory mitigation requirements. Ad hoc in-lieu fee programs are not governed by an in-lieu fee program instrument.

"Approved in-lieu fee program" means a program involving the restoration, establishment, enhancement, or, in certain circumstances, preservation of wetlands resources through funds paid to a governmental or nonprofit natural resources management entity for the purchase of credits to satisfy compensatory mitigation requirements. The operation and use of an approved in-lieu fee program are governed by an in-lieu fee program instrument approved as provided in federal law.

<u>"Commission" means the Virginia Marine Resources</u> Commission.

"Compensatory mitigation" means the restoration, establishment, enhancement, or, in certain circumstances, preservation of wetlands resources for the purpose of offsetting unavoidable adverse impacts of a permitted development activity that remain after all appropriate and practicable avoidance and minimization has been achieved.

"Mitigation" means all actions, both taken and not taken, which that eliminate or materially reduce the adverse effects of a proposed activity on the living and nonliving components of a wetland system or their ability to interact. Mitigation includes compensatory mitigation.

#### 4VAC20-390-20. Policy.

In spite of the passage of the Virginia Wetlands Act and the Federal Water Pollution Control Act in 1972, as a Chesapeake Bay Program partner, has committed to achieving a no-net loss of existing wetlands acreage and function in regulatory programs. In addition, the Virginia Coastal Resilience Master Plan recognizes the importance of tidal wetlands as natural flood buffers. Despite this, the pressures to use or develop tidal wetlands along Virginia's shoreline, have continued to accelerate as evidenced by the increasing number of permit applications being submitted. While losses are controlled by existing permit programs, data compiled by the Virginia Institute of Marine Science (VIMS) over the last 11 years (1993 2004) has shown a total permitted loss of 132 acres of tidal wetlands. Of these losses, most are associated with shoreline stabilization projects where each individual project may account for only a few hundred square feet of impact. Compensation for these losses has not usually been required. In fact, during the same period only 20.3 acres of mitigation have been required some impacts to tidal wetlands from development activity are unavoidable. Research, however has demonstrated that certain wetlands can be established or reestablished in areas where wetlands are not presently found, wetlands that were previously lost or degraded can be reestablished, and wetland functions in existing wetlands can be improved. As such, compensation compensatory mitigation for permitted wetland losses is viewed as a means of offsetting impacts of necessary projects.

The commission, through this policy, intends to encourage encourages, where appropriate, the compensation of compensatory mitigation for all permitted tidal wetland losses, especially vegetated losses impacts, provided all other mitigative measures have been considered to avoid and minimize any impact. This should include compensation on site, compensation within the watershed, compensation through the use of a mitigation bank as authorized by § 28.2-1308 of the Code of Virginia or through acceptance of an applicant's offer of payment to an in lieu fee account established at the local, regional or state level and dedicated to wetland creation and restoration.

The need to compensate for all permitted wetland losses is further emphasized by the Commonwealth's commitment to the restoration of the Chesapeake Bay. In 2000, Virginia, as a Chesapeake Bay Program partner committed to "achieve a nonet loss of existing wetlands acreage and function in the signatories' regulatory programs." If Virginia is to meet this goal, wetland losses permitted through the tidal wetland regulatory program, no matter how small, must be replaced.

#### 4VAC20-390-30. General criteria.

A. It shall remain the policy of the Commonwealth to mitigate or avoid, minimize the loss of, and then compensate for impacts to wetlands and the adverse ecological effects of all permitted activities through the implementation of the principles set forth in the existing Wetlands Guidelines promulgated by the commission. To determine whether compensation is warranted and permissible a two tiered mechanism will be implemented. This dual approach will consist first of an evaluation of necessity for the proposed wetlands loss (see specific criteria below). If the proposal passes this evaluation, compensation will be required and implemented as set forth in the second phase, the Supplemental Guidelines of this policy, 4VAC20 390 50.

The primary thrust of combining the existing Wetlands Guidelines with the two-tiered compensation guidelines aim is to preserve the wetlands as much as possible in their natural state and to consider appropriate requirements for compensation compensatory mitigation only after it has been proven that the loss of impact to the natural resource is unavoidable and that the project will have the highest public and private benefit.

A reading of the original Wetlands Act clearly indicates that the General Assembly intended for the Commonwealth's wetland resources to be preserved in their "natural state," and emphasized through its declaration of policy, the importance of an overall ecological approach to wetlands management. "The Commonwealth of Virginia hereby recognizes the unique character of the wetlands, an irreplaceable natural resource which, in its natural state, is essential to the ecological systems of the tidal rivers, bays and estuaries of the Commonwealth." (Emphasis added)

The General Assembly has also originally stated that where economic development in the wetlands is clearly necessary and justified it will be accommodated while preserving the wetlands resource.

".... it is declared to be the public policy of this Commonwealth to preserve the wetlands and to prevent their despoliation and destruction and to accommodate necessary economic development in a manner consistent with wetlands preservation." (Originally adopted under § 62.1-13.1 of the Code of Virginia, now under Powers and Duties of the Commission pursuant to § 28.2 1301 of the Code of Virginia) (Emphasis added)

In § 28.2 1308 of the Code of Virginia the General Assembly mandated the preservation of the ecological systems within wetlands of primary ecological significance and then stated:

"Development in Tidewater, Virginia, to the maximum extent practical, shall be concentrated in wetlands of lesser ecological significance, in vegetated wetlands which have been irreversibly disturbed before July 1, 1972, in nonvegetated wetlands which have been irreversibly disturbed prior to January 1, 1983, and in areas of Tidewater, Virginia, outside of wetlands."

The General Assembly has clearly spelled out that "necessary economic development" is to be accommodated in Tidewater, Virginia, but that the emphasis is on wetlands preservation in their natural state.

Since use and development of tidal wetlands are regulated through the Wetlands Zoning Ordinance, commitments to preserve other existing tidal wetlands are not ordinarily an acceptable form of compensation.

- B. A permittee's commitment to preserve existing tidal wetlands can, under certain circumstances, be a form of compensatory mitigation.
- C. Mitigation, including compensatory mitigation, shall be required for both vegetated and nonvegetated wetlands unless site-specific information indicates such mitigation is not necessary.
- <u>D.</u> Where compensatory mitigation is required, the ratio of the area of required compensatory mitigation to the area of approved impact should, in most cases, be at least one to one.

## 4VAC20-390-40. Specific criteria. (Repealed.)

In order for a proposal to be authorized to destroy wetlands and compensate for same in some prescribed manner, the three criteria listed below must be met. If the proposal cannot meet one or more of these criteria, the activity shall be denied, or

must occur in areas apart from the wetlands. Should it satisfy all three criteria, however, compensation for the wetlands lost is required. Since the proposed activity should stand on its own merits in the permit approval process, compensation should not be used to justify permit issuance.

- 1. All reasonable mitigative actions, including alternate siting, which would eliminate or minimize wetlands loss or disturbance shall be incorporated in the proposal.
- 2. The proposal shall clearly be water dependent in nature.
- 3. The proposal shall demonstrate clearly its need to be in the wetlands and its overwhelming public and private benefits.

### 4VAC20-390-50. Supplemental guidelines.

- A. When a permit is issued for the use, development of, or activities in wetlands, the permit shall where appropriate require the provision of compensatory mitigation.
- B. If compensation compensatory mitigation is required, then the following guidelines should be given due consideration and, if appropriate, may be included as conditions of the permit. In any case, on-site compensation at the project site is the preferred location alternative with off site, in the same watershed, as a consideration when on site is not feasible. Locating a compensation site outside the river basin of the project is not acceptable unless it is done as part of a statecoordinated program of ecological enhancement. The sequence of acceptable must specify the appropriate mitigation option and amount of mitigation required as a condition of the permit. Permit applicants are responsible for proposing an appropriate compensatory mitigation option to offset unavoidable impacts. Unless otherwise permitted by law, the compensatory mitigation should occur in or have an approved service area that includes the same U.S. Geological Survey (USGS) cataloging unit or adjacent USGS cataloging unit in the same watershed as the permitted project. The commission or a wetlands board shall select the compensatory mitigation options should be as follows: On site, option in the following order of preference: (i) use of an approved mitigation bank, (ii) use of an approved in-lieu fee program, (iii) permitteeresponsible on-site and in-kind mitigation, or (iv) permitteeresponsible mitigation through off-site or out-of-kind mitigation within the same watershed or mitigation bank in the watershed, or through a proffered payment of an in lieu fee if on site and off site compensation are shown by the applicant to be impractical considering the project location.
- B-C. Use of mitigation banks. Pursuant to § 28.2-1308 of the Code of Virginia, when any activity involving the loss of tidal wetlands authorized by the commission or a wetlands board is conditioned upon compensatory mitigation, the applicant may be permitted to satisfy all or part of such mitigation requirements by the purchase or use of credits from any approved wetlands mitigation bank. When approving the use of a compensatory mitigation bank, the number and type of

credits the permittee is required to secure must be specified by the commission or a wetlands board. The credits secured should be of a type to replicate, as nearly as practicable, the functions of the impacted wetlands.

- D. Approved in-lieu fee programs. An applicant may be permitted to satisfy all or part of any compensatory mitigation requirements by the purchase or use of credits from an approved in-lieu fee program. When approving the use of an approved in-lieu fee program, the number and type of credits the permittee is required to secure must be specified by the commission or a wetlands board. The credits secured should be of a type to replicate, as nearly as practicable, the functions of the impacted wetlands.
- <u>E.</u> Use of on-site and off-site compensation. When on-site or off-site compensation is required as a condition of permit approval, the following items should be considered. The commission or wetlands board may wish to condition any approval on the receipt of an acceptable compensation plan before issuance of the final permit for an approved project. apply:
  - 1. A The applicant must provide a detailed plan, including a scaled plan view drawing, should be submitted describing the objectives of the wetland compensation, the type of wetland to be created, the mean tide range at the site, the proposed elevations relative to a tidal datum, the exact location, the areal extent, the method of marsh wetland establishment and, the vegetation to be planted, the exact time frame timeframe from initial work to completion, and an abatement plan for any plants listed on the Virginia Invasive Species Plant List promulgated by the Virginia Department of Conservation and Recreation. The plan should also include plans for address replanting areas where vegetation fails to grow. The permittee must secure approval of the plan by the commission or a wetlands board prior to commencing impacts to tidal wetlands.
  - 2. Once the grading is completed at the planting site, it should be inspected by a competent authority to insure ensure that the elevations are appropriate for the vegetation to be planted and that the surface drainage is effective.
  - 3. The compensation plan and its implementation should be accomplished by experienced professionals knowledgeable of the general and site-specific requirements for wetland establishment and long-term survival.
  - 4. A performance bond or letter of credit should be required and remain in force until the new wetland is successfully established; a minimum of two growing seasons have passed and a required planting success rate established by the commission or a wetlands board has been achieved.
  - 5. The compensation marsh replacement wetland should be designed to replace as nearly as possible, the functional values functions of the lost resource on an equal or greater basis. In general this means creating a marsh of similar plant

