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).

February 2020 through December 2020

Volume: Issue	Material Submitted By Noon*	Will Be Published On
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
36:18	April 8, 2020	April 27, 2020
36:19	April 22. 2020	May 11, 2020
36:20	May 6, 2020	May 25, 2020
36:21	May 20, 2020	June 8, 2020
36:22	June 3, 2020	June 22, 2020
36:23	June 17, 2020	July 6, 2020
36:24	July 1, 2020	July 20, 2020
36:25	July 15, 2020	August 3, 2020
36:26	July 29, 2020	August 17, 2020
37:1	August 12, 2020	August 31, 2020
37:2	August 26, 2020	September 14, 2020
37:3	September 9, 2020	September 28, 2020
37:4	September 23, 2020	October 12, 2020
37:5	October 7, 2020	October 26, 2020
37:6	October 21, 2020	November 9, 2020
37:7	November 4, 2020	November 23, 2020
37:8	November 16, 2020 **(Monday)**	December 7, 2020
37:9	December 2, 2020	December 21, 2020

*Filing deadlines are Wednesdays unless otherwise specified.

TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF DENTISTRY

Agency Decision

Title of Regulation: **18VAC60-21. Regulations Governing the Practice of Dentistry**.

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

Name of Petitioner: Deborah Blanchard, DDS.

Nature of Petitioner's Request: To delete the requirements for the dentist to be present in the facility and to examine a patient during the time services are being provided (18VAC60-21-120 D).

Agency Decision: Request denied.

Statement of Reason for Decision: At its December 13, 2019, meeting, the board considered the petition and public comment, both in support and in opposition. Following the recommendation of the board's regulatory and legislative committee, the board decided not to initiate rulemaking and confirmed its current requirement that a dentist be present in the facility and examine the patient during the time services are being provided by a dental hygienist. The board does have regulations for general supervision that do not require the dentist to be present, provided certain conditions and restrictions are met.

Agency Contact: Sandra Reen, Executive Director, Board of Dentistry, 9960 Mayland Drive, Suite 300, Richmond, VA 23233, telephone (804) 367-4437, or email sandra.reen@dhp.virginia.gov.

VA.R. Doc. No. R20-04 Filed December 13, 2019, 11:36 a.m.

TITLE 9. ENVIRONMENT

STATE AIR POLLUTION CONTROL BOARD

Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the State Air Pollution Control Board conducted a small business impact review of **9VAC5-130, Regulation for Open Burning**, and determined that this regulation should be retained in its current form. The State Air Pollution Control Board is publishing its report of findings dated December 2, 2019, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

This regulation continues to be needed. It provides sources with the most cost-effective means of fulfilling ongoing state and federal requirements that protect air quality. There were no comments received that requested a change to the regulation. The regulation's level of complexity is appropriate to ensure that the regulated entity is able to meet its legal mandate as efficiently and cost-effectively as possible. This regulation does not overlap, duplicate, or conflict with any state law or other state regulation.

This regulation was last updated in 2012. Over time, it generally becomes less expensive to characterize, measure, and mitigate the regulated pollutants that contribute to poor air quality. This regulation continues to provide the most efficient and cost-effective means to determine the level and impact of excess emissions and to control those excess emissions.

The department, through examination of the regulation, has determined that the regulatory requirements currently minimize the economic impact of emission control regulations on small businesses and thereby minimize the impact on existing and potential Virginia employers and their ability to maintain and increase the number of jobs in the Commonwealth.

Contact Information: Gary Graham, Regulatory Analyst, Office of Regulatory Affairs, Department of Environmental Quality, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4103, FAX (804) 698-4319, or email gary.graham@deq.virginia.gov.

TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

COMMON INTEREST COMMUNITY BOARD

Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Common Interest Community Board conducted a small business impact review of **18VAC48-10, Public Participation Guidelines**, and determined that this regulation should be retained in its current form. The Common Interest Community Board is publishing its report of findings dated December 6, 2019, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

Section 2.2-4007.02 of the Code of Virginia mandates that the agency solicit the input of interested parties in the formation and development of its regulations. Therefore, the continued need for the regulation is established in statute. The regulation is necessary to protect public health, safety, and welfare by establishing public participation guidelines that promote public involvement in the development, amendment, or repeal of an agency's regulation. By soliciting the input of interested parties, the agency is better equipped to effectively regulate an occupation or profession.

Since no complaints or comments were received during the public comment period, there does not appear to be a reason to amend or repeal the regulation. The regulation is clearly written and easily understandable. The regulation does not overlap, duplicate, or conflict with federal or state law or regulation.

