VIRGINIA REGISTER OF REGULATIONS

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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

An agency wishing to adopt, amend, or repeal regulations must first publish 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 proposal 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 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 (JCAR) 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 changes made to the proposed regulation 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*.

The agency shall suspend the regulatory process for 30 days when it receives requests from 25 or more individuals to solicit additional public comment, unless the agency determines that the changes have minor or inconsequential 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 exemption from certain provisions of the Administrative Process Act for agency regulations deemed by the Governor to be noncontroversial. To use this process, Governor's concurrence is required and advance notice must be provided to certain legislative committees. Fast-track regulations will become effective on the date noted in the regulatory action if no objections to using the process are filed in accordance with § 2.2-4012.1.

EMERGENCY REGULATIONS

Pursuant to § 2.2-4011 of the Code of Virginia, an agency, upon consultation with the Attorney General, and at the discretion of the Governor, may adopt emergency regulations that are necessitated by an emergency situation. An agency may also adopt an emergency regulation when Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment. The emergency regulation becomes operative upon its adoption and filing with the Registrar of Regulations, unless a later date is specified. Emergency regulations are limited to no more than 18 months in duration; however, may be extended for six months under certain circumstances as provided for in § 2.2-4011 D. Emergency regulations are published as soon as possible in the *Register*.

During the time the emergency status is in effect, the agency may proceed with the adoption of permanent regulations through the usual procedures. To begin promulgating the replacement regulation, the agency must (i) file the Notice of Intended Regulatory Action with the Registrar within 60 days of the effective date of the emergency regulation and (ii) file the proposed regulation with the Registrar within 180 days of the effective date of the emergency regulation. 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.

PUBLICATION SCHEDULE AND DEADLINES

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

April 2019 through April 2020

Volume: Issue	Material Submitted By Noon*	Will Be Published On
35:17	March 27, 2019	April 15, 2019
35:18	April 10, 2019	April 29, 2019
35:19	April 24, 2019	May 13, 2019
35:20	May 8, 2019	May 27, 2019
35:21	May 22, 2019	June 10, 2019
35:22	June 5, 2019	June 24, 2019
35:23	June 19, 2019	July 8, 2019
35:24	July 3, 2019	July 22, 2019
35:25	July 17, 2019	August 5, 2019
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36:1	August 14, 2019	September 2, 2019
36:2	August 28, 2019	September 16, 2019
36:3	September 11, 2019	September 30, 2019
36:4	September 25, 2019	October 14, 2019
36:5	October 9, 2019	October 28, 2019
36:6	October 23, 2019	November 11, 2019
36:7	November 6, 2019	November 25, 2019
36:8	November 18, 2019 **(Monday)**	December 9, 2019
36:9	December 4, 2019	December 23, 2019
36:10	December 18, 2019	January 6, 2020
36:11	January 1, 2020	January 20, 2020
36:12	January 15, 2020	February 3, 2020
36:13	January 29, 2020	February 17, 2020
36:14	February 12. 2020	March 2, 2020
36:15	February 26, 2020	March 16, 2020
36:16	March 11, 2020	March 30, 2020
36:17	March 25, 2020	April 13, 2020

*Filing deadlines are Wednesdays unless otherwise specified.

TITLE 11. GAMING

CHARITABLE GAMING BOARD

Initial Agency Notice

Title of Regulation: **11VAC15-40. Charitable Gaming Regulations.**

Statutory Authority: § 18.2-340.15 of the Code of Virginia.

Name of Petitioner: Nathan A. Freels, Powerhouse Gaming.

Nature of Petitioner's Request: Petitioner requests that the Charitable Gaming Board amend Charitable Gaming Regulations to allow "for the calculation of Use of Proceeds be adjusted such that electronic pulltabs are calculated as 2% of the charitable gaming gross receipts specifically realized from the use of electronic pulltabs."

Agency Plan for Disposition of Request: The Charitable Gaming Board will consider this request at its next scheduled meeting following the public comment period. This meeting will occur on June 18, 2019.

Public Comment Deadline: April 7, 2019.

Agency Contact: Michael Menefee, Program Manager, Charitable and Regulatory Programs, Department of Agriculture and Consumer Services, 102 Governor Street, Richmond, VA 23219, telephone (804) 786-3983, or email michael.menefee@cdacs.virginia.gov.

VA.R. Doc. No. R19-26; Filed February 18, 2019, 12:31 p.m.

TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF AUDIOLOGY AND SPEECH-LANGUAGE PATHOLOGY

Initial Agency Notice

Title of Regulation: **18VAC30-21. Regulations Governing Audiology and Speech-Language Pathology.**

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

Name of Petitioner: Catherine Satterfield.

Nature of Petitioner's Request: To recognize health care organizations accredited by DNV-GL Healthcare for approval of continuing education.

Agency Plan for Disposition of Request: The petition will be published on March 18, 2019, in the Virginia Register of Regulations and also posted on the Virginia Regulatory Town Hall at www.townhall.virginia.gov to receive public comment ending April 17, 2019. Following receipt of all comments on the petition to amend regulations, the board will decide whether to make any changes to the regulatory language. This matter will be on the board's agenda for its first meeting after the public comment period, which will be on a date in July yet to be determined.

Public Comment Deadline: April 17, 2019.

Agency Contact: Elaine J. Yeatts, Regulatory Coordinator, Department of Health Professions, 9960 Mayland Drive, Suite 300, Richmond, VA 23233, telephone (804) 367-4688, or email elaine.yeatts@dhp.virginia.gov.

VA.R. Doc. No. R19-29; Filed February 26, 2019, 9:43 a.m.

BOARD OF NURSING

Initial Agency Notice

Title of Regulation: **18VAC90-19. Regulations Governing the Practice of Nursing.**

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

Name of Petitioner: Linda Thurby-Hay.

Nature of Petitioner's Request: To revise all regulations relating to the registration and practice of clinical nurse specialists.

Agency Plan for Disposition of Request: In accordance with Virginia law, the petition will be published on March 18, 2019, in the Virginia Register of Regulations and also posted on the Virginia Regulatory Town Hall at www.townhall.virginia.gov to receive public comment ending April 17, 2019. Following receipt of all comments on the petition to amend regulations, the board will decide whether to make any changes to the regulatory language. This matter will be on the board's agenda for its first meeting after the public comment period, which is scheduled for May 21, 2019.

Public Comment Deadline: April 17, 2019.

Agency Contact: Elaine J. Yeatts, Regulatory Coordinator, Department of Health Professions, 9960 Mayland Drive, Suite 300, Richmond, VA 23233, telephone (804) 367-4688, or email elaine.yeatts@dhp.virginia.gov.

VA.R. Doc. No. R19-28; Filed February 26, 2019, 4:15 p.m.

BOARD OF PHYSICAL THERAPY

Agency Decision

Title of Regulation: **18VAC112-20. Regulations Governing the Practice of Physical Therapy.**

Statutory Authority: §§ 54.1-2400 and 54.1-3474 of the Code of Virginia.

Name of Petitioner: Rosemarie Curley.

Nature of Petitioner's Request: To add the National Strength and Conditioning Association (NSCA) to the list of organizations approved as continuing education providers.

Agency Decision: Request granted.

Statement of Reason for Decision: At the board meeting on February 19, 2019, the board voted to refer the matter to the Legislative/Regulatory Committee for further review and to include the possible amendment in the Notice of Intended Regulatory Action that will be published pursuant to a periodic review of 18VAC112-20, Regulations Governing the Practice of Physical Therapy.

Agency Contact: Elaine J. Yeatts, Regulatory Coordinator, Department of Health Professions, 9960 Mayland Drive, Suite 300, Richmond, VA 23233, telephone (804) 367-4688, or email elaine.yeatts@dhp.virginia.gov.

VA.R. Doc. No. R19-14; Filed February 20, 2019, 10:16 a.m.

TITLE 24. TRANSPORTATION AND MOTOR VEHICLES

COMMISSION ON THE VIRGINIA ALCOHOL SAFETY ACTION PROGRAM

Initial Agency Notice

Title of Regulation: **24VAC35-60. Ignition Interlock Regulations.**

Statutory Authority: § 18.2-270.2 of the Code of Virginia.

Name of Petitioner: Cynthia Ellen Hites.

Nature of Petitioner's Request: "I, Cynthia Ellen Hites, as a citizen of the Commonwealth of Virginia, pursuant to § 2.2-4007 of the Code of Virginia, do humbly submit this petition for the following amendment of Virginia Administrative Code 24VAC35-60-50. Currently, Virginia statute 24VAC35-60-50 D, 9 reads: 'D. Service providers may charge offenders for ignition interlock services at rates up to, but not to exceed, the following:... 9. $50 for violation resets, when the violation is determined to be the fault of the offender.' As the law exists, in the event of 'mouth alcohol,' machine malfunction, or one of the host of non-ethanol readings expected by interlock companies for compounds in personal hygiene products, ignition interlock providers can withhold citizens' ability to utilize their personal vehicle until they provide the interlock company $50. This is tantamount to extortion. Until all evidence can be considered in a court of law, a violation cannot be determined. Due to this fact, a violation reset fee cannot be collected until a 'violation' can be determined by a judge. I propose that 24VAC35-60-50, within section D, #9, which allows a $50 reset fee to be collected by ignition interlock providers, be removed in its entirety. Currently, ASAP case managers are precluded from considering or accepting any evidence aside from the devices' failed readings. Employing circular logic, Section IV of the VASAP Process and Procedures Manual states: 'Under no circumstances shall the ASAP accept any other means of clearing a failing BAC registered on an interlock device other than the device itself. This includes, but is not limited to preliminary breath test machines, urine screens, etc...' When a petition was filed in 2018 to allow case managers to consider additional evidence when citing a violation, VASAP's Richard Foy responded with the following statements: 'The petitioner is suggesting that ASAP case managers...accept and consider additional evidence submitted by the client to include such things as urine screens, blood tests, preliminary breath tests, and police or other eyewitness testimony. All of that is to be considered prior to determining whether an ignition interlock violation occurred. Doing this would raise some questions and concerns. That's something the court would consider, and VASAP is not going to be comfortable in considering those results because it tends to put us in a judicial role. We believe any additional information...would be best presented to the court in a non-compliance hearing...' Ignition interlock machines use inherently non-ethanol specific electrochemical fuel cell technology. This means an ethanol violation may be suspected by a case manager, but all evidence must be considered to determine an ethanol violation, and only a judge can make that determination upon preponderance of the evidence. Commissioners, please amend this statute and remove #9 from 24VAC35-60-50, section D. It's wholly unfair to charge Virginians a 'violation' reset fee prior to conviction. Very Sincerely, Cynthia Hites."