- structure to that being lost. This may not be the case where a lesser value marsh is involved (i.e. Group 4 or 5 wetlands). A minimum 1:1 areal exchange is required in all cases. The ratio of required compensation to approved loss should be specified by the commission or wetlands board and may be based on the use of the Function Specific Credit Calculation Method established by the Virginia Institute of Marine Science (VIMS) and contained in the Guidelines for the Establishment, Use and Operation of Tidal Wetland Mitigation Banks in Virginia.
- 6. The eompensation compensatory mitigation should be accomplished prior to, or concurrently with, the construction of the proposed project. Before any activity under the permit may begin, the permittee must own hold all interests in the compensatory mitigation site that are needed to carry out the compensatory mitigation.
- 7. All reasonable steps must be taken to avoid or minimize any adverse environmental effects associated with the compensation compensatory mitigation activities themselves.
- 8. In selecting a compensation site, one aquatic community should not be sacrificed to "create" another. In cases where dredged material must be placed overboard, the area may be used to create marsh, oyster rock or improve the resource value of the bottom.
- 9. The type of plant community proposed as compensation must have a demonstrated history of successful establishment in order to be acceptable.
- 10. Manipulating the plant species composition of an existing marsh community, as a form of compensation, is unacceptable.
- 11. Nonvegetated wetlands should be treated on an equal basis with vegetated wetlands with regard to compensation and mitigation, unless site specific information indicates one is more valuable than the other.
- 12. 8. Both short-term and long-term monitoring of compensation compensatory mitigation sites should be considered on a case-by-case basis. For unproven types of compensation the applicant The permittee will be responsible for funding such monitoring as is deemed necessary.
- 13. Conservation or other easements to be held in perpetuity should be required for the compensation marsh. Easements accepted by the commission will be processed in accordance with the provisions of § 28.2 1301 of the Code of Virginia 9. An appropriate site protection instrument that will protect the site in perpetuity should be required for the compensatory mitigation site, except in cases where both the impact to wetlands and the compensatory mitigation required are determined by the wetlands board or the commission to be de minimis.

C. Use of mitigation banks. Pursuant to § 28.2 1308 of the Code of Virginia, when any activity involving the loss of tidal wetlands authorized by the commission or a wetlands board is conditioned upon compensatory mitigation the applicant may be permitted to satisfy all or part of such mitigation requirements by the purchase or use of credits from any approved wetlands mitigation bank. Guidelines for the Establishment, Use and Operation of Tidal Wetland Mitigation Banks in Virginia have been promulgated by the commission. Unless the applicant can demonstrate compliance with specific eriteria contained in § 28.2-1308 for use of a compensatory mitigation bank outside the watershed where a permitted project is located, the use of a mitigation bank for permitted activities requiring compensation must be in the same USGS cataloging unit or adjacent USGS cataloging unit in the same watershed. When approving the use of a compensatory mitigation bank the ratio of required compensation to approved loss must be specified by the commission or wetlands board and should incorporate the use of Function Specific Credit Calculation Method established by the Virginia Institute of Marine Science (VIMS) and contained in the Guidelines for the Establishment, Use and Operation of Tidal Wetland Mitigation Banks in Virginia.

D. Use of in lieu fees. The use of in lieu fees should be the last form of mitigation used to offset permitted wetland losses and must be the result of an agreed upon permit condition between the applicant and the commission or wetlands board provided the applicant can demonstrate that on site or off site compensation options are not practical and no compensatory mitigation banks have been established in the project watershed. Localities are encouraged to establish a fund for such payments that is dedicated to tidal wetlands restoration and creation. At the local level this could be the same fund established for the receipt of civil charges or civil penalties. Administration of such a fund should include an ability to trace the contribution of in lieu fees to eventual use in actual wetland restoration or creation projects. If payments are made to other dedicated wetland restoration funds this should be recognized in the permit issued by the board. In no case should an in lieu fee amount be accepted for less than the cost of necessary compensation acreage or the purchase of necessary credits in an approved bank. This is intended to prevent the avoidance of use of on site or off site compensation, or compensatory mitigation bank for a cheaper alternative that would not be able to fund the same level of wetland restoration or creation required by on site or off site compensation or through use of a compensatory mitigation bank. Use of the fund could be for actual tidal wetland creation or restoration projects in the locality or for the purchase of credits in an approved compensatory mitigation bank that is authorized subsequent to the receipt of any in lieu fee. Localities are encouraged to combine any in lieu fee with other potential or available funds for wetland restoration or creation projects.

#### 4VAC20-390-60. Ad hoc in-lieu fees.

Compensatory mitigation requirements may be met by payment of an ad hoc in-lieu fee only in exceptional circumstances where federal regulators do not require compensatory mitigation and the applicant demonstrates that other forms of compensatory mitigation are not available. The use of ad hoc in-lieu fees must be the result of an agreed-upon permit condition between the applicant and the commission or a wetlands board. Localities are encouraged to establish a fund for such payments that is dedicated to tidal wetlands restoration and creation. This could be the same fund established for the receipt of civil charges or civil penalties. Administration of such a fund should include an ability to trace the contribution of ad hoc in-lieu fees to eventual use in actual wetland restoration or wetland creation projects. If payments are made to other dedicated wetland restoration funds, this should be recognized in the permit issued by the commission or a wetlands board. In no case should an ad hoc in-lieu fee amount be accepted that is less than the cost at the prevailing market rate of establishing an area of wetlands that exceeds the area of wetlands impacted by a ratio of at least two to one. Use of the fund could be for actual tidal wetland creation or wetland restoration projects in the locality or for the purchase of credits in an approved compensatory mitigation bank that is authorized subsequent to the receipt of any ad hoc in-lieu fee. Localities are encouraged to combine any ad hoc in-lieu fee with other potential or available funds for wetland restoration or wetland establishment projects.

VA.R. Doc. No. R25-8135; Filed January 28, 2025, 2:00 p.m.



### **TITLE 8. EDUCATION**

#### **GEORGE MASON UNIVERSITY**

#### **Final Regulation**

REGISTRAR'S NOTICE: George Mason University is claiming an exemption from the Administrative Process Act in accordance with § 2.2-4002 A 6 of the Code of Virginia, which exempts educational institutions operated by the Commonwealth.

<u>Titles of Regulations:</u> 8VAC35-10. Parking Citation Appeals (repealing 8VAC35-10-10 through 8VAC35-10-90).

8VAC35-22. Parking Regulation (repealing 8VAC35-22-10 through 8VAC35-22-70).

**8VAC35-31. Space Use (amending 8VAC35-31-40).** 

8VAC35-80. Unclaimed Personal Property (repealing 8VAC35-80-10, 8VAC35-80-20, 8VAC35-80-30).

Statutory Authority: §§ 23.1-1301 and 23.1-1503 of the Code of Virginia.

Effective Date: March 26, 2025.

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Agency Contact: Elizabeth Woodley, University Ethics Officer and Outside Interests Manager, George Mason University, 4400 University Drive, MSN 6D6, Fairfax, VA 22030, telephone (703) 993-2661, FAX (703) 993-2340, or email <a href="ewoodley@gmu.edu">ewoodley@gmu.edu</a>. Summary:

The amendments (i) provide that entry upon or use of university property shall be in accordance with all applicable university policies and procedures, (ii) limit use of the educational enclave by the general public to this persons having a business or educational reason, and (iii) repeal outdated and unnecessary provisions.

# 8VAC35-31-40. Entry upon, and use of, University university property.

A. Entry upon, or use of, university property in the educational enclave shall be in accord with all applicable university policies, and procedures and all applicable law. No use of university property shall be permitted that (i) is inconsistent with the mission of the university, (ii) interferes with or disrupts the educational or operational functions of the university, or (iii) endangers health and safety or creates unsanitary conditions.

B. Entry upon, or use <u>Use</u> of, university property outside the educational enclave for noncommercial purposes by the general public not affiliated with the university is permitted if otherwise lawful and does not interfere with limited to persons having a business or educational functions reason closely related to George Mason <u>University's mission and programs during regular operating hours.</u>

C. Entry upon, or use of, university property for commercial purposes shall be in accord with all applicable university policies.

VA.R. Doc. No. R25-8185; Filed January 29, 2025, 9:54 a.m.

### **TITLE 12. HEALTH**

#### STATE BOARD OF HEALTH

#### **Notice of Effective Date**

Title of Regulation: 12VAC5-630. Private Well Regulations (amending 12VAC5-630-10, 12VAC5-630-20, 12VAC5-630-30, 12VAC5-630-50 through 12VAC5-630-120, 12VAC5-630-140 through 12VAC5-630-330, 12VAC5-630-350, 12VAC5-630-360, 12VAC5-630-380 through 12VAC5-630-430, 12VAC5-630-450, 12VAC5-630-460; adding 12VAC5-630-331, 12VAC5-630-431; repealing 12VAC5-630-40, 12VAC5-630-370, 12VAC5-630-440, 12VAC5-630-470, 12VAC5-630-480).

<u>Statutory Authority:</u> §§ 32.1-12 and 32.1-176.4 of the Code of Virginia.

On September 22, 2022, the State Board of Health adopted significant revisions to Private Well Regulations (12VAC5-630). The final regulation was published October 7, 2024, Volume 41, Issue 4 of the Virginia Register (41:4 VA.R. 531-

558 October 7, 2024) with an effective date of November 6, 2024.

On November 1, 2024, the State Health Commissioner, pursuant to § 32.1-20 of the Code of Virginia and on behalf of the State Board of Health, suspended the effective date of certain provisions in 12VAC5-630-410 F 6 because the State Board of Health received multiple public comments objecting to those provisions. The suspension of the regulatory process for the specific provisions was published November 18, 2024, Volume 41, Issue 7 (41:7 VA.R. 868 November 18, 2024). And, on November 1, 2024, pursuant to § 32.1-20 of the Code of Virginia and on behalf of the State Board of Health, the State Health Commissioner adopted the text of the subdivision as published in the notice of suspension.

The State Health Commissioner has adopted the final text as the text became effective November 6, 2024, and currently appears in the the Virginia Administrative Code as shown in 12VAC5-630-410 F 6. The effective date of the regulation is February 24, 2025. Copies of the adopted text are available online at https://townhall.virginia.gov/l/ViewStage.cfm?stage id=9812 or by written request or email request to the agency contact.

Effective Date: February 24, 2025.

Agency Contact: John Kotyk, Legislative and Regulatory Coordinator, Virginia Department of Health, James Madison Building, 109 Governor Street, Richmond, VA 23219, telephone (804) 864-7437, or email john.kotyk@vdh.virginia.gov.