Agency Plan for Disposition of Request: The Commission on Virginia Alcohol Safety Action Program will consider this petition at its quarterly meeting on September 13, 2019.

Public Comment Deadline: June 28, 2019.

Agency Contact: Richard Foy, Regulatory Coordinator, Commission on the Virginia Alcohol Safety Action Program, 701 East Franklin Street, Suite 1110, Richmond, VA 23219, telephone (804) 786-5895, or email rfoy@vasap.virginia.gov.

VA.R. Doc. No. R19-27; Filed February 15, 2019, 11:59 a.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.

Title of Regulation: **4VAC20-620. Pertaining to Summer Flounder (amending 4VAC20-620-40).**

Statutory Authority: § 28.2-201 of the Code of Virginia.

Effective Date: March 1, 2019.

Agency Contact: Jennifer Farmer, Regulatory Coordinator, Marine Resources Commission, 2600 Washington Avenue, 3rd Floor, Newport News, VA 23607, telephone (757) 247-2248 or email jennifer.farmer@mrc.virginia.gov.

Summary:

For summer flounder commercially harvested offshore (federal waters) and landed in Virginia, the amendments set the landing dates as March 1 through April 19 and the possession and landing limits as 10,000 pounds.

4VAC20-620-40. Commercial vessel possession and landing limitations.

A. It shall be unlawful for any person harvesting summer flounder outside of Virginia's waters to do any of the following, except as described in subsections B, C, D, and E of this section:

1. Possess aboard any vessel in Virginia waters any amount of summer flounder in excess of 10% by weight of Atlantic croaker or the combined landings, on board a vessel, of black sea bass, scup, squid, scallops and Atlantic mackerel.

2. Possess aboard any vessel in Virginia waters any amount of summer flounder in excess of 1,500 pounds landed in combination with Atlantic croaker.

3. Fail to sell the vessel's entire harvest of all species at the point of landing.

B. Nothing in this chapter shall preclude a vessel from possessing any North Carolina or New Jersey vessel possession limit of summer flounder in Virginia; however, no vessel that possesses the North Carolina or New Jersey vessel possession limit of summer flounder shall offload any amount of that possession limit, except as described in subsection J of this section.

C. From March 1 through April ~~30~~ 19, it shall be unlawful for any person harvesting summer flounder outside of Virginia waters to do any of the following:

1. Possess aboard any vessel in Virginia waters any amount of summer flounder in excess of the combined total of the Virginia landing limit described in subdivision 2 of this subsection and the amount of the legal North Carolina or New Jersey landing limit or trip limit.

2. Land in Virginia more than a total of ~~7,500~~ 10,000 pounds of summer flounder.

3. Land in Virginia any amount of summer flounder more than once in any consecutive five-day period.

D. From October 16 through December 31, it shall be unlawful for any person harvesting summer flounder outside of Virginia waters to do any of the following:

1. Possess aboard any vessel in Virginia waters any amount of summer flounder in excess of the combined total of the Virginia landing limit described in subdivision 2 of this subsection and the amount of the legal North Carolina or New Jersey landing limit or trip limit.

2. Land in Virginia more than a total of 7,000 pounds of summer flounder.

3. Land in Virginia any amount of summer flounder more than once in any consecutive five-day period.

E. From January 1 through December 31, any boat or vessel issued a valid federal summer flounder moratorium permit and owned and operated by a legal Virginia Commercial Hook-and-Line Licensee that possesses a Restricted Summer Flounder Endorsement shall be restricted to a possession and landing limit of 200 pounds of summer flounder, except as described in 4VAC20-620-30 F.

F. Upon request by a marine police officer, the seafood buyer or processor shall offload and accurately determine the total weight of all summer flounder aboard any vessel landing summer flounder in Virginia.

G. Any possession limit described in this section shall be determined by the weight in pounds of summer flounder as customarily packed, boxed and weighed by the seafood buyer or processor. The weight of any summer flounder in pounds found in excess of any possession limit described in this

section shall be prima facie evidence of violation of this chapter. Persons in possession of summer flounder aboard any vessel in excess of the possession limit shall be in violation of this chapter unless that vessel has requested and been granted safe harbor. Any buyer or processor offloading or accepting any quantity of summer flounder from any vessel in excess of the possession limit shall be in violation of this chapter, except as described by subsection J of this section. A buyer or processor may accept or buy summer flounder from a vessel that has secured safe harbor, provided that vessel has satisfied the requirements described in subsection J of this section.

H. If a person violates the possession limits described in this section, the entire amount of summer flounder in that person's possession shall be confiscated. Any confiscated summer flounder shall be considered as a removal from the appropriate commercial harvest or landings quota. Upon confiscation, the marine police officer shall inventory the confiscated summer flounder and, at a minimum, secure two bids for purchase of the confiscated summer flounder from approved and licensed seafood buyers. The confiscated fish will be sold to the highest bidder, and all funds derived from such sale shall be deposited for the Commonwealth pending court resolution of the charge of violating the possession limits established by this chapter. All of the collected funds will be returned to the accused upon a finding of innocence or forfeited to the Commonwealth upon a finding of guilty.

I. It shall be unlawful for a licensed seafood buyer or federally permitted seafood buyer to fail to contact the Marine Resources Commission Operation Station prior to a vessel offloading summer flounder harvested outside of Virginia. The buyer shall provide to the Marine Resources Commission the name of the vessel, its captain, an estimate of the amount in pounds of summer flounder on board that vessel, and the anticipated or approximate offloading time. Once offloading of any vessel is complete and the weight of the landed summer flounder has been determined, the buyer shall contact the Marine Resources Commission Operations Station and report the vessel name and corresponding weight of summer flounder landed. It shall be unlawful for any person to offload from a boat or vessel for commercial purposes any summer flounder during the period of 9 p.m. to 7 a.m.

J. Any boat or vessel that has entered Virginia waters for safe harbor shall only offload summer flounder when the state that licenses that vessel requests to transfer quota to Virginia, in the amount that corresponds to that vessel's possession limit, and the commissioner agrees to accept that transfer of quota.

K. After any commercial harvest or landing quota as described in 4VAC20-620-30 has been attained and announced as such, any boat or vessel possessing summer flounder on board may enter Virginia waters for safe harbor but shall contact the Marine Resources Commission Operation Center in advance of such entry into Virginia waters.

L. It shall be unlawful for any person harvesting summer flounder outside of Virginia waters to possess aboard any vessel, in Virginia, any amount of summer flounder, once it has been projected and announced that 100% of the quota described in 4VAC20-620-30 A has been taken.

VA.R. Doc. No. R19-5849; Filed February 27, 2019, 1:54 p.m.

TITLE 9. ENVIRONMENT

VIRGINIA WASTE MANAGEMENT BOARD

Final Regulation

REGISTRAR'S NOTICE: The Virginia Waste Management Board is claiming an exemption from Article 2 of the Administrative Process Act in accordance with § 2.2-4006 A 3, which excludes regulations that consist only of changes in style or form or corrections of technical errors. The board will receive, consider, and respond to petitions by any interested person at any time with respect to reconsideration or revision.

Title of Regulation: **9VAC20-90. Solid Waste Management Permit Action Fees and Annual Fees (amending 9VAC20-90-40).**

Statutory Authority: §§ 10.1-1402 and 10.1-1402.1 of the Code of Virginia.

Effective Date: April 17, 2019.

Agency Contact: Melissa Porterfield, Department of Environmental Quality, 1111 East Main Street, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4238, FAX (804) 698-4019, or email melissa.porterfield@deq.virginia.gov.

Summary:

The amendment corrects a citation to the Virginia Waste Management Act.

9VAC20-90-40. Administration of regulation.

A. The Virginia Waste Management Board promulgates and enforces regulations that it deems necessary to carry out its powers and duties.

B. The director is authorized and directed to administer these regulations in accordance with the Virginia Waste Management Act, §§ 10.1-1400 through ~~10.1-1457~~ 10.1-1458 of the Code of Virginia.

VA.R. Doc. No. R19-5537; Filed February 20, 2019, 8:01 a.m.

TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF PHARMACY

Proposed Regulation

Title of Regulation: **18VAC110-60. Regulations Governing Pharmaceutical Processors (adding 18VAC110-60-10 through 18VAC110-60-330).**

Statutory Authority: §§ 54.1-3442.6 and 54.1-3447 of the Code of Virginia.

Public Hearing Information:

March 26, 2019 - 9:10 a.m. - Department of Health Professions, Perimeter Center, 9960 Mayland Drive, 2nd floor, Board Room 2, Richmond, VA 23233

Public Comment Deadline: May 17, 2019.

Agency Contact: Caroline Juran, RPh, Executive Director, Board of Pharmacy, 9960 Mayland Drive, Suite 300, Richmond, VA 23233, telephone (804) 367-4456, FAX (804) 527-4472, or email caroline.juran@dhp.virginia.gov.

Basis: Section 54.1-3408.3 of the Code of Virginia states that the board shall promulgate regulations to implement the registration process for practitioners and patients. The regulations shall include (i) a mechanism for sufficiently identifying the practitioner issuing the written certification, the patient being treated by the practitioner, and, if such patient is a minor or an incapacitated adult as defined in § 18.2-369 of the Code of Virginia, the patient's parent or legal guardian; (ii) a process for ensuring that any changes in the information are reported in an appropriate timeframe; and (iii) a prohibition for the patient to be issued a written certification by more than one practitioner during any given time period.

Section 54.1-3442.6 A of the Code of Virginia states that the board shall establish an application fee and other general requirements for such application, and § 54.1-3442.6 B states that each permit shall expire annually on a date determined by the board in regulation. Section 54.1-3442.6 C states that the board shall adopt regulations establishing health, safety, and security requirements for pharmaceutical processors. The regulations shall include requirements for (i) physical standards; (ii) location restrictions; (iii) security systems and controls; (iv) minimum equipment and resources; (v) recordkeeping; (vi) labeling and packaging; (vii) quarterly inspections; (viii) processes for safely and securely cultivating Cannabis plants intended for producing cannabidiol oil and THC-A oil, for producing cannabidiol oil and THC-A oil, and for dispensing and delivering in person cannabidiol oil and THC-A oil to a registered patient or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian; (ix) a maximum number of marijuana plants a pharmaceutical processor may possess at any one time; (x) the secure disposal of plant remains; and (xi) a process for registering a cannabidiol oil and THC-A oil product. Section 54.1-3442.6 E states that the board shall require an applicant for a pharmaceutical processor permit to submit to fingerprinting and provide personal descriptive information to be forwarded along with his fingerprints through the Central Criminal Records Exchange to the Federal Bureau of Investigation for the purpose of obtaining criminal history record information regarding the applicant.

Section 54.1-3442.7 A of the Code of Virginia states that the board shall establish in regulation an amount of cannabidiol oil or THC-A oil that constitutes a 90-day supply to treat or alleviate the symptoms of a patient's diagnosed condition or disease.

Purpose: The purpose of the proposed regulatory action is compliance with Chapter 577 of the 2016 Acts of Assembly and with Chapters 246 and 809 and Chapter 567 of the 2018 Acts of Assembly, which mandated the adoption of regulations to implement the acts. The goals of the proposed regulation are accessibility of cannabidiol oil or THC-A oil for patients with any disease or condition diagnosed by a physician licensed in the Commonwealth in compliance with the conditions and restraints imposed by the statute and in consideration of the need for security of the facility and its contents and the integrity of the dispensed product.

Section 54.1-3442.6 C of the Code of Virginia requires the board to "adopt regulations establishing health, safety, and security requirements for pharmaceutical processors." The safeguards put in place in statute and regulation are essential to protect the health and safety of the general public and, in particular, the health of the patients to whom cannabidiol oil or THC-A oil is dispensed.

Substance: The proposed regulation sets out the requirements for issuance of permits to pharmaceutical processors for the cultivation, production, and dispensing of cannabidiol oil or THC-A oil. Regulations also establish requirements for registrations of physicians for writing certification to registered patients, parents, or legal guardians for possession of such oils. The proposed new chapter contains six parts, as follows:

Part I establishes definitions and fees to be charged to applicants, registrants, and permitted processors.

Part II, as specified in the legislation, establishes requirements for the issuance or denial of registration for certifying physicians, patients, parents, or legal guardians.

Part III sets out the application and approval process for issuing a permit to a pharmaceutical processor, including the information that must be submitted, the requirements for issuing conditional and then final approval, the rules for notification to the board of any changes or of closure of the processor, and the causes for action against a processor.

Part IV sets out the provisions for personnel at the pharmaceutical processor, including a requirement that a pharmacist with a current, unrestricted Virginia license provide personal supervision on the premises at all times during hours of operation or whenever the processor is accessed. It includes requirements for employee training, supervision of pharmacy technicians, and the responsibilities of the pharmacist-in-charge.

Part V sets out provisions for the operation of a pharmaceutical processor, including requirements for inventory, security, storage and handling, recordkeeping, and reportable events.

Part VI establishes requirements for the cultivation, production, and dispensing of cannabidiol oil, including labeling, laboratory and testing standards, handling dispensing errors and quality assurance, and proper disposal.

Issues: The advantages to the public include assurance of the safety and integrity of the product dispensed and security for the Cannabis and oils produced; there are no disadvantages to the public.

The advantage to the agency is more clarity in the rules for a permitted facility; there are no disadvantages to the agency.

This is a significant new program for the Board of Pharmacy and the Department of Health Professions in an evolving environment of medical marijuana with wide variance in the policies and models adopted across the United States and in a situation in which marijuana remains an illegal substance on the federal level.

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. Pursuant to 2016[1] and 2018[2] legislation, the Board of Pharmacy (Board) proposes to establish a permanent regulation to replace an emergency regulation governing the cultivation of cannabis for production and sale of cannabidiol (CBD) oil and Tetrahydrocannabinolic acid (THC-A) oil.

Result of Analysis. The benefits likely exceed the costs for all proposed changes. A different design would likely yield improved economic results for at least one proposed change.

Estimated Economic Impact. Legislation enacted in 2016 required the Board to promulgate regulations addressing CBD oil and THC-A oil, including registration by the Board of practitioners and patients, and the issuance by the Board of permits for pharmaceutical processors to manufacture and provide these oils for the treatment of intractable epilepsy.[3] The statute authorized only neurologists and doctors that specialize in treatment of epilepsy to issue written certificates for obtaining these oils.

CBD and THC-A are the two primary cannabinoids that occur naturally in the Cannabis sativa plant, most commonly known as cannabis. Both of these substances interact with the cannabinoid receptors found in the human body and brain, and both are minimally psychoactive, which means that they do not have an intoxicating effect.[4] While either CBD or THC-A can provide relief from some of the same medical conditions, for some other medical conditions one may be better suited than the other. CBD and THC-A oils are normally administered orally, sublingually via an oral syringe, or in a capsule, but it is possible to inhale via vaping or a nebulizer.

Pursuant to 2016 legislation, the Board established emergency regulations that became effective August 7, 2017.[5] Later, 2018 legislation required the Board to amend its emergency regulations to allow any doctor of medicine or osteopathy to recommend the oils for any diagnosed condition or disease that the doctor believes would benefit from their use. The 2018 legislation also made numerous other amendments to the original statute and required the Board to promulgate additional regulations for other aspects of CBD and THC-A oil production and sale.[6]

Consequently, the Board proposes to establish a permanent comprehensive regulation governing all aspects of these oils (e.g., application; issuance, denial, revocation, suspension of licenses and certifications, their duration, and fees; cultivation; production; packaging; labeling; testing; distribution; dispensing; storage; disposal; safekeeping; reporting; recordkeeping; training; prohibited practices; etc.) for processors, doctors, employees involved, and patients or their legal guardians.

The enabling legislation limits the number of permits the Board may issue to "one for each health service area [HSA] established by the Board of Health." Currently there are five HSAs statewide; each HSA covers nine, 26, 27, 32, and 41 localities, respectively.

Pursuant to the emergency regulations, the Board received 51 applications along with a $10,000 fee per application, and issued five permits. These five entities will (per the regulation) pay an initial permit fee of $60,000 and pay an annual renewal fee of $10,000 for each permit. These and other fees would be used to cover the Board's expenses to evaluate applications, issue permits and certificates, conduct inspections, take actions for violations, etc.[7]

Currently, processors are setting up their operations, and CBD and THC-A oils have not yet been sold; the Board expects sales to start sometime in 2019. Statute limits each registered patient to no more than a 90-day supply of CBD or THC-A oil in a 90-day period and states that "prior to the initial dispensing" of oil pursuant to each written certification, the patient, parent, or legal guardian must present their certification and a current photo identification "at the location of the pharmaceutical processor." Pursuant to § 54.1-3408.3, each such certification expires after one year.

The five processors will be the only entities authorized to produce and sell CBD and THC-A oils in their assigned HSA. The news media have reported on the locations of four of the five permitted processors, indicating facilities will be opened in Bristol, Staunton, Richmond, and Manassas; the location in the Hampton Roads-based HSA does not appear to be available.[8] According to board staff, registered patients are not restricted to purchasing oils only in their HSA, and may purchase from any processor in the Commonwealth. As a result, it appears that a patient may purchase from the closest processor, regardless of which HSA they reside in. However, the patient must physically present their photo identification and the renewed certificate annually at the location of each processor they choose to purchase from.

Estimated Economic Impact on Processors:

Under the proposed regulatory design, an economic benefit would accrue to the processors. Even though they would incur costs associated with fees, setting up initial operations, and compliance with health, safety, and security requirements, they would apply for a permit only if they expect benefits would exceed the costs. In fact, because there is very limited competition and no price controls contemplated in the regulation, the permitted processors have the flexibility to set prices to ensure a certain level of revenues. Therefore, the proposed regulation should provide a net benefit to processors.

Under the proposed regulatory design, the only apparent factor that would work to keep prices under control in a given HSA is the option for patients to buy oils from processors in other HSAs. However, depending on the distance patients must travel to the next-closest processor, the transportation costs (including charges associated with use of an authorized delivery agent) may offset any potential savings available from the lower prices offered by another processor. Any such potential savings may be further reduced given the statutory requirements that the maximum amount that can be dispensed (and purchased) at one time is a 90-day supply, and that a patient must present documentation "at the location of the pharmaceutical processor" once each year.

Within the proposed regulation, other factors that may minimize the potential for market competition that could lead to lower prices include the mechanism whereby the incumbent processors may renew their permits annually, for an indefinite period of time, as long as they comply with the regulation. In addition, under the current statutory framework no more than five processors statewide may be permitted. In combination, these factors impact the opportunity for prices to be lowered through competitive forces by limiting the number of new firms that could enter the market.

Estimated Economic Impact on Patients:

The proposed regulation would benefit all patients by allowing them to legally purchase CBD or THC-A oil in the Commonwealth. The Board has issued registration cards to 283 patients so far, even though no CBD or THC-A oil is available for sale, and proposes to establish certain fees for patients.[9] Although the legal access to CBD or THC-A oil is the main benefit, some patients may also have peace of mind from carrying a registration card which may help them avoid potential legal issues that may otherwise result from possession of these oils. Because only those patients who value the access to these oils more than the cost of the fees would obtain a registration card, we can reliably infer that the benefits of registration would exceed the cost of registration for these patients.

However, the ability of some patients to benefit from legal use of these oils, especially patients with lower incomes, may be somewhat limited if prices are higher than would otherwise exist if the market consisted of more than five processors. In addition, the distance between patient's location and the location of the nearest processor may be a limiting factor for their access to the oils, as the patients would have to absorb travel time and costs to purchase the oils or pay a delivery fee. Because the legislation only allows purchases to occur in five locations, it would not be uncommon for many patients to travel more than few hours to get to the nearest processor. Thus, travel costs or delivery fees would add to the price of oils and may limit patient access.

Estimated Economic Impact on Practitioners:

Similar to the patients, doctors who decide to obtain registration to recommend CBD or THC-A oil indicate that the benefits of doing so exceed the costs for them. The main benefits to the registered doctors are the potential to expand their customer base through patients who would benefit from these oils, as well as providing more effective treatment for current patients. The proposed regulation limits the number of such patients a doctor may treat to 600 at any given time, but allows the doctor to petition the Board for a higher limit. The proposed regulation also establishes a $50 fee for initial registration, a $50 fee for annual renewal, and $50 for replacement certificate to recommend the oils. According to DHP, there are 230 registered doctors.

Other Estimated Economic Impacts:

The issuance of certificates and permits to patients, doctors, and processors and enforcement of the proposed rules would require additional staff time for the Department of Health Professions (DHP). DHP has already dedicated two employees on a part-time basis to meet the current workload demands, and anticipates that three more full-time positions would be needed once the oils are offered for sale. The funding source for the four positions will be the fees collected.

The five localities where the processors will be operating would see a positive impact from this regulation as the processors hire new employees to grow and process the plant

and get the final products ready for sale. However, the five localities may also have to deal with attempts to steal these oils or the cannabis plants from the processors or their delivery agents.