VA.R. Doc. No. R19-5654; Filed January 28, 2025, 4:00 p.m.

# DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

#### **Fast-Track Regulation**

<u>Title of Regulation:</u> 12VAC30-130. Amount, Duration and Scope of Selected Services (adding 12VAC30-130-3040, 12VAC30-130-3050, 12VAC30-130-3060).

<u>Statutory Authority:</u> §§ 32.1-324 and 32.1-325 of the Code of Virginia.

<u>Public Hearing Information:</u> No public hearing is currently scheduled.

Public Comment Deadline: March 26, 2025.

Effective Date: April 10, 2025.

Agency Contact: Emily McClellan, Regulatory Supervisor, Policy Division, Department of Medical Assistance Services, 600 East Broad Street, Suite 1300, Richmond, VA 23219, telephone (804) 371-4300, FAX (804) 786-1680, or email emily.mcclellan@dmas.virginia.gov.

<u>Basis:</u> Section 32.1-325 of the Code of Virginia grants the Board of Medical Assistance Services the authority to administer and amend the Plan for Medical Assistance. Section 32.1-324 of the Code of Virginia authorizes the

director of the Department of Medical Assistance Services (DMAS) to administer and amend the Plan for Medical Assistance according to the board's requirements.

<u>Purpose</u>: The purpose of this action is to provide a paid sick leave benefit for consumer-directed attendants. This benefit will make it easier for families to find care providers for individuals who need these services and will benefit the health and welfare of the public by providing sick leave for individuals providing care to vulnerable Medicaid members. This benefit will enhance the health and welfare of the public by reducing the spread of illness while allowing the attendants to take paid sick leave when needed.

Rationale for Using Fast-Track Rulemaking Process: This action is expected to be noncontroversial because the amendments outline a benefit for consumer-directed (CD) attendants, who previously have received no benefits providing their services to eligible individuals. The proposed methods and requirements for determination and calculation in the regulation both adhere to basic guidelines outlined in Chapter 449 of 2021 Acts of Assembly, Special Session I, and are not expected to be burdensome to the population of CD attendants interested in receiving the benefit.

<u>Substance:</u> This action provides Medicaid personal care attendants with one hour of sick leave for every 30 hours worked with a maximum of 40 hours per year.

<u>Issues:</u> This action creates no disadvantages to the public, the agency, the Commonwealth, or the regulated community. The advantages of this action to the public and the Commonwealth are that the action aligns the regulation with federal and state requirements and codifies the agency's procedures and requirements as it relates to how CD attendants become eligible for the paid sick leave benefit, how the eligibility is calculated, and when and how the paid sick leave benefit is issued by the Fiscal or employer agents.

### <u>Department of Planning and Budget Economic Impact</u> Analysis:

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Code of Virginia and Executive Order 19. The analysis presented represents DPB's best estimate of the potential economic impacts as of the date of this analysis.<sup>1</sup>

Summary of the Proposed Amendments to Regulation. Pursuant to Chapter 449 of the 2021 Special Session I Acts of the Assembly<sup>2</sup>, the Director of the Department of Medical Assistance Services (DMAS), acting on behalf of the State Board of Medical Assistance Services (board), proposes to incorporate in the regulation paid sick leave benefits for Medicaid consumer-directed (CD) attendants that were implemented in November 2021.

Background. This regulatory action incorporates in the regulatory text the requirements of Article 2.1 of the Virginia Minimum Wage Act (§40.1-33.3 et seq. of the Code of

Virginia), which passed during the 2021 General Assembly.<sup>3</sup> The legislation provided paid sick leave benefits to home health workers, which the legislation defines as individuals who provide "personal care, respite, or companion services to an individual who receives consumer-directed services under the state plan for medical assistance services." This definition refers to attendants in Medicaid's consumer directed model of care. These attendants provide personal care, respite, or companion services to Medicaid-eligible individuals in the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) program, Medicaid Works program, and three of Virginia's four § 1915(c) Home-and-Community-Based Services Waivers: Community Living, Family and Individual Supports, and Commonwealth Coordinated Care Plus. The parameters of the paid sick leave benefit eventually adopted by DMAS follow the guidelines provided in the legislation. As such, it is available to attendants who work "on average at least 20 hours per week or 90 hours per month." Attendants accrue one hour of sick leave for every 30 hours of work, up to a total of 40 hours in a given fiscal year. No more than 40 hours of unused sick leave can be rolled over to the next fiscal year. Eligibility for sick leave is determined by the fiscal-employer agent (FEA) of the Medicaid member. Under this arrangement, the Medicaid member is the employer referred to in the legislation,4 and the FEA is a vendor who serves as the employer's agent under the Internal Revenue Code as an employer agent on behalf of the employer.<sup>5</sup> The FEAs already provide payroll and tax processing for the consumer-directed model for both fee-for-service and managed care members. The FEA looks at the hours worked in every quarter and if the attendant is deemed eligible, the attendant is assumed to be eligible for the rest of the fiscal year. If an attendant is not eligible in one quarter, the FEA keeps checking the eligibility status in the following quarter.

Estimated Benefits and Costs: During the 2021 legislative session, the fiscal impact of this benefit was estimated to be \$3,443,865 in state general funds and an additional \$3,443,865 in federal matching funds, covering approximately 30,390 eligible attendants in a given year. Item 313 BBBBBB of the 2021 Appropriation Act provided the authority and funds to implement this new benefit, and the federal Centers for Medicare and Medicaid Services approved this change on October 6, 2021. In November 2021, DMAS started determining eligibility and providing sick leave. Therefore the main impact of this regulatory action is to incorporate the sick leave benefit for Medicaid consumer-directed attendants into the regulatory text. The legislation itself however clearly benefits the attendants who accrue sick leave by providing compensation for the times they are sick and cannot work, thereby enabling them to rest and recover. The Medicaid members served by these attendants are also expected to benefit in terms of their attendants being less likely to come in contact with them when sick. When sick, attendants are not likely to be as productive and their sickness may be contagious. One half of the total costs of this benefit is absorbed by the general fund and the remaining half is provided by the federal government. While general fund dollars represent an expenditure of state funds, which could potentially be used for

other purposes, the federal funds are a net injection into the Commonwealth's economy. In other words, if it was not for this purpose, the federal funds would not be available. Thus, the additional federal funds should help expand Virginia's economy.

Businesses and Other Entities Affected. This regulation applies to approximately 30,390 consumer-directed attendants eligible for the paid sick leave benefit. The Code of Virginia requires DPB to assess whether an adverse impact may result from the proposed regulation. An adverse impact is indicated if there is any increase in net cost or reduction in net revenue for any entity, even if the benefits exceed the costs for all entities combined. The main impact of this action is to codify DMAS procedures and requirements in the regulation as they relate to how consumer-directed attendants become eligible for the paid sick leave benefit, how the eligibility is calculated, and when and how the paid sick leave benefit is issued by the FEAs. Thus, no adverse impact is indicated.

Small Businesses<sup>7</sup> Affected. <sup>8</sup> The proposed changes do not appear to adversely affect small businesses.

Localities<sup>9</sup> Affected.<sup>10</sup> The proposed amendments apply the same in all of the localities of the Commonwealth and do not create costs for local government.

Projected Impact on Employment. The provision of the sick leave as a result of the legislation would increase the demand for labor, because another attendant would be needed to cover for those attendants who use the sick leave benefit. However, the regulation itself is not expected to impact employment because it is implementing pre-existing statutory provisions and the program is already in effect.

Effects on the Use and Value of Private Property. The proposed regulation is not expected to affect the use and value of private property nor real estate development costs.

employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million."

 $^{10}$  Section 2.2-4007.04 defines "particularly affected" as bearing disproportionate material impact.

Agency Response to Economic Impact Analysis: The Department of Medical Assistance Services has reviewed the economic impact analysis prepared by the Department of Planning and Budget and raises no issues with this analysis.

#### **Summary:**

Pursuant to Chapter 449 of 2021 Acts of Assembly, Special Session I, the amendments provide paid sick leave benefits to attendants who provide personal care, respite care, or companion services to Medicaid-eligible individuals through the consumer-directed model of service.

# Part XVIII Consumer-Directed Attendants

#### 12VAC30-130-3040. Definitions.

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

"Consumer-directed attendant" or "CD attendant" means a person who provides, via the consumer-directed model of services, personal care, companion services, or respite care, or any combination of these three services. "Consumer-directed" or "CD" means the model of service delivery under which the individual enrolled in the waiver or benefit program or the individual's employer of record, as appropriate, is responsible for hiring, training, supervising, and firing of the attendants who render the services that are reimbursed by DMAS.

"DMAS" means the Department of Medical Assistance Services.

"Employer of record" or "EOR" means the person who performs the functions of the employer in the consumer-directed model of service delivery. The EOR may be the individual enrolled in the waiver or benefit program, a family member, caregiver, or another person.

<u>"Fiscal or employer agent" or "FEA" means a state agency or other entity as determined by DMAS that meets the requirements of 42 CFR 441.484.</u>

<sup>&</sup>lt;sup>1</sup> Section 2.2-4007.04 of the Code of Virginia requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the analysis should include but not be limited to: (1) the projected number of businesses or other entities to whom the proposed regulatory action would apply, (2) the identity of any localities and types of businesses or other entities particularly affected, (3) the projected number of persons and employment positions to be affected, (4) the projected costs to affected businesses or entities to implement or comply with the regulation, and (5) the impact on the use and value of private property.

<sup>&</sup>lt;sup>2</sup> https://lis.virginia.gov/cgi-bin/legp604.exe?212+ful+CHAP0449.

<sup>3</sup> Thid

<sup>&</sup>lt;sup>4</sup> See https://vamedicaid.dmas.virginia.gov/sites/default/files/2023-07/CCC Plus Appendix C (updated 9.1.21)\_Final.pdf.

See https://www.irs.gov/government-entities/federal-state-local-governments/third-party-payer-arrangements-section-3504-agents.

<sup>&</sup>lt;sup>6</sup> Pursuant to § 2.2-4007.04 D: In the event this economic impact analysis reveals that the proposed regulation would have an adverse economic impact on businesses or would impose a significant adverse economic impact on a locality, business, or entity particularly affected, the Department of Planning and Budget shall advise the Joint Commission on Administrative Rules, the House Committee on Appropriations, and the Senate Committee on Finance. Statute does not define "adverse impact," state whether only Virginia entities should be considered, nor indicate whether an adverse impact results from regulatory requirements mandated by legislation.