Finally, the proposed regulation is expected to reduce crime. The enabling legislation made what used to be a misdemeanor crime a lawful activity, and made the certificate from the Board an affirmative defense against any misdemeanor charge the patient may face for possession of CBD and THC-A oils. As a result, the number of misdemeanor charges and convictions for possession of these oils should decline. A decline in crime would free up the resources required for enforcement, prosecution, and incarceration of a number of cases and reduce the burden on the criminal justice system.

Alternative Regulatory Designs:

As discussed above, the proposed regulation would produce a net benefit to processors, patients, and doctors. However, statutory limitations on the number of processors, plus the impact of transportation and other costs, could limit the ability of some patients to benefit from the lower prices that would likely exist in a more competitive market. If changes to this statutory framework were made, alternative regulatory designs could be pursued that could potentially allow patients to more fully realize the benefits resulting from this regulation. These alternatives include either increasing the number of processors, or limiting the number of annual renewals, in order to allow additional processors to enter the market. If either course was chosen, the Board could then request new proposals with a lowest price guarantee (e.g., per ounce of the oils) for the duration of the permit, or with higher permit fees. These alternatives could increase the net benefits to patients by lowering prices or providing revenues that could be used to support compassionate need programs.

Businesses and Entities Affected. This regulation applies to CBD and THC-A oil processors, patients, and doctors. Currently, there are five processors with conditional approval, 283 registered patients, and 230 registered doctors. The number of registered patients and doctors would likely significantly increase when the processors actually start selling CBD or THC-A oil.[10]

Localities Particularly Affected. The proposed regulation would disproportionately affect the five particular localities where the processors are operating. These affected localities would likely see an increase in economic activity stemming from increased employment and business activity by the processors. However, there may also be instances of theft at the processor facilities or from the processor's delivery agents.

Projected Impact on Employment. The proposed regulation would have a positive impact on employment, particularly in the areas where processors operate.

Effects on the Use and Value of Private Property. The proposed regulation would have a large positive impact on the asset value of processors as a result of the potential perpetual price setting power they are granted.

Real Estate Development Costs. Except for potential impacts, near the location of the five processors the proposed amendments would not directly affect real estate development costs.

Small Businesses:

Definition. Pursuant to § 2.2-4007.04 of the Code of Virginia, 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."

Costs and Other Effects. The proposed amendments would not impose costs on small businesses. Whether any of the processors would qualify as a small business is not known. If they would qualify as small businesses, the other effects on them would be the same as the impact on processors described above.

Alternative Method that Minimizes Adverse Impact. The proposed regulation does not impose adverse impacts on small businesses.

Adverse Impacts:

Businesses. The proposed regulation does not impose adverse impacts on businesses.

Localities. The proposed regulation may adversely affect particular localities in terms of the increased risk of theft at the processor facilities or from the processor's delivery agents.

Other Entities. The proposed regulation does not impose adverse impacts on other entities.

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[1]http://lis.virginia.gov/cgi-bin/legp604.exe?161+ful+CHAP0577

[2]http://lis.virginia.gov/cgi-bin/legp604.exe?181+ful+CHAP0246 & http://lis.virginia.gov/cgi-bin/legp604.exe?181+ful+CHAP0567

[3]In the statute, cannabidiol oil is defined as processed Cannabis plant extract that contains at least 15 percent cannabidiol but no more than five percent tetrahydrocannabinol, or a dilution of the resin of the Cannabis plant that contains at least 50 milligrams of cannabidiol per milliliter but not more than five percent tetrahydrocannabinol; and THC-A oil is defined as processed Cannabis plant extract that contains at least 15 percent tetrahydrocannabinol acid but not more than five percent tetrahydrocannabinol, or a dilution of the resin of the Cannabis plant that contains at least 50 milligrams of tetrahydrocannabinol acid per milliliter but not more than five percent tetrahydrocannabinol.

[4]National Academies of Sciences, Engineering, and Medicine, The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and Recommendations for Research. National Academies Press (US); January 12, 2017.

[5]http://townhall.virginia.gov/l/ViewStage.cfm?stageid=7740

[6]http://lis.virginia.gov/cgi-bin/legp604.exe?181+ful+CHAP0567

[7]In addition to these permit and renewal fees, the proposed regulation establishes other fees: $100 for change of a processor name or of any other information provided on the application; $1,000 for any acquisition, expansion, remodel, change of location; $1,000 for re-inspection; and $25 for registration of each CBD or THC-A oil product.

[8]Richmond Times-Dispatch, Virginia regulators pick five companies to open state's first medical cannabis dispensaries, September 25, 2018.

[9]The board proposes to establish a $50 fee for initial registration of a patient, a $50 fee for annual renewal, a $25 fee for initial registration of a parent or guardian (in the emergency regulation, this fee was $50), a $25 fee for renewal of parent or guardian registration, and a $25 fee for replacement of lost, stolen, destroyed certificates.

[10]According to a presentation made to the Board on July 1, 2016, 1% of the population have epilepsy and 1/3 of this population do not respond to currently approved drug therapy, which translates to 27,000 Virginians. Source: http://townhall.virginia.gov/l/GetFile.cfm?File=meeting\30\24620\Minutes_DHP_24620_v3.pdf

Agency's Response to Economic Impact Analysis: The Board of Pharmacy concurs with the analysis of the Department of Planning and Budget.

Summary:

Pursuant to Chapter 577 of the 2016 Acts of Assembly, Chapter 613 of the 2017 Acts of Assembly, and Chapters 246 and 809 and Chapter 567 of the 2018 Acts of Assembly, the Board of Pharmacy is promulgating a new chapter, 18VAC110-60, governing the registration process for a patient who has been issued a written certification for the use of cannabidiol oil or THC-A oil and the issuance of a permit for a pharmaceutical processor to manufacture and provide cannabidiol oil and THC-A oil to a registered patient. The proposed chapter sets out the requirements for issuance of permits to pharmaceutical processors for the cultivation, production, and dispensing of cannabidiol oil or THC-A oil and establishes requirements for registrations of physicians for writing certification to registered patients, parents, or legal guardians for possession of such oils.

The proposed chapter establishes (i) definitions and fees to be charged to applicants, registrants, and permitted processors; (ii) as specified in the legislation, requirements for issuance or denial of registration for certifying physicians, patients, parents, or legal guardians; (iii) the application and approval process for issuing a permit to a pharmaceutical processor, including the information that must be submitted, the requirements for issuing conditional and then final approval, the rules for notification to the board of any changes or of closure of the processor, and the causes for action against a processor; (iv) provisions for personnel at the pharmaceutical processor, including a requirement that a pharmacist with a current, unrestricted Virginia license provide personal supervision on the premises at all times during hours of operation or whenever the processor is accessed and requirements for employee training and supervision of pharmacy technicians and responsibilities of the pharmacist-in-charge; (v) provisions for the operation of a pharmaceutical processor, including requirements for inventory, security, storage and handling, recordkeeping, and reportable events; and (vi) requirements for the cultivation, production, and dispensing of cannabidiol oil or THC-A oil, including labeling, laboratory and testing standards, handling dispensing errors, quality assurance, and proper disposal.

CHAPTER 60
REGULATIONS GOVERNING PHARMACEUTICAL PROCESSORS

Part I
General Provisions

18VAC110-60-10. Definitions.

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

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

"Board" means the Board of Pharmacy.

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

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

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

a. Incorrect oil;

b. Incorrect oil strength;

c. Incorrect dosage form;

d. Incorrect patient; or

e. Inadequate or incorrect packaging, labeling, or directions.

2. Failure to exercise professional judgment in identifying and managing:

a. Known therapeutic duplication;

b. Known drug-disease contraindications;

c. Known drug-drug interactions;

d. Incorrect drug dosage or duration of drug treatment;

e. Known drug-allergy interactions;

f. A clinically significant, avoidable delay in therapy; or

g. Any other significant, actual, or potential problem with a patient's drug therapy.

3. Delivery of an oil to the incorrect patient.

4. An act or omission relating to the dispensing of cannabidiol oil or THC-A oil that results in, or may reasonably be expected to result in, injury to or death of a registered patient or results in any detrimental change to the medical treatment for the patient.

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

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

"PIC" means the pharmacist-in-charge.

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

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

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

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

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

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

Room or Phase	Temperature	Humidity
Mother room	65 - 75°	50% - 60%
Nursery phase	71 - 85° F	65% - 75%
Vegetation phase	71 - 85° F	55% - 65%
Flower/harvest phase	71 - 85° F	55% - 60%
Drying/extraction rooms	< 75° F	55% - 60%

18VAC110-60-20. Fees.

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

B. Registration of practitioner.

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

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

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

D. Pharmaceutical processor permit.

1. Application.	$10,000
2. Initial permit.	$60,000
3. Annual renewal of permit.	$10,000
4. Change of name of processor.	$100
5. Change of PIC or any other information provided on the permit application.	$100
6. Any acquisition, expansion, remodel, or change of location requiring an inspection.	$1,000
7. Reinspection fee.	$1,000
8. Registration of each cannabidiol oil or THC-A oil product.	$25

Part II
Requirements for Practitioners and Patients

18VAC110-60-30. Requirements for a practitioner issuing a certification.

A. Prior to issuing a certification for cannabidiol oil or THC-A oil for any diagnosed condition or disease, the practitioner shall meet the requirements of § 54.1-3408.3 of the Code of Virginia, shall submit an application and fee as prescribed in 18VAC110-60-20, and shall be registered with the board.

B. A practitioner issuing a certification shall:

1. Conduct an assessment and evaluation of the patient in order to develop a treatment plan for the patient, which shall include an examination of the patient and the patient's medical history, prescription history, and current medical condition, including an in-person physical examination;

2. Diagnose the patient;

3. Be of the opinion that the potential benefits of cannabidiol oil or THC-A oil would likely outweigh the health risks of such use to the qualifying patient;

4. Explain proper administration and the potential risks and benefits of the cannabidiol oil or THC-A oil to the qualifying patient and, if the qualifying patient lacks legal capacity, to a parent or legal guardian prior to issuing the written certification;

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

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

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

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

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

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

F. A practitioner shall not issue certifications for cannabidiol oil or THC-A oil to more than 600 patients at any given time. However, the practitioner may petition the Board of Pharmacy and Board of Medicine for an increased number of patients for whom certifications may be issued, upon submission of evidence that the limitation represents potential patient harm.

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

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

A. A practitioner who issues certifications shall not:

1. Directly or indirectly accept, solicit, or receive anything of value from any person associated with a pharmaceutical processor or provider of paraphernalia, excluding information on products or educational materials on the benefits and risks of cannabidiol oil or THC-A oil;

2. Offer a discount or any other thing of value to a qualifying patient, parent, or guardian based on the patient's agreement or decision to use a particular

pharmaceutical processor or cannabidiol oil or THC-A oil product;

3. Examine a qualifying patient for purposes of diagnosing the condition or disease at a location where cannabidiol oil or THC-A oil is dispensed or produced; or

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

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

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

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

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

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

1. A copy of the certification issued by a registered practitioner;

2. Proof of residency of the qualifying patient and proof of residency of a parent or legal guardian, if applicable, such as a government-issued identification card or tax receipt;

3. Proof of identity of the qualifying patient and, if the patient is a minor, proof of identity of the parent or legal guardian in the form of a government-issued identification card;

4. Proof of the qualifying patient's age in the form of a birth certificate or other government-issued identification;

5. Payment of the appropriate fees; and

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

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

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

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

A. The board may deny an application or renewal of the registration of a qualifying patient, parent, or legal guardian if the applicant:

1. Does not meet the requirements set forth in law or regulation or fails to provide complete information on the application form;

2. Does not provide acceptable proof of identity, residency, or age of the patient to the board;

3. Provides false, misleading, or incorrect information to the board;

4. Has had a qualifying registration of a qualifying patient, parent, or legal guardian denied, suspended, or revoked by the board in the previous six months;

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

6. Has a prior conviction of a violation of any law pertaining to controlled substances.

B. If the board denies an application or renewal of a qualifying patient, parent, or legal guardian applicant, the board shall provide the applicant with notice of the grounds for the denial and shall inform the applicant of the right to request a hearing pursuant to § 2.2-4019 of the Code of Virginia.

18VAC110-60-70. Reporting requirements for practitioners, patients, parents, or legal guardians.

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

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

certifying practitioner. The patient, parent, or legal guardian shall report such changes on a form prescribed by the board.

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

D. If a patient, parent, or legal guardian becomes aware of the loss, theft, or destruction of the registration of such patient, parent, or legal guardian, the patient, parent, or legal guardian 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 inactivate the initial registration upon receiving such notice and issue a replacement registration upon receiving the applicable fee, provided the applicant continues to satisfy the requirements of law and regulation.

18VAC110-60-80. Proper storage and disposal of cannabidiol oil or THC-A oil by patients, parents, or legal guardians.

A. A registered patient, parent, or legal guardian shall exercise reasonable caution to store cannabidiol oil or THC-A oil in a manner to prevent theft, loss, or access by unauthorized persons.

B. A registered patient, parent, or legal guardian shall dispose of all usable cannabidiol oil or THC-A oil in the registered patient, parent, or legal guardian's possession no later than 10 calendar days after the expiration of the patient's registration if such registration is not renewed, or sooner should the patient no longer wish to possess cannabidiol oil or THC-A oil. A registered patient, parent, or legal guardian shall complete such disposal by one of the following methods:

1. By removing the oil from the original container and mixing it with an undesirable substance such as used coffee grounds, dirt, or kitty litter. The mixture shall be placed in a sealable bag, empty can, or other container to prevent the drug from leaking or breaking out of a garbage bag.

2. By transferring it to law enforcement via a medication drop-box or drug take-back event if permissible under state and federal law.

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

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

1. The patient's practitioner notifies the board that the practitioner is withdrawing the written certification submitted on behalf of the patient, and 30 days after the practitioner's withdrawal of the written certification the patient has not obtained a valid written certification from a different practitioner;

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

3. The patient, parent, or legal guardian is no longer a resident of Virginia;

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

5. The patient, parent, or legal guardian provided or sold cannabidiol oil or THC-A oil to any person, including another registered patient, parent, or legal guardian;

6. The patient, parent, or legal guardian permitted another person to use the registration of the patient, parent, or legal guardian;

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

8. The registration of the patient, parent, or legal guardian was lost, stolen, or destroyed, and the patient, parent, or legal guardian failed to notify the board or notified the board of such incident more than five business days after becoming aware that the registration was lost, stolen, or destroyed;

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

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

Part III
Application and Approval Process for Pharmaceutical Processors

18VAC110-60-100. Publication of notice for submission of applications.

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

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

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

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

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

B. Submission of initial application.

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

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

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

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

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

e. Documents sufficient to establish that the applicant is authorized to conduct business in Virginia and that all applicable state and local building, fire, and zoning requirements and local ordinances are met or will be met prior to issuance of a permit;

f. Information necessary for the board to conduct a criminal background check on the applicant;

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

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

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

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

k. A blueprint of the proposed pharmaceutical processor 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 oils; (iii) the location of all areas that may contain Cannabis plants, cannabidiol oil, or THC-A oil; (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 cannabidiol oil or THC-A oil and to safely dispense such products; and

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

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

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

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

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

18VAC110-60-120. Conditional approval.

A. Following the deadline for receipt of applications, the board shall evaluate each complete and timely submitted application and may grant conditional approval on a competitive basis based on compliance with requirements set forth in 18VAC110-60-110.

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 18VAC110-60-110 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, the cannabidiol oil, or the THC-A oil;

4. The applicant's ability to maintain the knowledge, understanding, judgment, procedures, security controls, and ethics to ensure optimal safety and accuracy in the dispensing and sale of cannabidiol oil or THC-A oil;

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 state or federal regulation that is not inconsistent with the law and regulations regarding pharmaceutical processors.

C. The board may disqualify any applicant who:

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

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

3. Fails to pay all applicable fees; or

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

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

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

18VAC110-60-130. 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:

1. Designation of a PIC;

2. Evidence of criminal background checks for all employees and delivery agents of the processor to ensure compliance with § 54.1-3442.6 of the Code of Virginia;

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

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

B. The permit shall not be awarded until any deficiency identified by inspectors has been corrected and the facility has been satisfactorily reinspected if warranted.

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

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

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

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

G. Once the permit is issued, Cannabis may not be grown or held in the pharmaceutical processor earlier than two weeks prior to the opening date designated on the application. Once Cannabis has been placed in the pharmaceutical processor, a pharmacist shall be present during hours of operation to ensure the safety, security, and integrity of the Cannabis. If there is a change in the designated opening date, the pharmaceutical processor shall notify the board office, and a pharmacist shall continue to be on site on a daily basis.

18VAC110-60-140. Notification of changes by pharmaceutical processor.

A. Unless otherwise provided in law or regulation, the PIC designated on the application to be in full and actual charge of the pharmaceutical processor shall provide any notification or information that is required from a pharmaceutical processor.

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

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

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

2. Cannabis shall not be moved to a new location until approval is granted by the inspector or board staff.

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

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

1. Notify the board;

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

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

B. The proposed disposition of all Cannabis, dispensing records, patient information records, and other required records shall be reported to the board. If the Cannabis and records are to be transferred to another processor located in Virginia, the owner shall inform the board and the patients and include on the public notice the name and address of the processor to whom the Cannabis and records are being transferred and the date of transfer.

C. Exceptions to the public notice shall be approved by the board and may include sudden closing due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, or other emergency circumstances. If the pharmaceutical processor is not able to meet the notification requirements, the owner shall ensure that the board and public are properly notified as soon as he knows of the closure and shall disclose the emergency circumstances preventing the notification within the required deadlines.

D. In the event of an exception to the notice, the PIC or owner shall provide notice as far in advance of closing as allowed by the circumstances.

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

1. Upon any change in ownership of an existing pharmaceutical processor, the dispensing records for the two years immediately preceding the date of change of ownership and other required patient information shall be provided to the new owners on the date of change of ownership in substantially the same format as previously used immediately prior to the transfer to provide continuity of services.

2. The previous owner shall be held responsible for assuring the proper and lawful transfer of records on the date of the transfer.

18VAC110-60-160. Grounds for action against a pharmaceutical processor permit.

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

1. Any criminal conviction under federal or state statutes or regulations or local ordinances, unless the conviction was based on a federal statute or regulation related to the possession, purchase, or sale of cannabidiol oil or THC-A oil that is authorized under state law and regulations;

2. Any civil action under any federal or state statute or regulation or local ordinance (i) relating to the applicant's, licensee's, permit holder's, or registrant's profession or (ii) involving drugs, medical devices, or fraudulent practices, including fraudulent billing practices;

3. Failure to maintain effective controls against diversion, theft, or loss of Cannabis, cannabidiol oil or THC-A oil, or other controlled substances;

4. Intentionally or through negligence obscuring, damaging, or defacing a permit or registration card;

5. Permitting another person to use the permit of a permit holder or registration of a qualifying patient, parent, or legal guardian;

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

7. Discontinuance of business for more than 60 days, unless the board approves an extension of such period for good cause shown upon a written request from a pharmaceutical processor. Good cause includes exigent circumstances that necessitate the closing of the facility. Good cause shall not include a voluntary closing of the pharmaceutical processor or production facility.

Part IV
Requirements for Pharmaceutical Processor Personnel

18VAC110-60-170. Pharmaceutical processor employee licenses and registrations.

A. A pharmacist with a current, unrestricted license issued by the board practicing at the location of the address on the pharmaceutical processor application shall be in full and

actual charge of a pharmaceutical processor and serve as the pharmacist-in-charge.

B. A pharmacist with a current, unrestricted license issued by the board shall provide personal supervision on the premises of the pharmaceutical processor at all times during hours of operation or whenever the processor is being accessed.

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

1. The entry of drug dispensing information and drug history into a data system or other recordkeeping system;

2. The preparation of labels for dispensing the oils or patient information;

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

4. The measuring of the oil to be dispensed;

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

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

7. The selling of the oil to the registered patient, parent, or legal guardian; and

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

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

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

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

G. A pharmacist on duty shall directly supervise the activities in all areas designated for cultivation, extraction, and dispensing or have a process in place, approved by the board, that provides adequate supervision to protect the security of the Cannabis, seeds, extracts, cannabidiol oil, and THC-A oil and ensure quality of the dispensed oils.

H. At no time shall a pharmaceutical processor operate or be accessed without a pharmacist on duty.

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

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

18VAC110-60-180. Employee training.

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

1. The proper use of security measures and controls that have been adopted for the prevention of diversion, theft, or loss of Cannabis, to include the seeds, any parts or extracts of the Cannabis plants, cannabidiol oil, and THC-A oil;

2. Procedures and instructions for responding to an emergency;

3. Professional conduct, ethics, and state and federal statutes and regulations regarding patient confidentiality; and

4. Developments in the field of the medical use of cannabidiol oil or THC-A oil.

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

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

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

1. The name of the person receiving the training;

2. The dates of the training;

3. A general description of the topics covered;

4. The name of the person supervising the training; and

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

E. When a change of pharmaceutical processor PIC occurs, the new PIC shall review the training record and sign it, indicating that the new PIC understands its contents.

F. A pharmaceutical processor shall maintain the record documenting the employee training and make it available in accordance with regulations.