 $<sup>^7</sup>$  Pursuant to § 2.2-4007.04, small business is defined as "a business entity, including its affiliates, that (i) is independently owned and operated and (ii)

<sup>&</sup>lt;sup>8</sup> If the proposed regulatory action may have an adverse effect on small businesses, § 2.2-4007.04 requires that such economic impact analyses include: (1) an identification and estimate of the number of small businesses subject to the proposed regulation, (2) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the proposed regulation, including the type of professional skills necessary for preparing required reports and other documents, (3) a statement of the probable effect of the proposed regulation on affected small businesses, and (4) a description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation. Additionally, pursuant to § 2.2-4007.1 of the Code of Virginia, if there is a finding that a proposed regulation may have an adverse impact on small business, the Joint Commission on Administrative Rules shall be notified.

<sup>&</sup>lt;sup>9</sup> "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulatory change are most likely to occur.

#### 12VAC30-130-3050. Scope.

- A. The paid sick leave benefit for consumer-directed attendants applies to any CD attendant who meets the eligibility requirements at 12VAC30-130-3060 A 2, consistent with the requirements of Article 2.1 (§ 40.1-33.3 et seq.) of Chapter 3 of Title 40.1 of the Code of Virginia.
- B. The paid sick leave benefit shall only apply to CD attendants who perform consumer-directed services in accordance with the requirements under the following programs or waivers:
  - 1. Early Periodic Screening, Diagnostic, and Treatment benefit program (12VAC30-50-130);
  - 2. Medicaid Works benefit program (12VAC30-60-200);
  - 3. Commonwealth Coordinated Care Plus Waiver (Part X (12VAC30-120-900 et seq.) of 12VAC30-120);
  - 4. Community Living Waiver (12VAC30-122-250); or
  - 5. Family and Individual Support Waiver (12VAC30-122-260).

## 12VAC30-130-3060. Eligibility and Use.

- A. The FEA shall have the responsibility of determining eligibility for paid sick leave each state fiscal year quarter.
  - 1. A CD attendant shall be determined eligible to earn paid sick leave based on a quarterly evaluation of the CD attendant's hours worked for the EOR.
  - 2. The FEA shall calculate the average number of hours the CD attendant worked for the EOR during the quarter. CD attendants who work an average of 20 hours per week or at least 90 hours per month for the quarter shall be eligible to earn paid sick leave.
  - 3. Work shift entries shall be submitted by the CD attendant and approved by the EOR within 20 days of the end of the preceding quarter in order to be included in the eligibility determination.
- B. The FEA shall have the responsibility of documenting the accrual and use of sick leave hours by the CD attendant. The benefit shall be available to eligible CD attendants no later than the first day of the second month after the quarter has concluded.
  - 1. Once a CD attendant has been determined eligible to accrue the paid sick leave benefit, the CD attendant's eligibility shall remain in effect for the duration of the CD attendant's employment.
  - 2. Eligible CD attendants shall accrue the paid sick leave benefit in accordance with § 40.1-33.4 of the Code of Virginia at the rate of one hour for every 30 hours worked.
  - 3. No eligible CD attendant shall accrue more than 40 hours of paid sick leave benefit in a state fiscal year. Any amount

- of paid sick leave benefit carried over from the previous state fiscal year shall not count toward accrual in the current state fiscal year.
- 4. In accordance with § 40.1-33.4 of the Code of Virginia, any unused paid sick leave benefit shall be carried over to the state fiscal year following the state fiscal year in which it was accrued. No unused paid sick leave benefit shall be carried over for more than one state fiscal year.
- 5. Any CD attendant who qualified and accrued a paid sick leave benefit in the immediately prior fiscal year shall be entitled to use the benefit in accordance with Article 2.1 (§ 40.1-33.3 et seq.) of Chapter 3 of Title 40.1 of the Code of Virginia, even if the CD attendant is not eligible for the benefit in the current state fiscal year.
- 6. Should a CD attendant be determined ineligible to accrue the benefit, the FEA shall reevaluate the CD attendant's eligibility upon the conclusion of the following quarter.
- C. No use of this paid sick leave benefit by an eligible CD attendant shall be counted as hours worked for purposes of the following:
  - 1. Calculation for overtime pay;
  - 2. Accrual of additional paid sick leave benefit hours; or
  - 3. Determination of future eligibility for this paid sick leave benefit.
- D. Allowable uses of this paid sick leave benefit by a CD attendant shall be in accordance with § 40.1-33.5 of the Code of Virginia.
  - 1. The CD attendant shall not be required to identify a replacement for any hours in which the CD attendant uses this paid sick leave benefit. When a CD attendant uses the paid sick leave benefit, it shall be the responsibility of the EOR to utilize the documented backup plan for the individual who receives CD services.
  - 2. The EOR shall not require the CD attendant to make up any hours missed providing CD services for hours that the CD attendant used paid sick leave.
- E. Pursuant to § 40.1-33.6 of the Code of Virginia, the EOR shall not engage in any retaliatory action because of an eligible CD attendant's request or use of the paid sick leave benefit or because of an allegation that the EOR has violated a provision of Article 2.1 (§ 40.1-33.3 et seq.) of Chapter 3 of Title 40.1 of the Code of Virginia.
- F. No sick leave balances accrued during employment shall be paid out to the attendant at termination.

VA.R. Doc. No. R25-6917; Filed January 27, 2025, 2:23 p.m.



# TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

# BOARD FOR HEARING AID SPECIALISTS AND OPTICIANS

#### **Final Regulation**

<u>Title of Regulation:</u> 18VAC80-20. Hearing Aid Specialists Regulations (amending 18VAC80-20-30, 18VAC80-20-40).

Statutory Authority: § 54.1-201 of the Code of Virginia.

Effective Date: April 28, 2025.

Agency Contact: Kelley Smith, Executive Director, Board for Hearing Aid Specialists and Opticians, 9960 Mayland Drive, Suite 400, Richmond, VA 23233, telephone (804) 367-8590, FAX (866) 245-9693, or email hasopt@dpor.virginia.gov.

#### Summary:

The amendments (i) require a minimum of nine months of training in the profession prior to taking the hearing aid specialist exam, (ii) extend the duration of the temporary permit to 18 months, and (iii) create an additional pathway to gain sufficient experience to qualify for licensure. Changes to the proposed regulation update forms required by the regulation and the name of the agency sponsoring the apprentice program and provide that a registered apprenticeship is held to be a board-approved temporary permit.

<u>Summary of Public Comments and Agency's Response:</u> No public comments were received by the promulgating agency.

### 18VAC80-20-30. Basic qualifications for licensure.

- A. Every applicant for a license shall provide information on his an application establishing that:
  - 1. The applicant is at least 18 years of age.
  - 2. The applicant has successfully completed high school or a high school equivalency course.
  - 3. The applicant has training and experience that covers the following subjects as they pertain to hearing aid fitting and the sale of hearing aids, accessories, and services:
    - a. Basic physics of sound;
    - b. Basic maintenance and repair of hearing aids;
    - c. The anatomy and physiology of the ear;
    - d. Introduction to psychological aspects of hearing loss;
    - e. The function of hearing aids and amplification;
    - f. Visible disorders of the ear requiring medical referrals;
    - g. Practical tests utilized for selection or modification of hearing aids;
    - h. Pure tone audiometry, including air conduction, bone conduction, and related tests;

- i. Live voice or recorded voice speech audiometry, including speech reception threshold testing and speech discrimination testing;
- j. Masking when indicated;
- k. Recording and evaluating audiograms and speech audiometry to determine the proper selection and adaptation of hearing aids;
- 1. Taking earmold impressions;
- m. Proper earmold selection;
- n. Adequate instruction in proper hearing aid orientation;
- o. Necessity of proper procedures in after-fitting checkup; and
- p. Availability of social service resources and other special resources for the hearing impaired.
- 4. The applicant has provided one of the following as verification of completion of training and experience as described in subdivision 3 of this subsection:
  - a. A statement on a form provided by the board signed by the licensed sponsor certifying that the requirements have been met and that the applicant has completed at least six months of experience under the temporary permit; or
  - b. A certified true copy of a transcript of courses completed at an accredited college or university, or other notarized documentation of completion of the required experience and training: or
  - c. An apprenticeship completion form from the Virginia Department of [ Labor Workforce Development ] and [ Industry Advancement ] reflecting completion of a registered apprenticeship, including all required related instruction, or an equivalent out-of-state registered apprenticeship.
- 5. The applicant has not been convicted or found guilty of any crime directly related to the practice of fitting or dealing in hearing aids, regardless of the manner of adjudication, in any jurisdiction of the United States. Except for misdemeanor marijuana convictions and misdemeanor convictions that occurred five or more years prior to the date of application, with no subsequent convictions, all criminal convictions shall be considered as part of the totality of the circumstances of each applicant. The applicant review of prior convictions shall be subject to the requirements of § 54.1-204 of the Code of Virginia. Any plea of nolo contendere shall be considered a conviction for purposes of this subdivision. The record of a conviction authenticated in such form as to be admissible in evidence under the laws of the jurisdiction where convicted shall be admissible as prima facie evidence of such conviction or guilt.
- 6. The applicant is in good standing as a licensed hearing aid specialist in every jurisdiction where licensed. The applicant must disclose if he the applicant has had a license as a hearing aid specialist that was suspended, revoked, or

surrendered in connection with a disciplinary action or that has been the subject of discipline in any jurisdiction prior to applying for licensure in Virginia. At the time of application for licensure, the applicant must also disclose any disciplinary action taken in another jurisdiction in connection with the applicant's practice as a hearing aid specialist. The applicant must also disclose whether he the applicant has been previously licensed in Virginia as a hearing aid specialist.

- 7. The applicant has disclosed his the applicant's physical address. A post office box is not acceptable.
- 8. The nonresident applicant for a license has filed and maintained with the department an irrevocable consent for the department to serve as service agent for all actions filed in any court in Virginia.
- 9. The applicant has submitted the required application with the proper fee as referenced in 18VAC80-20-70 and signed, as part of the application, a statement that the applicant has read and understands Chapter 15 (§ 54.1-1500 et seq.) of Title 54.1 of the Code of Virginia and this chapter.
- B. The board may make further inquiries and investigations with respect to the qualifications of the applicant or require a personal interview or both. The board may refuse initial licensure due to the applicant's failure to comply with entry requirements. The licensee is entitled to a review of such action. Appeals from such actions shall be in accordance with the provisions of the Administrative Process Act, Chapter 40 (§ 2.2-4000 et seq.) of Title 2.2 of the Code of Virginia.

#### 18VAC80-20-40. Temporary permit.

A. Any individual may apply for a temporary permit, which is to be used solely for the purpose of gaining the training and experience required to become a licensed hearing aid specialist in Virginia. The licensed sponsor shall be identified on the application for a temporary permit, and the licensed sponsor shall comply strictly with the provisions of subdivisions [BD] 1 and [BD] 2 of this section.