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

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

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

1. Is on duty where the pharmacy technician is performing routine cannabidiol oil or THC-A oil production or dispensing functions; and

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

C. Pharmacy technicians shall not:

1. Counsel a registered patient or the patient's parent or legal guardian regarding (i) cannabidiol oil, THC-A oil, or other drugs either before or after cannabidiol oil or THC-A oil has been dispensed or (ii) any medical information contained in a patient medication record;

2. Consult with the practitioner who certified the qualifying patient, or the practitioner's agent, regarding a patient or any medical information pertaining to the patient's cannabidiol oil or THC-A oil or any other drug the patient may be taking;

3. Interpret the patient's clinical data or provide medical advice;

4. Determine whether a different formulation of cannabidiol oil or THC-A oil should be substituted for the cannabidiol oil or THC-A oil product or formulation recommended by the practitioner or requested by the registered patient or parent or legal guardian; or

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

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

A. No person shall be PIC for more than one pharmaceutical processor or for one processor and a pharmacy 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.

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

C. The pharmaceutical processor PIC shall be responsible for ensuring that:

1. Pharmacy technicians are registered and all employees are properly trained;

2. All record retention requirements are met;

3. All requirements for the physical security of the Cannabis, to include the seeds, any parts or extracts of the Cannabis plants, the cannabidiol oil, and the THC-A oil are met;

4. The pharmaceutical processor has appropriate pharmaceutical reference materials to ensure that cannabidiol oil or THC-A oil can be properly dispensed;

5. The following items are conspicuously posted in the pharmaceutical processor in a location and in a manner so as to be clearly and readily identifiable to registered patients, parents, or legal guardians:

a. Pharmaceutical processor permit;

b. Licenses for all pharmacists practicing at the pharmaceutical processor; and

c. The price of all cannabidiol oil or THC-A oil products offered by the pharmaceutical processor; and

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

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

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

F. A PIC who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the PIC. If the PIC knows of an upcoming absence of longer than 30

days, he shall be responsible for notifying the board and returning the permit. For unanticipated absences by the PIC that exceed 15 days with no known return date within the next 15 days, the permit holder shall immediately notify the board and shall obtain a new PIC.

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

Part V
Operation of a Pharmaceutical Processor

18VAC110-60-210. General provisions.

A. A pharmaceutical processor shall sell cannabidiol oil or THC-A oil only in a child-resistant, secure, and light-resistant container. Upon a written request from the registered patient, parent, or legal guardian, the oil may be dispensed in a non-child-resistant container so long as all labeling is maintained with the product.

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

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

1. A person whose responsibilities necessitate access to the pharmaceutical processor and then for only as long as necessary to perform the person's job duties; or

2. A person who is a registered patient, parent, or legal guardian, in which case such person shall not be permitted behind the service counter or in other areas where Cannabis plants, extracts, cannabidiol oil, or THC-A oil is stored.

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

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

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

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

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

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

18VAC110-60-220. Pharmaceutical processor prohibitions.

A. No pharmaceutical processor shall:

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

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

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

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

B. No pharmaceutical processor shall be open or in operation, and no person shall be in the pharmaceutical processor, unless a pharmacist is on the premises and directly supervising the activity within the pharmaceutical processor. At all other times, the pharmaceutical processor shall be closed and properly secured.

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

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

1. Name and location of the processor;

2. Contact information for the processor;

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

4. Laboratory results;

5. Product information and pricing; and

6. Directions to the processor facility.

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

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

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

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

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

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

4. If an emergency requires the presence of a visitor and makes it impractical for the pharmaceutical processor to obtain a waiver from the board, the processor shall provide written notice to the board as soon as practicable after the onset of the emergency. Such notice shall include the name and company affiliation of the visitor, the purpose of the visit, and the date and time of the visit. A pharmaceutical processor shall monitor the visitor and maintain a log of such visit as required by this subsection.

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

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

18VAC110-60-230. Inventory requirements.

A. Each pharmaceutical processor prior to commencing business shall:

1. Conduct an initial comprehensive inventory of all Cannabis plants, including the seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil, at the facility. The inventory shall include, at a minimum, the date of the inventory, a summary of the inventory findings, and the name, signature, and title of the pharmacist or pharmacy technician who conducted the inventory. If a facility commences business with no Cannabis on hand, the pharmacist shall record this fact as the initial inventory; and

2. Establish ongoing inventory controls and procedures for the conduct of inventory reviews and comprehensive inventories of all Cannabis plants, including the seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil, that shall enable the facility to detect any diversion, theft, or loss in a timely manner.

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

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

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

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

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

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

18VAC110-60-240. Security requirements.

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

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

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

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

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

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

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

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

8. Not allow keys to be left in the locks or accessible to non-pharmacists.

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

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

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

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

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

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

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

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

2. The video system shall have:

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

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

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

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

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

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

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

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

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

18VAC110-60-250. Requirements for the storage and handling of Cannabis, cannabidiol oil, or THC-A oil.

A. A pharmaceutical processor shall:

1. Have storage areas that provide adequate lighting, ventilation, sanitation, temperature, and humidity as defined in 18VAC110-60-10 and space, equipment, and security conditions for the cultivation of Cannabis and the production and dispensing of cannabidiol oil or THC-A oil;

2. Separate for storage in a quarantined area Cannabis plants, seeds, parts of plants, extracts, including cannabidiol oil or THC-A oil, that is outdated, damaged, deteriorated, misbranded, or adulterated, or whose containers or packaging have been opened or breached, until such Cannabis plants, seeds, parts of plants, extracts, cannabidiol oil, or THC-A oil are destroyed;

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

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

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

1. Restrict movement between compartments;

2. Provide for different colored identification cards for facility employees based on the compartment to which they are assigned at a given time so as to ensure that only employees necessary for a particular function have access to that compartment of the facility;

3. Require pocketless clothing for all production facility employees working in an area containing Cannabis plants, seeds, and extracts, including cannabidiol oil or THC-A oil; and

4. Document the chain of custody of all Cannabis plants, parts of plants, seeds, extracts, cannabidiol oil, and THC-A oil products.

C. The PIC shall establish, maintain, and comply with written policies and procedures for the cultivation, production, security, storage, and inventory of Cannabis, including seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil. Such policies and procedures shall include methods for identifying, recording, and reporting diversion, theft, or loss, and for correcting all errors and inaccuracies in inventories. Pharmaceutical processors shall include in their written policies and procedures a process for the following:

1. Handling mandatory and voluntary recalls of cannabidiol oil or THC-A oil. The process shall be adequate to deal with recalls due to any action initiated at the request of the board and any voluntary action by the pharmaceutical processor to (i) remove defective or potentially defective cannabidiol oil or THC-A oil from the market or (ii) promote public health and safety by replacing existing cannabidiol oil or THC-A oil with improved products or packaging;

2. Preparing for, protecting against, and handling any crises that affect the security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency;

3. Ensuring that any outdated, damaged, deteriorated, misbranded, or adulterated Cannabis, including seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil, is segregated from all other Cannabis, seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil and destroyed. This procedure shall provide for written documentation of the Cannabis, including seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil disposition; and

4. Ensuring the oldest stock of Cannabis, including seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil product is used first. The procedure may permit deviation from this requirement if such deviation is temporary and appropriate.

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

18VAC110-60-260. Recordkeeping requirements.

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

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

2. Is capable of providing safeguards against erasures and unauthorized changes in data after the information has been entered and verified by the pharmacist; and

3. Is capable of being reconstructed in the event of a computer malfunction or accident resulting in the destruction of the data bank.

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

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

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

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

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

1. An alarm activation or other event that requires a response by public safety personnel;

2. A breach of security;

3. The failure of the security alarm system due to a loss of electrical support or mechanical malfunction that is expected to last longer than eight hours; and

4. Corrective measures taken if any.

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

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

18VAC110-60-280. Cultivation and production of cannabidiol oil or THC-A oil.

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

B. Cultivation methods for Cannabis plants and extraction methods used to produce the cannabidiol oil and THC-A shall be performed in a manner deemed safe and effective based on current standards or scientific literature.

C. Any Cannabis plant, seed, parts of plant, extract, cannabidiol oil, or THC-A oil not in compliance with this section shall be deemed adulterated.

18VAC110-60-285. Registration of products.

A. A pharmaceutical processor shall assign a brand name to each product of cannabidiol oil or THC-A oil. The pharmaceutical processor shall register each brand name with the board on a form prescribed by the board prior to any dispensing and shall associate each brand name with a specific laboratory test that includes a terpenes profile and a list of all active ingredients, including:

1. Tetrahydrocannabinol (THC);

2. Tetrahydrocannabinol acid (THC-A);

3. Cannabidiols (CBD);

4. Cannabidiolic acid (CBDA); and

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

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

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

1. Is identical to or confusingly similar to the name of an existing commercially available product;

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

3. Is confusingly similar to the name of a previously approved cannabidiol oil or THC-A oil product brand name;

4. Is obscene or indecent;

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

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

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

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

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

A. Cannabidiol oil or THC-A oil produced as a batch shall not be adulterated.

B. Cannabidiol oil or THC-A oil produced as a batch shall be:

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

2. Labeled with:

a. The name and address of the pharmaceutical processor;

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

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

d. The date of testing and packaging;

e. The expiration date;

f. The quantity of cannabidiol oil or THC-A oil contained in the batch;

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

(1) Tetrahydrocannabinol (THC);

(2) Tetrahydrocannabinol acid (THC-A);

(3) Cannabidiol (CBD);

(4) Cannabidiolic acid (CBDA); and

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

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

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

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

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

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

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

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

5. The quantity of cannabidiol oil or THC-A oil contained in the package;

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

a. Tetrahydrocannabinol (THC);

b. Tetrahydrocannabinol acid (THC-A); and

c. Cannabidiol (CBD);

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

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

9. The name of the certifying practitioner;

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

11. Name and address of the pharmaceutical processor; and

12. Any cautionary statement required by statute or regulation.

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

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

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

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

1. Is independent from all other persons involved in the cannabidiol oil or THC-A oil industry in Virginia, which shall mean that no person with a direct or indirect interest in the laboratory shall have a direct or indirect financial interest in a pharmacist, pharmaceutical processor, certifying practitioner, or any other entity that may benefit from the production, manufacture, dispensing, sale, purchase, or use of cannabidiol oil or THC-A oil; and

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.

B. Immediately prior to producing any cannabidiol oil or THC-A oil product, a pharmaceutical processor shall segregate all harvested Cannabis into homogenized batches. A pharmaceutical processor shall make a sample available from each batch for a laboratory to (i) test for microbiological contaminants, mycotoxins, heavy metals, and pesticide chemical residue and (ii) conduct an active ingredient analysis.

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

D. Under no circumstances shall a pharmaceutical processor include Cannabis in a cannabidiol oil or THC-A oil product or sell it prior to the time that the laboratory has completed its testing and analysis and provided a certificate of analysis to the pharmaceutical processor or other designated facility employee.

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

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

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

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

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

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

Metal	Natural Health Products Acceptable Limits ug/kg body weight/Day
Arsenic	<0.14
Cadmium	<0.09
Lead	<0.29
Mercury	<0.29

4. For purposes of the pesticide chemical residue test, a Cannabis sample shall be deemed to have passed if it satisfies the most stringent acceptable standard for a pesticide chemical residue in any food item as set forth in Subpart C of the federal Environmental Protection Agency's regulations for Tolerances and Exemptions for Pesticide Chemical Residues in Food, 40 CFR Part 180.

G. If a sample of Cannabis passes the microbiological, mycotoxin, heavy metal, and pesticide chemical residue test, the entire batch may be utilized by the processor for immediate manufacturing, packaging, and labeling for sale.

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

I. Each pharmaceutical processor shall have such laboratory results available upon request to registered patients, parents, or legal guardians and registered practitioners who have certified qualifying patients.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

9. The name or initials of the dispensing pharmacist;

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

11. Any necessary cautionary statement; and

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

D. The cannabidiol oil or THC-A oil shall be dispensed in child-resistant packaging, except as provided in 18VAC110-60-210 A. A package shall be deemed child-resistant if it

satisfies the standard for "special packaging" as set forth in the Poison Prevention Packaging Act of 1970 Regulations, 16 CFR 1700.1(b)(4).

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

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

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

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

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

A. A pharmaceutical processor shall implement and comply with a quality assurance program that describes, in writing, policies and procedures to detect, identify, and prevent dispensing errors. A pharmaceutical processor shall distribute the written policies and procedures to all pharmaceutical processor employees and shall make the written policies and procedures readily available on the premises of the pharmaceutical processor. The policies and procedures shall include:

1. Directions for communicating the details of a dispensing error to the practitioner who certified a qualifying patient and to the qualifying patient, the patient's parent or legal guardian or appropriate family member if the patient is deceased or is unable to fully comprehend the communication. The communication shall describe methods of correcting the dispensing error or reducing the negative impact of the error on the qualifying patient; and

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

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

1. Inform pharmaceutical processor employees of changes to policy, procedure, systems, or processes made as a result of recommendations generated by the quality assurance program;

2. Notify all processor employees that the discovery or reporting of a dispensing error shall be relayed immediately to a pharmacist on duty;

3. Ensure that a pharmacist performs a quality assurance review for each dispensing error. A pharmacist shall commence such review as soon as is reasonably possible, but no later than two business days from the date the dispensing error is discovered; and

4. Create a record of every quality assurance review. This record shall contain at least the following:

a. The date of the quality assurance review and the names and titles of the persons performing the review;

b. The pertinent data and other information relating to the dispensing error reviewed;

c. Documentation of contact with the registered patient, parent, or legal guardian where applicable, and the practitioner who certified the patient;

d. The findings and determinations generated by the quality assurance review; and

e. Recommended changes to pharmaceutical processor policy, procedure, systems, or processes if any.

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

18VAC110-60-330. Disposal of cannabidiol oil or THC-A oil.

A. To mitigate the risk of diversion, a pharmaceutical processor shall routinely and promptly dispose of undesired, excess, unauthorized, obsolete, adulterated, misbranded, or deteriorated Cannabis plants, including seeds, parts of plants, extracts, cannabidiol oil, or THC-A oil by disposal in accordance with a plan approved by the board and in a manner as to render the cannabidiol oil or THC-A oil nonrecoverable.

B. The destruction shall be witnessed by the PIC and an agent of the board or another pharmacist not employed by the pharmaceutical processor. The persons disposing of the cannabidiol oil or THC-A oil shall maintain and make available a separate record of each such disposal indicating:

1. The date and time of disposal;

2. The manner of disposal;

3. The name and quantity of cannabidiol oil or THC-A oil disposed of; and

4. The signatures of the persons disposing of the cannabidiol oil or THC-A oil.

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

NOTICE: The following forms used in administering the regulation are not being published. The forms are available in electronic form only online at the listed website. Questions regarding the agency forms should be directed to the agency contact.

FORMS (18VAC110-60)

Application for registration of a patient, online form available at https://www.license.dhp.virginia.gov/apply

Application for registration of a parent or legal guardian, online form available at https://www.license.dhp.virginia.gov/apply

Application for registration of a practitioner to issue certifications, online form available at https://www.license.dhp.virginia.gov/apply

Application for a pharmaceutical processor

VA.R. Doc. No. R17-4878; Filed February 27, 2019, 9:24 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 initial or additional 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 comment period.

The following guidance documents have been submitted for publication by the listed agencies to initiate or extend 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, 900 East Main Street, Richmond, Virginia 23219.

BOARD OF AUDIOLOGY AND SPEECH-LANGUAGE PATHOLOGY

Title of Document: Guidance for Continuing Education (CE) Audits and Sanctioning for Failure to Complete CE.

Public Comment Deadline: April 17, 2019.

Effective Date: April 18, 2019.

Agency Contact: Leslie L. Knachel, Executive Director, Board of Audiology and Speech-Language Pathology, 9960 Mayland Drive, Suite 300, Richmond, VA 23233, telephone (804) 367-4630, FAX (804) 527-4471, or email audbd@dhp.virginia.gov.

BOARD OF COUNSELING

Titles of Documents:

Guidance Document on the Practice of Conversion Therapy.

Scopes of Practice for Persons Regulated by the Board to Provide Substance Abuse Treatment.

Public Comment Deadline: April 17, 2019.

Effective Date: April 18, 2019.

Agency Contact: Jaime Hoyle, Executive Director, Board of Counseling, 9960 Mayland Drive, Suite 300, Richmond, VA 23233, telephone (804) 367-4406, FAX (804) 527-4435, or email jaime.hoyle@dhp.virginia.gov.

ALCOHOLIC BEVERAGE CONTROL AUTHORITY

Small Business Impact Review - Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Alcoholic Beverage Control (ABC) Authority conducted a small business impact review of **3VAC5-10, Procedural Rules for the Conduct of Hearings Before the Board and its Hearing Officers** and determined that this regulation should be retained in its current form. The Alcoholic Beverage Control Authority is publishing its report of findings dated February 14, 2019, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

The regulation continues to be needed as it outlines the procedural rules for conducting hearings before the ABC Board or its hearing officers. The authority did not receive any complaints or comments from the public during the periodic review. The regulation is easy to understand and clearly written. The regulation is not redundant nor does it conflict with other federal or state regulations. The regulation is not complex. The last periodic review was completed in 2012, and there have not been any significant changes in technology, economic conditions, or other factors in the area affected by the regulation. No small business impact has been identified.

Contact Information: LaTonya D. Hucks-Watkins, Legal Liaison, Alcoholic Beverage Control Authority, 2901 Hermitage Road, Richmond, VA 23220, telephone (804) 213-4698, FAX (804) 213-4574, or email latonya.hucks@abc.virginia.gov.

Small Business Impact Review - Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Alcoholic Beverage Control Authority conducted a small business impact review of **3VAC5-60, Manufacturers and Wholesalers Operations**, and determined that this regulation should be retained in its current form. The Alcoholic Beverage Control Authority is publishing its report of findings dated February 14, 2019, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

The regulation continues to be needed as it provides guidance to licensed wholesalers and manufacturers of alcoholic beverages. The authority did not receive any complaints or comments from the public during the periodic review. The regulation is easy to understand and clearly written. The regulation is not redundant nor does it conflict with other federal or state regulations. The regulation is not complex. The last periodic review was completed in 2012, and there have not been any significant changes in technology, economic conditions, or other factors in the area affected by the regulation. No small business impact has been identified.

Contact Information: LaTonya D. Hucks-Watkins, Legal Liaison, Alcoholic Beverage Control Authority, 2901 Hermitage Road, Richmond, VA 23220, telephone (804) 213-4698, FAX (804) 213-4574, or email latonya.hucks@abc.virginia.gov.

DEPARTMENT OF BEHAVIORAL HEALTH AND DEVELOPMENTAL SERVICES

Seeking Comment on Proposed Variances to the Regulations to Assure the Rights of Individuals Receiving Services from Providers Licensed, Funded, or Operated by the Department of Behavioral Health and Developmental Services

Notice of action: The Department of Behavioral Health and Developmental Services (DBHDS), in accordance with Part VI, Variances (12VAC35-115-220), of the Regulations to Assure the Rights of Individuals Receiving Services from Providers Licensed, Funded, or Operated by the Department of Behavioral Health and Developmental Services (12VAC35-115), hereafter referred to as the "Human Rights Regulations," is announcing an opportunity for public comment on an application for proposed variances to the Human Rights Regulations submitted to the State Human Rights Committee (SHRC). The purpose of the regulations is to ensure and protect the legal and human rights of individuals receiving services in facilities or programs operated, licensed, or funded by DBHDS.

Each variance application references the specific part of the regulations to which a variance is needed, the proposed wording of the substitute rule or procedure, and the justification for a variance. Such application also describes time limits and other conditions for duration and the circumstances that will end the applicability of the variance. After considering all available information including comments, the SHRC intends to submit a written decision deferring, disapproving, modifying, or approving each variance application. All variances shall be approved for a specific time period. The decision and reasons for variance will be published in a later issue of the Virginia Register of Regulations.

Purpose of notice: The SHRC is seeking public comment on the application for proposed new variances to the Human Rights Regulations for the Virginia Center for Behavioral Rehabilitation (VCBR).

Variance to Procedures for Restrictions on Freedoms of Everyday Life, 12VAC35-115-100 B 3 a through B 3 e.

Requirements for the Imposition of Restrictions: The proposed variance would permit VCBR to place a resident on restrictions temporarily, without first meeting the criteria set forth in 12VAC35-115-100 B 3 a through B 3 e, if a resident displays behavior that is determined to be an immediate threat to the safety and security of the facility or the community.

Explanation: Individuals deemed by the court to be "sexually violent predators" may engage in behavior that requires an

immediate response to ensure the safety of individuals in the facility and the community. An appropriate response may be an immediate restriction on the freedoms of everyday life as outlined in 12VAC35-115-100 A 1 a through A 1 g. The immediate need to protect the safety and security of the facility or the community may be jeopardized by the process outlined in 12VAC35-115-100 B 3 a through B 3 e.

When immediate restrictions are imposed to ensure the safety and security of the facility or the community, such restrictions shall be in effect only until the next business day that the restricted resident's treatment team is able to meet, review the imposed restriction, and meet the requirements set forth in 12VAC35-115-100 B 3 a through B 3 e.