- 1. A temporary permit shall be issued for a period of 42 months and may be extended once for not longer than six 18 months. After a period of 18 months an extension is no longer possible and, the former temporary permit holder shall sit for the examination in accordance with this section.
- 2. The board may, at its discretion, extend the temporary permit for a temporary permit holder who suffers serious personal illness or injury, or death in his the temporary permit holder's immediate family, or obligation of military service or service in the Peace Corps, or for other good cause of similar magnitude approved by the board. Documentation of these circumstances must be received by the board no later than 12 months after the date of the expiration of the temporary permit or within six months of the completion of military or Peace Corps service, whichever is later.

- B. [ <u>A registered apprenticeship under the Virginia Department of Workforce Development and Advancement is held to be a board-approved temporary permit.</u>
- $\underline{C}$ . Every applicant for a temporary permit shall provide information upon application establishing that:
  - 1. The applicant for a temporary permit is at least 18 years of age.
  - 2. The applicant for a temporary permit has successfully completed high school or a high school equivalency course.
  - 3. The applicant has not been convicted or found guilty of any crime directly related to the practice of fitting or dealing in hearing aids, regardless of the manner of adjudication, in any jurisdiction of the United States. Except for misdemeanor marijuana convictions and misdemeanor convictions that occurred five or more years prior to the date of application, with no subsequent convictions, all criminal convictions shall be considered as part of the totality of the circumstances of each applicant. Review of prior convictions shall be subject to the requirements of § 54.1-204 of the Code of Virginia. Any plea of nolo contendere shall be considered a conviction for purposes of this subdivision. The record of a conviction authenticated in such form as to be admissible in evidence under the laws of the jurisdiction where convicted shall be admissible as prima facie evidence of such conviction or guilt.
  - 4. The applicant for a temporary permit is in good standing as a licensed hearing aid specialist in every jurisdiction where licensed. The applicant for a temporary permit must disclose if he the applicant has had a license as a hearing aid specialist that was suspended, revoked, or surrendered in connection with a disciplinary action or that has been the subject of discipline in any jurisdiction prior to applying for licensure in Virginia. At the time of application, the applicant for a temporary permit must also disclose any disciplinary action taken in another jurisdiction in connection with the applicant's practice as a hearing aid specialist. The applicant for a temporary permit must also disclose whether he the applicant has been licensed previously in Virginia as a hearing aid specialist.
  - 5. The applicant for a temporary permit has disclosed his the applicant's physical address. A post office box is not acceptable.
  - 6. The applicant for a temporary permit has submitted the required application with the proper fee referenced in 18VAC80-20-70 and has signed, as part of the application, a statement that the applicant has read and understands Chapter 15 (§ 54.1-1500 et seq.) of Title 54.1 of the Code of Virginia and this chapter.
- [  $\underline{C}$ ,  $\underline{D}$ .] The licensed hearing aid specialist who agrees to sponsor the applicant for a temporary permit shall certify on

the application that as sponsor, he the licensed hearing aid specialist:

- 1. Assumes full responsibility for the competence and proper conduct of the temporary permit holder with regard to all acts performed pursuant to the acquisition of training and experience in the fitting or dealing of hearing aids;
- 2. Will not assign the temporary permit holder to carry out independent field work without on-site direct supervision by the sponsor until the temporary permit holder is adequately trained for such activity;
- 3. Will personally provide and make available documentation, upon request by the board or its representative, showing the number of hours that direct supervision has occurred throughout the period of the temporary permit; and
- 4. Will return the temporary permit to the department should the training program be discontinued for any reason; and
- 5. Will not refer the temporary permit holder for testing until [ they have the permit holder has ] completed at least six months of training under the permit.
- [ $\cancel{D}$ ,  $\cancel{E}$ .] The licensed sponsor shall provide training and shall ensure that the temporary permit holder under his the licensed sponsor's supervision gains experience that covers the following subjects as they pertain to hearing aid fitting and the sale of hearing aids, accessories, and services:
  - 1. Basic physics of sound;
  - 2. Basic maintenance and repair of hearing aids;
  - 3. The anatomy and physiology of the ear;
  - 4. Introduction to psychological aspects of hearing loss;
  - 5. The function of hearing aids and amplification;
  - 6. Visible disorders of the ear requiring medical referrals;
  - 7. Practical tests utilized for selection or modification of hearing aids;
  - 8. Pure tone audiometry, including air conduction, bone conduction, and related tests;
  - 9. Live voice or recorded voice speech audiometry, including speech reception threshold testing and speech discrimination testing;
  - 10. Masking when indicated;
  - 11. Recording and evaluating audiograms and speech audiometry to determine the proper selection and adaptation of hearing aids;
  - 12. Taking earmold impressions;
  - 13. Proper earmold selection;
  - 14. Adequate instruction in proper hearing aid orientation;

- 15. Necessity of proper procedures in after-fitting checkup;
- 16. Availability of social service resources and other special resources for the hearing impaired.
- [ E. F. ] The board may make further inquiries and investigations with respect to the qualifications of the applicant for a temporary permit or require a personal interview, or both.
- [F.G.] All correspondence from the board to the temporary permit holder not otherwise exempt from disclosure, shall be addressed to both the temporary permit holder and the licensed sponsor and shall be sent to the business address of the licensed sponsor.

NOTICE: The following forms used in administering the regulation have been filed by the agency. Amended or added forms are reflected in the listing and are published following the listing. Online users of this issue of the Virginia Register of Regulations may also click on the name to access a form. The forms are also available from the agency contact or may be viewed at the Office of Registrar of Regulations, General Assembly Building, 201 North Ninth Street, Fourth Floor, Richmond, Virginia 23219.

[ FORMS (18VAC80-20)

Hearing Aid Specialist License Application, A440-2101LIC v3 (rev. 2/2017)

Hearing Aid Specialist Temporary Permit Application, A440-2102TP-PKG-v4 (rev. 2/2017)

<u>Hearing Aid Specialist License Application, A440-2101LIC-v11 (rev. 4/2025)</u>

<u>Hearing Aid Specialist Temporary Permit Application, A440-</u>2102TP\_PKG-v10 (rev. 4/2025)

Hearing Aid Specialist License Reinstatement Application, A440-2101REI-v3 (rev. 2/2017)

Hearing Aid Specialist Re-examination Application, A440-2101REEX-v2 (rev. 9/2013)

Hearing Aid Specialist Training & and Experience Form, A440-21TREXP-v2 (eff. 9/2013)

VA.R. Doc. No. R22-6712; Filed January 28, 2025, 5:07 p.m.

#### **BOARD OF OPTOMETRY**

### **Final Regulation**

<u>Title of Regulation:</u> 18VAC105-20. Regulations Governing the Practice of Optometry (amending 18VAC105-20-5, 18VAC105-20-10, 18VAC105-20-20, 18VAC105-20-60; adding 18VAC105-20-80 through 18VAC105-20-110).

Statutory Authority: §§ 54.1-2400 and 54.1-3223 of the Code of Virginia.

Effective Date: May 1, 2025.

Agency Contact: Kelli Moss, Executive Director, Board of Optometry, 9960 Mayland Drive, Suite 300, Henrico, VA 23233, telephone (804) 597-4077, FAX (804) 793-9145, or email kelli.moss@dhp.virginia.gov.

### Summary:

Pursuant to Chapters 16 and 17 of the 2022 Acts of Assembly, the amendments establish criteria for certification of optometrists to provide certain laser surgeries, including (i) adding definitions specific to laser surgery; (ii) requiring a laser surgery certification, including provisions for fees, education, and clinical training, whether in a school setting or via proctored sessions; (iii) specifying requirements for proctoring and proctors; (iv) adding reporting requirements, including reporting requirements to maintain a quality assurance review process; (v) establishing fees related to certification; and (vi) providing renewal requirements. Changes to the proposed regulation include technical edits.

<u>Summary of Public Comments and Agency's Response:</u> A summary of comments made by the public and the agency's response may be obtained from the promulgating agency or viewed at the office of the Registrar of Regulations.

#### 18VAC105-20-5. Definitions.

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

"Acute pain" means pain that occurs within the normal course of a disease or condition for which controlled substances may be prescribed for no more than three months.

"Active clinical practice" means an average of 20 hours per week or 640 hours per year of providing patient care.

"Adnexa" is defined as the conjoined, subordinate, or immediately associated anatomic parts of the human eye, including eyelids and eyebrows.

"Board" means the Virginia Board of Optometry.

"Chronic pain" means nonmalignant pain that goes beyond the normal course of a disease or condition for which controlled substances may be prescribed for a period greater than three months.

"Controlled substance" means drugs listed in the Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia) in Schedules II through V.

"Laser surgery certification" means a certification issued by the board to a Virginia-licensed TPA-certified optometrist who has demonstrated compliance with the board's criteria for performance of peripheral iridotomy, selective laser trabeculoplasty, and YAG capsulotomy.

"LSPE" means the Laser and Surgical Procedures Examination administered by the NBEO.

"MME" means morphine milligram equivalent.

"NBEO" means the National Board of Examiners in Optometry.

"Prescription Monitoring Program" means the electronic system within the Department of Health Professions that monitors the dispensing of certain controlled substances.

"Proctored session" means any surgery on a live patient or procedure performed on a model eye that is observed and evaluated by a proctor for the purpose of obtaining laser surgery certification pursuant to [ subdivision 4 b of ] 18VAC105-20-80 [ 4-b ].

"Proctoring" means an objective evaluation of an optometrist's clinical competence to perform laser surgery pursuant to § 54.1-3225 of the Code of Virginia.

"TMOD" means the treatment and management of ocular disease portion of the NBEO examination.

"TPA" means therapeutic pharmaceutical agents.

"TPA certification" means authorization by the Virginia Board of Optometry for an optometrist to treat diseases and abnormal conditions of the human eye and its adnexa and to prescribe and administer certain therapeutic pharmaceutical agents.

#### 18VAC105-20-10. Requirements for licensure.

- A. The applicant, in order to be eligible for licensure to practice optometry in the Commonwealth, shall meet the requirements for TPA certification in 18VAC105-20-16 and shall:
  - 1. Be a graduate of a school of optometry accredited by the Accreditation Council on Optometric Education or other accrediting body deemed by the board to be substantially equivalent; and have an official transcript verifying graduation sent to the board;
  - 2. Request submission of an official report from the NBEO of a score received on each required part of the NBEO examination or other board-approved examination;
  - 3. Submit a completed application and the prescribed fee; and
  - 4. Sign a statement attesting that the applicant has read, understands, and will comply with the statutes and regulations governing the practice of optometry in Virginia.
- B. On or after January 1, 2033, all applicants to practice optometry in the Commonwealth shall meet the requirements for laser surgery in 18VAC105-20-80.
- <u>C.</u> The board may waive the requirement of graduation from an accredited school of optometry for an applicant who holds a current, unrestricted license in another United States jurisdiction and has been engaged in active clinical practice for 36 out of the 60 months immediately preceding application for licensure in Virginia.

- C. D. Required examinations. For the purpose of § 54.1-3211 of the Code of Virginia, the board adopts all parts of the NBEO examination as its written examination for licensure. After July 1, 1997, the board shall require passage as determined by the board of Parts I, II, and III of the NBEO examination, including passage of TMOD.
- D. E. If an applicant has been licensed in another jurisdiction, the following requirements shall also apply:
  - 1. The applicant shall attest that the applicant is not a respondent in a pending or unresolved malpractice claim.
  - 2. Each jurisdiction in which the applicant is or has been licensed shall verify that:
    - a. The license is current and unrestricted, or if the license has lapsed, it is eligible for reinstatement;
    - b. All continuing education requirements have been completed, if applicable;
    - c. The applicant is not a respondent in any pending or unresolved board action; and
    - d. The applicant has not committed any act that would constitute a violation of § 54.1-3204 or 54.1-3215 of the Code of Virginia.
  - 3. An applicant licensed in another jurisdiction who has not been engaged in active practice within the 12 months immediately preceding application for licensure in Virginia shall be required to complete 20 hours of continuing education as specified in 18VAC105-20-70.
  - 4. In the case of a federal service optometrist, the commanding officer shall also verify that the applicant is in good standing.

#### 18VAC105-20-20. Fees.

A. Required fees.

Initial application and licensure (including with TPA certification)	\$250
Initial application for licensure with TPA certification and laser surgery certification	<u>\$350</u>
Application for laser surgery certification	<u>\$200</u>
Annual licensure renewal without TPA certification	\$150
Annual licensure renewal with TPA certification	\$200
Annual licensure renewal with TPA certification and laser surgery certification	<u>\$250</u>
Annual renewal of inactive license	\$100
Late renewal without TPA certification of any license	\$50

Late renewal with TPA certification	<del>\$65</del>
Late renewal of inactive license	<del>\$35</del>
Handling fee for returned check or dishonored credit card or debit card	\$50
Reinstatement application fee (including renewal and late fees)	\$400
Reinstatement application after disciplinary action	\$500
Duplicate wall certificate	\$25
Duplicate license	\$10
Licensure verification	\$10

B. Unless otherwise specified, all fees are nonrefundable.

C. From October 31, 2018, to December 31, 2018, the following fees shall be in effect:

Annual licensure renewal without TPA certification	<del>\$75</del>
Annual licensure renewal with TPA certification	<del>\$100</del>
Annual professional designation renewal (per location)	<del>\$25</del>

# 18VAC105-20-60. Renewal of licensure; reinstatement; renewal fees.

- A. Every person authorized by the board to practice optometry shall, on or before December 31 of 2018 March 31 of each year, submit a completed renewal form and pay the prescribed annual licensure fee. Beginning with calendar year 2020, the renewal of licensure deadline shall be March 31 of each year. For calendar year 2019, no renewal is required.
- B. It shall be the duty and responsibility of each licensee to assure ensure that the board has the licensee's current address of record and the public address, if different from the address of record. All changes of address or name shall be furnished to the board within 30 days after the change occurs. All notices required by law or by these rules and regulations are to be deemed to be validly tendered when mailed to the address of record given and shall not relieve the licensee of the obligation to comply.
- C. The license of every any person who does not complete the renewal form and submit the renewal fee each year for a licensure period may be renewed for up to one year by paying the prescribed renewal fee and late fee, provided the requirements of 18VAC105-20-70 have been met. After the renewal deadline, a license that has not been renewed is lapsed.

Practicing optometry in Virginia with a lapsed license may subject the licensee to disciplinary action.

- D. An optometrist whose license has been lapsed for more than one year and who wishes to resume practice in Virginia shall apply for reinstatement. The executive director may grant reinstatement, provided that:
  - 1. <u>a.</u> The applicant has a current, unrestricted license in another United States jurisdiction and has been engaged in active clinical practice within the 12 months immediately preceding application for reinstatement; or
    - 2. <u>b.</u> The applicant has satisfied current requirements for continuing education as specified in 18VAC105-20-70 for the period in which the license has been lapsed, not to exceed two years; and
  - 3. 2. The applicant has paid the prescribed reinstatement application fee.

# 18VAC105-20-80. Requirements for laser surgery certification.

An applicant for laser surgery certification shall submit to the board:

- 1. A completed application for laser surgery certification;
- 2. The prescribed fee;
- 3. An educational attestation from a dean or designee of a school of optometry or an instructor of a laser surgery certification course approved by the board that verifies that the applicant received didactic and clinical laser surgery training in the following subjects:
  - a. Laser physics, hazards, and safety;
  - b. Biophysics of laser;
  - c. Laser application in clinical optometry;
  - d. Laser tissue interactions;
  - e. Laser indications, contraindications, and potential complications;
  - f. Gonioscopy;
  - g. Laser therapy for open-angle glaucoma;
  - h. Posterior capsulotomy;
  - i. Common complications, lids, lashes, and lacrimal;
  - j. Medicolegal aspects of anterior segment procedures;
  - k. Peripheral iridotomy; and
  - 1. Laser trabeculoplasty.

The required attestation from the dean or designee of a school of optometry or an instructor of a laser surgery certification course approved by the board shall be submitted on a form prescribed by the board; and

- 4. Evidence of one of the following:
  - a. Passage of the Laser Section of the LSPE, for which the applicant must request submission of an official report

- from the NBEO of the score received on the Laser Section of the LSPE: or
- b. Proctored sessions in compliance with 18VAC105-20-90, which may be obtained during education training described in subdivision 3 of this section.

## 18VAC105-20-90. Requirements for proctoring.

- A. Applicants for laser surgery certification who have not provided the board with a passing score on the Laser Section of the LSPE must submit evidence on a form provided by the board of at least two proctored sessions for each of the following laser procedures:
  - 1. Peripheral iridotomy;
  - 2. Selective laser trabeculoplasty; and
  - 3. YAG capsulotomy.
- B. Proctors.
- 1. Pursuant to § 54.1-2400.01:1 of the Code of Virginia, a proctored session performed within the Commonwealth to qualify a TPA-certified optometrist for a laser surgery certification that consists of surgery on a live patient must be proctored by a licensed doctor of medicine or osteopathy who specializes in ophthalmology.
- 2. A proctored session performed within the Commonwealth to qualify a TPA-certified optometrist for a laser surgery certification that is performed on a model eye may be proctored by an individual holding a license in the Commonwealth or another jurisdiction who is authorized or certified to perform laser surgery on the eye and who does so as part of a regular course of practice.
- 3. The proctor must be in attendance in the room while the proctored session is performed, regardless of the jurisdiction in which the proctoring occurs.
- 4. Evidence of proctored sessions shall include a report by the proctor on a form provided by the board that:
  - <u>a. Evaluates the clinical competency of the individual being proctored;</u>
  - b. Describes the number and type of cases proctored; and
  - c. Includes the proctor's name, license type, license number, and state of licensure.

#### 18VAC105-20-100. Reporting requirements.

- A. An optometrist certified to perform laser surgery by the board shall report the following information to the board on a quarterly basis:
  - 1. The number and type of laser surgeries performed by the optometrist;
  - 2. The conditions treated for each laser surgery performed; and
  - 3. Any adverse treatment outcomes associated with such procedures that required a referral to an ophthalmologist for treatment.

B. The requirements of subsection A [ of this section ] shall expire on July 1, 2025.

## 18VAC105-20-110. Quality assurance review process.

A. Effective July 1, 2025, an optometrist certified to perform laser surgery by the board shall maintain documentation of the following for not less than three years:

- 1. The number and type of laser surgeries performed by the optometrist; and
- 2. Any adverse treatment outcomes associated with such procedures that required referral to an ophthalmologist for treatment.
- B. The board may conduct a random audit of licensees requiring a subject licensee to provide documentation required in subsection A [ of this section ] to the board within 30 days of notification of the audit.

VA.R. Doc. No. R23-7555; Filed February 3, 2025, 3:10 p.m.

# DEPARTMENT OF PROFESSIONAL AND OCCUPATIONAL REGULATION

### **Fast-Track Regulation**

<u>Title of Regulation:</u> 18VAC120-40. Virginia Professional Boxing and Wrestling Events Regulations (amending 18VAC120-40-295).

Statutory Authority: § 54.1-831 of the Code of Virginia; 15 USC § 6301 et seq.

<u>Public Hearing Information:</u> No public hearing is currently scheduled.

Public Comment Deadline: March 26, 2025.

Effective Date: May 1, 2025.

Agency Contact: Kathleen R. Nosbisch, Department of Professional and Occupational Regulation, 9960 Mayland Drive, Suite 400, Richmond, VA 23233, telephone (804) 367-8514, FAX (866) 465-6206, or email boxing@dpor.virginia.gov.

Basis: Section 54.1-201 of the Code of Virginia gives the boards of the Department of Professional and Occupational Regulation (DPOR) authority to promulgate regulations necessary to ensure continued competency, to prevent deceptive or misleading practices by practitioners, and to effectively administer the regulatory system administered by the board. Section 54.1-831 of the Code of Virginia authorizes the Director of DPOR to promulgate regulations to implement the federal Professional Boxing Safety Act of 1996 (15 USC § 6301 et seq.) and protect the public against incompetent, unqualified, unscrupulous, or unfit persons engaging in professional boxing and wrestling events.

<u>Purpose:</u> Boxers often reduce weight by dehydrating and other means before weigh-in to meet the weight specified in the boxer's contract. As a result, a boxer at weigh-in is often very dehydrated. After meeting the required weight, a boxer will

rehydrate to gain back their strength and weight. The rehydration and weight gain process can sometimes cause a boxer to gain more than 10 pounds, thereby resulting in the boxer being out of compliance with the current re-weigh requirement in the regulation. However, if a boxer is not permitted to sufficiently rehydrate and potentially exceed the 10-pound restriction, the boxer's health may be at risk. The proposed regulatory change is necessary to have an immediate effect in providing a safer weigh-in procedure. The amendments will allow boxers to fully rehydrate up to the time of the event. The second weigh-in requirement needs to be eliminated to protect the health, safety, and welfare of boxers. Most states do not require a second weigh-in prior to an event. This current requirement causes promoters and boxers to avoid holding events in Virginia.

Rationale for Using Fast-Track Rulemaking Process: After input from the public and other boxing commissions, the Boxing, Martial Arts, and Professional Wrestling Advisory Board determined that the second weigh-in requirement in the regulation creates potential adverse effects on the health of boxers. This action is not the result of a mandate. This action is expected to be noncontroversial and is appropriate for the fast-track rulemaking process as the amendments remove a burdensome requirement for boxers to better ensure the safety of boxers. This action does not increase existing requirements or impose new requirements on regulants. Moreover, this action will help ensure that the standards in the regulation are consistent with nationally recognized practice.