Procedures for ensuring residents' freedoms of everyday life within VCBR and procedures for implementing restrictions on those freedoms shall be outlined in Facility Instruction No. 201, Restrictions on Freedoms of Everyday Life.

Variances to these regulations by the listed state facility are reviewed by the SHRC at least annually, with reports to the SHRC regarding the variances as requested.

Public comment period: March 4, 2019, through April 3, 2019.

How to comment: The SHRC accepts written comments by email, fax, and postal mail. In order to be considered, comments must include the full name, address, and telephone number of the person commenting and be received by DBHDS, who will provide them to the SHRC, by the last day of the comment period. All information received is part of the public record.

To review a proposal: Variance applications and any supporting documentation may be obtained by contacting the listed DBHDS representative.

Contact Information: Deborah Lochart, Director, Office of Human Rights, Department of Behavioral Health and Developmental Services, 1220 East Bank Street, P.O. Box 1797, Richmond, VA 23218-1797, telephone (804) 786-0032, FAX (804) 804-371-2308, or email deb.lochart@dbhds.virginia.gov.

DEPARTMENT FOR THE BLIND AND VISION IMPAIRED

Small Business Impact Review - Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Department for the Blind and Vision Impaired conducted a small business impact review of **22VAC45-12, Public Participation Guidelines**, and determined that this regulation should be retained in its current form. The Department for the Blind and Vision Impaired is publishing its report of findings dated February 22, 2019, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

22VAC45-12 is required for the department to be in compliance with requirements set forth in §§ 2.2-4017 and 2.2-4007.02 of the Code of Virginia and Executive Order 14 (as amended July 2018). The agency has not received any complaints or public comments concerning the regulation.

The regulation is not necessarily complex but does describe in relative detail its purpose, definitions of relevant words and terms, and other specific public participation guidelines as required by the Code of Virginia. The regulation continues to be relevant because the agency administers workforce and independent living programs and services that impact the lives of individuals who are blind, vision impaired, and deafblind in the workforce and in the community.

This regulation was last evaluated June 2017, and does not conflict with state or federal regulation. There are no substantial changes in technology, economic conditions, or other factors that impact the importance of implementation of the regulation.

Economic impact on small business is negligible, and small business owners have the same opportunity for public participation as other interested stakeholders.

Contact Information: Susan K. Davis, Regulatory Coordinator, Department for the Blind and Vision Impaired, 401 Azalea Avenue, Richmond, VA 23227, telephone (804) 371-3184, FAX (804) 371-3157, or email susan.davis@dbvi.virginia.gov.

DEPARTMENT OF ENVIRONMENTAL QUALITY

Fountain Creek Solar LLC Notice of Intent Small Renewable Energy Project (Solar) Permit by Rule - Greensville County

Fountain Creek Solar LLC has provided the Department of Environmental Quality (DEQ) a notice of intent to submit the necessary documentation for a permit by rule for a small renewable energy project (solar) in Greensville County. The project is located approximately eight miles southwest of Emporia, bounded by Brink Road, Fish Road, and Fountain Creek Road at 36° 5'43.32" N 77° 40'19.98" W. The site consists of approximately 802 acres of land and will produce a maximum capacity of 80 megawatts. Currently the project will consist of approximately 240,000 modules, which may change based on improvements in technology and the availability of modules during procurement.

Contact Information: Mary E. Major, Department of Environmental Quality, 1111 East Main Street, Suite 1400, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4423, or email mary.major@deq.virginia.gov.

DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

Reduction in Inpatient Cost Sharing to Comply with Federal Regulation

Public comment period: February 28, 2019, through March 30, 2019.

The Virginia Department of Medical Assistance Services (DMAS) hereby affords the public notice of its intention to amend the State Plan for Medical Assistance to provide for changes to the Methods and Standards for Establishing Payment Rates-Inpatient Hospital Services (12VAC30-70) and Methods and Standards for Establishing Payment Rates - Other Types of Care (12VAC30-80).

This notice is intended to satisfy the requirements of 42 CFR 447.205 and of § 1902(a)(13) of the Social Security Act, 42 USC § 1396a(a)(13). A copy of this notice is available for public review from Sarah Samick, Policy, Planning, and Innovation Division, Department of Medical Assistance Services, 600 East Broad Street, Suite 1300, Richmond, VA 23219, or via email at sarah.samick@dmas.virginia.gov.

Public comments or inquiries may be submitted, in writing, within 30 days of publication of this notice to Ms. Samick, and such comments are available for review upon request. Comments may also be submitted, in writing, on the Virginia Regulatory Town Hall public comment forum at http://www.townhall.virginia.gov.

DMAS is decreasing the cost sharing amount charged per inpatient hospitalization from $100 to $75 in order to comply with federal rules at 42 CFR 447.52(b)(2).

The expenditures for this change is expected to be $39,514.

Contact Information: Emily McClellan, Regulatory Manager, Division of Policy and Research, Department of Medical Assistance Services, 600 East Broad Street, Suite 1300, Richmond, VA 23219, telephone (804) 371-4300, FAX (804) 786-1680, TDD (800) 343-0634, or email emily.mcclellan@dmas.virginia.gov.

DEPARTMENT OF MINES, MINERALS AND ENERGY

Pursuant to Executive Order 14 (as amended July 16, 2018) and §§ 2.2-4007.1 and 2.2-4017 of the Code of Virginia, the Department of Mines, Minerals and Energy is conducting a periodic review and small business impact review of **4VAC25-130, Coal Surface Mining Reclamation Regulations**. The review of this regulation will be guided by the principles in Executive Order 14 (as amended July 16, 2018).

The purpose of this review is to determine whether this regulation should be repealed, amended, or retained in its current form. Public comment is sought on the review of any issue relating to this regulation, including whether the regulation (i) is necessary for the protection of public health, safety, and welfare or for the economical performance of important governmental functions; (ii) minimizes the economic impact on small businesses in a manner consistent with the stated objectives of applicable law; and (iii) is clearly written and easily understandable.

The public comment period begins March 18, 2019, and ends April 8, 2019.

Comments may be submitted online to the Virginia Regulatory Town Hall at http://www.townhall.virginia.gov/L/Forums.cfm. Comments may also be sent to Michael Skiffington, Director of Policy and Planning, 1100 Bank Street, 8th Floor, Richmond, VA 23219, telephone (804) 692-3212, FAX (804) 692-3237, or email mike.skiffington@dmme.virginia.gov.

Comments must include the commenter's name and address (physical or email) information in order to receive a response to the comment from the agency. Following the close of the public comment period, a report of both reviews will be posted on the Virginia Regulatory Town Hall and a report of the small business impact review will be published in the Virginia Register of Regulations.

DEPARTMENT OF MOTOR VEHICLES

Notice of Periodic Review and Small Business Impact Review

Pursuant to Executive Order 14 (as amended July 16, 2018) and §§ 2.2-4007.1 and 2.2-4017 of the Code of Virginia, the Department of Motor Vehicles is conducting a periodic review and small business impact review of each listed regulation. The review of each regulation will be guided by the principles in Executive Order 14 (as amended July 16, 2018).

24VAC20-40, Rules and Regulations on Accident Prevention Courses for Older Drivers

24VAC20-80, Overload Permit Regulations

24VAC20-81, Hauling Permit Regulation

The purpose of this review is to determine whether each regulation should be repealed, amended, or retained in its current form. Public comment is sought on the review of any issue relating to each regulation, including whether the regulation (i) is necessary for the protection of public health, safety, and welfare or for the economical performance of important governmental functions; (ii) minimizes the economic impact on small businesses in a manner consistent with the stated objectives of applicable law; and (iii) is clearly written and easily understandable.

The public comment period begins March 18, 2019, and ends April 8, 2019.

Comments may be submitted online to the Virginia Regulatory Town Hall at http://www.townhall.virginia.gov/L/Forums.cfm. Comments may also be sent to Domica Winstead, Senior Policy Analyst, Department of Motor Vehicles, 2300 West Broad Street, Richmond, VA 23269, telephone (804) 367-1864, FAX (804) 367-4336, or email domica.winstead@dmv.virginia.gov.

Comments must include the commenter's name and address (physical or email) information in order to receive a response to the comment from the agency. Following the close of the public comment period, a report of the review will be posted on the Virginia Regulatory Town Hall and a report of the small business impact review will be published in the Virginia Register of Regulations.

STATE WATER CONTROL BOARD

Proposed Consent Special Order for Comcast Cable Communication Management LLC and TriWire Engineering Solutions Inc

An enforcement action has been initiated against Comcast Cable Communication Management LLC (Comcast) and TriWire Engineering Solutions Inc (TriWire) for alleged violations resulting from a fuel spill occurring at 2937 Galena Avenue, North Chesterfield, VA. The State Water Control Board proposes to issue a consent special order to Comcast and TriWire to address noncompliance with State Water Control Law. A description of the proposed action is available at the Department of Environmental Quality office named below or online at www.deq.virginia.gov. Jeff Reynolds will accept comments by email at jefferson.reynolds@deq.virginia.gov, FAX at (804) 527-5106, or postal mail at Department of Environmental Quality, Piedmont Regional Office, 4949-A Cox Road, Glen Allen, VA 23060, from March 18, 2019, to April 16, 2019.

Proposed Enforcement Action for Conny Oil Inc

An enforcement action has been proposed for Conny Oil Inc for violations of the State Water Control Law at Wythe Oil Distributors in Wytheville, Virginia. A description of the proposed action is available at the Department of Environmental Quality office named below or online at www.deq.virginia.gov. Ralph T. Hilt will accept comments by email at ralph.hilt@deq.virginia.gov, FAX at (276) 676-4899, or postal mail at Department of Environmental Quality, Southwest Regional Office, 355-A Deadmore Street, Abingdon, VA 24210, from March 19, 2019, through April 17, 2019.

VIRGINIA CODE COMMISSION

Notice to State Agencies

Contact Information: *Mailing Address:* Virginia Code Commission, Pocahontas Building, 900 East Main Street, 8th 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.

ERRATA

CRIMINAL JUSTICE SERVICES BOARD

Title of Regulation: **6VAC20-100. Rules Relating to Compulsory Minimum Training Standards for Correctional Officers of the Department of Corrections, Division of Adult Institutions.**

Publication: 34:21 VA.R. 2082-2112 June 11, 2018

Correction to Proposed Regulation:

Page 2110, 6VAC20-100-70 A, first line, strike "A." before "~~Each officer~~"

Page 2111, 6VAC20-100-70 B, underline subdivision 1 in its entirety

VA.R. Doc. No. R18-5427; Filed February 25, 2019