<u>Substance</u>: The amendments remove the requirements that boxers be reweighed two hours prior to an event's start time and that boxers weigh no more than 10 pounds from the boxer's contracted weight.

<u>Issues:</u> The primary advantage to the regulated community and to the public from this regulatory change is to better protect the health and safety of boxers by allowing boxers to properly rehydrate to normal body weight prior to a boxing event. An additional advantage is that removing the reweigh requirement will likely lead to an increase in the number of boxing events in Virginia. No disadvantages to the public or the Commonwealth have been identified.

<u>Department of Planning and Budget Economic Impact Analysis:</u>

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Code of Virginia and Executive Order 19. The analysis presented represents DPB's best estimate of the potential economic impacts as of the date of this analysis.<sup>1</sup>

Summary of the Proposed Amendments to Regulation. The Department of Professional and Occupational Regulation (DPOR) proposes to no longer require that boxers who weigh in 24 hours prior to the scheduled event also re-weigh two hours prior to the event's scheduled start time.

Background. Under the current regulation, boxers are weighed in 24 hours before the event start time and are required to meet their contracted weight. The boxers are then re-weighed two hours before the event start time and must not then exceed the weight specified in the contract by more than 10 pounds. According to DPOR, it is a common practice of boxers to reduce weight (by dehydrating and other means) before weighin to meet the weight specified in their contract. As a result, a boxer at weigh-in is often very dehydrated. After meeting the required weight, a boxer will rehydrate to gain back strength and weight. The rehydration and weight gain can sometimes be more than 10 pounds, thereby resulting in the boxer being out of compliance with the current re-weigh requirements in the regulation. However, if a boxer is not permitted to sufficiently rehydrate and potentially exceed the 10-pound restriction, the boxer's health may be at risk. After input from the public, boxers, promotors and other boxing commissions, the Boxing, Martial Arts, and Professional Wrestling Advisory Board determined that the second weigh-in requirement in the regulation creates potential adverse effects on the health of boxers and is not necessary. Also, DPOR staff determined that the nationally recognized practice was to have one weigh-in the day before the event. DPOR reports that this practice is followed by neighboring and nearby states (Maryland, North Carolina, South Carolina, Pennsylvania, and New Jersey), which only require the one weigh-in the day before the event.

Estimated Benefits and Costs: No longer requiring that boxers have a second weigh-in two hours before the event would likely be beneficial in that it could reduce health risk to boxers by allowing them to fully hydrate. The proposed change does not appear to introduce costs.

Businesses and Other Entities Affected. As of November 1, 2024, there were 91 boxers, 31 promoters, 186 trainers or cutmen, three managers, 31 matchmakers, and four boxing events licensed in the Commonwealth, all of which could be directly or indirectly affected by the proposed change.<sup>2</sup> The Code of Virginia requires DPB to assess whether an adverse impact may result from the proposed regulation.<sup>3</sup> An adverse impact is indicated if there is any increase in net cost or reduction in net benefit for any entity, even if the benefits exceed the costs for all entities combined.<sup>4</sup> As the proposed amendment neither increases net cost nor reduces net benefit, no adverse impact is indicated.

Small Businesses<sup>5</sup> Affected.<sup>6</sup> The proposed amendment does not adversely affect small businesses.

Localities<sup>7</sup> Affected.<sup>8</sup> The proposed amendment neither disproportionately affect particular localities nor increases costs for local governments.

Projected Impact on Employment. The proposed amendment does not appear to affect total employment.

Effects on the Use and Value of Private Property. The proposed amendment does not appear to substantively affect the use and value of private property. The proposed amendment does not affect real estate development costs.

- <sup>1</sup> Section 2.2-4007.04 of the Code of Virginia requires that such economic impact analyses determine the public benefits and costs of the proposed amendments. Further the analysis should include but not be limited to: (1) the projected number of businesses or other entities to whom the proposed regulatory action would apply, (2) the identity of any localities and types of businesses or other entities particularly affected, (3) the projected number of persons and employment positions to be affected, (4) the projected costs to affected businesses or entities to implement or comply with the regulation, and (5) the impact on the use and value of private property.
- <sup>2</sup> Data source: DPOR.
- <sup>3</sup> Pursuant to § 2.2-4007.04 D: In the event this economic impact analysis reveals that the proposed regulation would have an adverse economic impact on businesses or would impose a significant adverse economic impact on a locality, business, or entity particularly affected, the Department of Planning and Budget shall advise the Joint Commission on Administrative Rules, the House Committee on Appropriations, and the Senate Committee on Finance. Statute does not define "adverse impact," state whether only Virginia entities should be considered, nor indicate whether an adverse impact results from regulatory requirements mandated by legislation.
- <sup>4</sup> Statute does not define "adverse impact," state whether only Virginia entities should be considered, nor indicate whether an adverse impact results from regulatory requirements mandated by legislation. As a result, DPB has adopted a definition of adverse impact that assesses changes in net costs and benefits for each affected Virginia entity that directly results from discretionary changes to the regulation.
- <sup>5</sup> Pursuant to § 2.2-4007.04, small business is defined as "a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million."
- <sup>6</sup> If the proposed regulatory action may have an adverse effect on small businesses, § 2.2-4007.04 requires that such economic impact analyses include: (1) an identification and estimate of the number of small businesses subject to the proposed regulation, (2) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the proposed regulation, including the type of professional skills necessary for preparing required reports and other documents, (3) a statement of the probable effect of the proposed regulation on affected small businesses, and (4) a description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation. Additionally, pursuant to § 2.2-4007.1 of the Code of Virginia, if there is a finding that a proposed regulation may have an adverse impact on small business, the Joint Commission on Administrative Rules shall be notified.
- $^7$  "Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulatory change are most likely to occur.
- 8 Section 2.2-4007.04 defines "particularly affected" as bearing disproportionate material impact.

Agency Response to Economic Impact Analysis: The Department of Professional and Occupational Regulation concurs with the economic impact analysis prepared by the Department of Planning and Budget.

#### **Summary:**

The amendments remove the requirement for boxers to reweigh two hours prior to the scheduled start time for a boxing event when the weigh-in occurs 24 hours prior to the event start time.

# 18VAC120-40-295. Weight classes and weigh-ins and prefight meeting.

A. Weight classes are as follows:

Volume 41, Issue 14

Weight Class	Weight in Lbs	Max Weight Spread	Glove sizes
Mini-Flyweight	105 <del>&amp;</del> <u>and</u> below	3 lbs	8 oz
Light-Flyweight	105.1 - 108	3 lbs	8 oz
Flyweight	108.1 - 112	3 lbs	8 oz
Junior Bantamweight	112.1 - 115	3 lbs	8 oz
Bantamweight	115.1 - 118	3 lbs	8 oz
Junior Featherweight	118.1 - 122	4 lbs	8 oz
Featherweight	122.1 - 126	4 lbs	8 oz
Junior Lightweight	126.1 - 130	4 lbs	8 oz
Lightweight	130.1 - 135	5 lbs	8 oz
Junior Welterweight	135.1 - 140	5 lbs	8 oz
Welterweight	140.1 - 147	7 lbs	8 oz
Super Welterweight	147.1 - 154	7 lbs	10 oz
Middleweight	154.1 - 160	7 lbs	10 oz
Super Middleweight	160.1 - 168	7 lbs	10 oz
Light-Heavyweight	168.1 - 175	7 lbs	10 oz
Cruiserweight	175.1 - 200	12 lbs	10 oz
Heavyweight	200.1 and up	No limit	10 oz

- B. No boxer may engage in a contest without the approval of the department or its the department's contractor if the difference in weight between the boxers exceeds the allowance shown in subsection A of this section.
- C. If one of the two boxers in a contest is above or below the weights shown in subsection A of this section, both boxers shall wear the gloves of the higher weight.
- D. Boxers shall be weighed within 24 hours prior to the scheduled event. Each boxer and second shall appear at a time and place designated by the promoter and approved by the department or its the department's contractor to be weighed on scales approved by the department or its the department's contractor in the presence of each other, the promoter or his the promoter's representative, and a designee of the department or its the department's contractor. Boxers shall have all weight removed from their bodies before the weigh-in but may wear shorts in the case of males, and shorts and shirts in the case of

females. Once weigh-ins commence, the scales shall not be moved until weigh-ins are complete.

- E. When weigh-ins occur within 24 hours, but not less than 12 hours prior to the event's scheduled start time, the boxer shall not exceed the weight specified in his the contract with the promoter. If a boxer exceeds the weight specified in the contract he, the boxer shall not compete unless he the boxer:
  - 1. Loses the weight exceeded in the contract at least 12 hours prior to the event's scheduled start time;
  - 2. Loses all but two pounds of the weight exceeded in the contract at least 12 hours prior to the event's scheduled start time and loses the final two pounds at least six hours prior to the event's scheduled start time; or
  - 3. Renegotiates the contract.

Boxers who weigh in 24 hours prior to the scheduled event shall be required to re weigh two hours prior to the event's scheduled start time and will not be permitted to exceed the weight specified in the contract by more than 10 pounds.

- F. When weigh-ins occur less than 12 hours prior to an event's scheduled start time, the boxer shall not exceed the weight specified in the contract. No boxer shall be permitted to lose more than two pounds within 12 hours of a contest. If a boxer weighs more than two pounds over the weight specified in the contract, he the boxer shall not compete unless he the boxer:
  - 1. Loses up to two pounds at least six hours prior to the event's scheduled start time; or
  - 2. Renegotiates his the contract.
- G. The promoter is responsible for ensuring that all boxers and seconds are present at the prefight meeting. Any second who does not attend the prefight meeting will not be permitted in the corner of their boxer. All boxers will report to the event location and their locker rooms at the specified time on the night of the event. Once the boxer reports to the event facility and to the locker room he, the boxer will be disqualified if he the boxer leaves the locker room before time for the bout or leaves the facility before the end of the bout.

VA.R. Doc. No. R25-7637; Filed January 24, 2025, 9:17 a.m.

## **GUIDANCE DOCUMENTS**

### **PUBLIC COMMENT OPPORTUNITY**

Pursuant to § 2.2-4002.1 of the Code of Virginia, a certified guidance document is subject to a 30-day public comment period after publication in the Virginia Register of Regulations and prior to the guidance document's effective date. During the public comment period, comments may be made through the Virginia Regulatory Town Hall website (http://www.townhall.virginia.gov) or sent to the agency contact. Under subsection C of § 2.2-4002.1, the effective date of the guidance document may be delayed for an additional period. The guidance document may also be withdrawn.

The following guidance documents have been submitted for publication by the listed agencies for a public comment period. Online users of this issue of the Virginia Register of Regulations may click on the name of a guidance document to access it. Guidance documents are also available on the Virginia Regulatory Town Hall (http://www.townhall.virginia.gov) or from the agency contact or may be viewed at the Office of the Registrar of Regulations, General Assembly Building, 201 North Ninth Street, Fourth Floor, Richmond, Virginia 23219.

#### **BOARD OF DENTISTRY**

<u>Titles of Documents:</u> Clinical Competency Requirements for Applicants for Licensure, Reactivation, or Reinstatement.

Practice of Dental Hygienists under Remote Supervision.

Public Comment Deadline: March 26, 2025.

Effective Date: March 27, 2025.

Agency Contact: Erin Barrett, Director of Legislative and Regulatory Affairs, Department of Health Professions, 9960 Mayland Drive, Suite 300, Henrico, VA 23233, telephone (804) 750-3912, or email erin.barrett@dhp.virginia.gov.

## **VIRGINIA INFORMATION TECHNOLOGIES AGENCY**

<u>Title of Document:</u> Virginia Real Property Electronic Recording Standard.

Public Comment Deadline: March 26, 2025.

Effective Date: March 27, 2025.

Agency Contact: Joshua Heslinga, Director, Legal and Legislative Services, Virginia Information Technologies Agency, 7325 Beaufont Springs Drive, Richmond, VA 23225, telephone (804) 551-2902, or email joshua.heslinga@vita.virginia.gov.

#### STATE BOARD OF SOCIAL SERVICES

<u>Title of Document:</u> Child and Families Services Manual, Chapter C: Child Protective Services.

Public Comment Deadline: March 26, 2025.

Effective Date: March 27, 2025.in the

Agency Contact: Karin Clark, Regulatory Coordinator, Department of Social Services, 801 East Main Street, Room 1507, Richmond, VA 23219, telephone (804) 726-7017, or email karin.clark@dss.virginia.gov.

## **Guidance Documents**

The following guidance documents have been submitted for deletion and the listed agencies have opened up a 30-day public comment period. The listed agencies had previously identified these documents as certified guidance documents, pursuant to § 2.2-4002.1 of the Code of Virginia. Online users of this issue of the Virginia Register of Regulations may click on the name of a guidance document to view the deleted document and comment. This information is also available on the Virginia Regulatory Town Hall (http://www.townhall.virginia.gov) or from the agency contact.

#### DEPARTMENT FOR THE DEAF AND HARD-OF-HEARING

<u>Titles of Documents:</u> Directory of Qualified Interpreters Procedures.

Interpreter Services Procedures.

Virginia Quality Assurance Screening Applicant Packet.

Public Comment Deadline: March 26, 2025.

Effective Date: March 27, 2025.

<u>Agency Contact:</u> Eric Raff, Director, Department for the Deaf and Hard-of-Hearing, 1602 Rolling Hills Drive, Suite 203, Henrico, VA 23229-5012, telephone (804) 404-9090, or email eric.raff@vddhh.virginia.gov.

# DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

<u>Titles of Documents:</u> Chapter 2 of the Alzheimer's Assisted Living Services Waiver Manual.

Chapter 4 of the Alzheimer's Assisted Living Services Waiver Manual.

Chapter 5 of the Alzheimer's Assisted Living Services Waiver Manual.

Chapter 6 of the Alzheimer's Assisted Living Services Waiver Manual.

Chapter 7 of the Alzheimer's Assisted Living Services Waiver Manual.

Public Comment Deadline: March 26, 2025.

Effective Date: March 27, 2025.

Agency Contact: Syreeta Stewart, Regulatory Coordinator, Department of Medical Assistance Services, 600 East Broad Street, Suite 1300, Richmond, VA 23219, telephone (804) 298-3863, or email syreeta.stewart@dmas.virginia.gov.

#### **COMMONWEALTH TRANSPORTATION BOARD**

Title of Document: Locally Administered Projects Manual.

Public Comment Deadline: March 26, 2025.

Effective Date: March 27, 2025.

Agency Contact: Steven P. Jack, Regulatory Manager, Virginia Department of Transportation, 1401 East Broad Street, Richmond, VA 23219, telephone (804) 786-3885, or email steven.jack@vdot.virginia.gov.

## **GENERAL NOTICES**

#### **DEPARTMENT OF ENVIRONMENTAL QUALITY**

### Proposed Enforcement Action for Aqua Virginia Inc.

The Department of Environmental Quality (DEQ) is proposing an enforcement action for Aqua Virginia Inc. for violations of the State Water Control Law and regulations in Frederick County, Virginia. The proposed order is available from the DEQ contact or at <a href="https://www.deq.virginia.gov/permits/public-notices/enforcement-actions">https://www.deq.virginia.gov/permits/public-notices/enforcement-actions</a>. The DEQ contact will accept written comments from February 24, 2025, to March 25, 2025.

<u>Contact Information:</u> Francesca Wright, Senior Enforcement Specialist, Department of Environmental Quality, Valley Regional Office, P.O. Box 3000, Harrisonburg, VA 22801, or email francesca.wright@deq.virginia.gov.

# Proposed Enforcement Action for CVPA Management Inc.

The Virginia Department of Environmental Quality (DEQ) is proposing an enforcement action for CVPA Management Inc. for violations of the State Water Control Law and regulations in Chesapeake, Virginia. The proposed order is available from the DEQ contact listed or at <a href="https://www.deq.virginia.gov/permits/public-notices/enforcement-actions">https://www.deq.virginia.gov/permits/public-notices/enforcement-actions</a>. The DEQ contact will accept comments by email or postal mail from February 24, 2025, through March 26, 2025.

<u>Contact Information:</u> John Brandt, Enforcement Manager, Department of Environmental Quality, 5636 Southern Boulevard, Virginia Beach, VA 23462, or email john.brandt@deq.virginia.gov.

#### Proposed Enforcement Action for HSV Holiday LLC

The Department of Environmental Quality (DEQ) is proposing an enforcement action for HSV Holiday LLC for violations of the State Water Control Law and regulations in Rockingham County, Virginia. The proposed order is available from the DEQ contact or at https://www.deq.virginia.gov/permits/public-notices/enforcement-actions. The DEQ contact will accept written comments from February 24, 2025, to March 25, 2025.

<u>Contact Information:</u> Francesca Wright, Senior Enforcement Specialist, Department of Environmental Quality, Valley Regional Office, P.O. Box 3000, Harrisonburg, VA 22801, or email francesca.wright@deq.virginia.gov.

## Public Meeting and Opportunity for Public Comment for a Cleanup Study and Cleanup Plan for Hat and Black Creeks in Nelson County

Purpose of Notice: The Department of Environmental Quality (DEQ) seeks public comment on two reports for Hat and Black Creeks in Nelson County: a cleanup study, also known as a

total maximum daily load (TMDL) report, and a cleanup plan, known as an implementation plan (IP).

These streams are listed as impaired waters and require a cleanup study because monitoring data indicate that the waters do not meet Virginia's water quality standards for Aquatic Life (benthic impairment). Section 303(d) of the Clean Water Act and § 62.1-44.19:7 C of the Code of Virginia require DEQ to develop cleanup studies to address pollutants responsible for causing waters to be on Virginia's § 303(d) list of impaired waters. A component of a cleanup study is the wasteload allocation (WLA); therefore, this notice is provided pursuant to § 2.2-4006 A 14 of the Code of Virginia for adopting the WLA into the Water Quality Management Planning Regulation (9VAC25-720) after completion of the study. The adoption of the WLA may require new or additional requirements for entities holding a Virginia Pollutant Discharge Elimination System (VPDES) permit in these watersheds. Once a cleanup study is developed, § 62.1-44.19:7 of the Code of Virginia outlines the requirements needed in a cleanup plan to address the pollutants addressed in the study.

A study has been completed for Hat and Black Creeks to identify pollutant sources and recommend reductions needed from the sources to meet water quality standards. The cleanup plan identifies corrective actions needed to improve water quality and discusses the associated costs and environmental benefits of the actions. At the meeting, DEQ will present an overview of both reports and their results. Citizens are invited to provide comment on both reports.

Cleanup Study and Plan Location: The cleanup study and plan address the following impaired stream segments: the Hat Creek stream segment, located in Nelson County, is 9.5 miles long, begins at the headwaters of Hat Creek, and continues to the confluence with the Tye River. The Black Creek stream segment, located in Nelson County, is 2.0 miles long, begins at the headwaters of Black Creek, and continues to the confluence with the Tye River.

Public Meeting: The final public meeting on the development of the cleanup study and cleanup plan will be held at the Nelson Center, 8445 Thomas Nelson Highway, Lovingston, VA 22949, on March 5, 2025, at 5:30 p.m. In the event of inclement weather, the meeting will be held on March 12, 2025, at the same time and location.

Public Comment Period: March 5, 2025, to April 4, 2025.

How to Comment: DEQ accepts comments orally at the public meeting or by email, fax, or postal mail. All comments must be received by DEQ during the comment period. Submittals must include the name, organization represented (if any), mailing addresses, and telephone numbers of the commenter or requester.

The public may review the cleanup study at https://www.deq.virginia.gov/our-programs/water/water-quality/tmdl-development/tmdls-under-development. The

## **General Notices**

public may review the cleanup plan at https://www.deq.virginia.gov/our-programs/water/water-quality/implementation/implementation-plans-under-development.

<u>Contact Information:</u> Nesha McRae, Department of Environmental Quality, Valley Regional Office, 4411 Early Road, Harrisonburg, VA 24401, telephone (540) 217-7173, or email nesha.mcrae@deq.virginia.gov.

#### VIRGINIA CODE COMMISSION

#### **Notice to State Agencies**

**Contact Information:** *Mailing Address:* Virginia Code Commission, General Assembly Building, 201 North Ninth Street, Fourth Floor, Richmond, VA 23219; *Telephone:* (804) 698-1810; *Email:* varegs@dls.virginia.gov.

**Meeting Notices:** Section 2.2-3707 C of the Code of Virginia requires state agencies to post meeting notices on their websites and on the Commonwealth Calendar at https://commonwealthcalendar.virginia.gov.

Cumulative Table of Virginia Administrative Code Sections Adopted, Amended, or Repealed: A table listing regulation sections that have been amended, added, or repealed in the Virginia Register of Regulations since the regulations were originally published or last supplemented in the print version of the Virginia Administrative Code is available at http://register.dls.virginia.gov/documents/cumultab.pdf.

Filing Material for Publication in the Virginia Register of Regulations: Agencies use the Regulation Information System (RIS) to file regulations and related items for publication in the Virginia Register of Regulations. The Registrar's office works closely with the Department of Planning and Budget (DPB) to coordinate the system with the Virginia Regulatory Town Hall. RIS and Town Hall complement and enhance one another by sharing pertinent regulatory information.