The most recent periodic review of the regulation occurred in 2015. On December 5, 2019, the board discussed the regulation and for the reasons stated determined that the regulation should not be amended or repealed but retained in its current form.

Contact Information: Trisha Henshaw, Executive Director, Common Interest Community Board, 9960 Mayland Drive, Suite 400, Richmond, VA 23233, telephone (804) 367-8510, FAX (866) 490-2723, or email cic@dpor.virginia.gov.

Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Common Interest Community Board conducted a small business impact review of **18VAC48-45, Time-Share Regulations**, and determined that this regulation should be retained in its current form. The Common Interest Community Board is publishing its report of findings dated December 6, 2019, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

Sections 54.1-2349 and 55.1-2247 of the Code of Virginia mandate that the Common Interest Community Board promulgate regulations. The continued need for the regulation

is established in statute. Repeal of the regulation would remove the current public protections provided by the regulation.

The Common Interest Community Board provides protection to the public welfare of the citizens of the Commonwealth by ensuring full and accurate disclosure in the offering and disposition of time-share interests, time-share exchange programs, and alternative purchases and by establishing standards of conduct for time-share developers and time-share resellers.

Since no complaints or comments were received during the public comment period, there does not appear to be a reason to amend or repeal the regulation. The regulation is clearly written and easily understandable and does not overlap, duplicate, or conflict with federal or state law or regulation.

This regulation became effective on March 1, 2016, and this is the first periodic review of the regulation. On December 5, 2019, the board discussed the regulation and for the reasons stated determined through proper unanimous vote that the regulation should not be amended or repealed but retained in its current form.

Contact Information: Trisha Henshaw, Executive Director, Common Interest Community Board, 9960 Mayland Drive, Suite 400, Richmond, VA 23233, telephone (804) 367-8510, FAX (866) 490-2723, or email cic@dpor.virginia.gov.

Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Common Interest Community Board conducted a small business impact review of **18VAC48-50, Common Interest Community Manager Regulations**, and determined that this regulation should be retained in its current form. The Common Interest Community Board is publishing its report of findings dated December 16, 2019, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

Section 54.1-2349 of the Code of Virginia mandates that the Common Interest Community Board promulgate regulations to carry out the duties imposed upon it by Chapter 23.3 (§ 54.1-2345 et seq.) of Title 54.1 of the Code of Virginia. The continued need for the regulation is established in statute. Repeal of the regulation would remove the current public protections provided by the regulation.

Common interest community associations do not appear to be small businesses as contemplated under § 2.2-4007.1 of the Code of Virginia. The Common Interest Community Board provides protection to the public welfare of the citizens of the Commonwealth by ensuring common interest community managers meet minimum standards for competence and integrity.

The regulation is clearly written and easily understandable and does not overlap, duplicate, or conflict with federal or state law or regulation. Based on the comment received during the public comment period, there does not appear to be a reason to repeal the regulation. There also does not appear to be a reason to amend the regulation at this time. However, the decision to retain a regulation in its current form does not prevent the board from conducting review or amendment of the regulation in the future.

The most recent periodic review of the regulation occurred in 2015. On December 5, 2019, the board discussed the regulation and for the reasons stated determined that the regulation should not be amended or repealed but retained in its current form.

Contact Information: Trisha Henshaw, Executive Director, Common Interest Community Board, 9960 Mayland Drive, Suite 400, Richmond, VA 23233, telephone (804) 367-8510, FAX (866) 490-2723, or email cic@dpor.virginia.gov.

Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Common Interest Community Board conducted a small business impact review of **18VAC48-60, Common Interest Community Board Management Information Fund Regulations**, and determined that this regulation should be retained in its current form. The Common Interest Community Board is publishing its report of findings dated December 6, 2019, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

Sections 54.1-2349 and 54.1-2351 of the Code of Virginia mandate that the Common Interest Community Board promulgate regulations. The continued need for the regulation is established in statute. Repeal of the regulation would remove the current public protections provided by the regulation. The requirements for common interest associations to file annual reports with the board and make payments into the fund are established by statute.

Common Interest Community associations do not appear to be small businesses as contemplated under § 2.2-4007.1 of the Code of Virginia. Since no complaints or comments were received during the public comment period, there does not appear to be a reason to amend or repeal the regulation. The regulation is clearly written and easily understandable and does not overlap, duplicate, or conflict with federal or state law or regulation.

The most recent periodic review of the regulation occurred in 2015. On December 5, 2019, the board discussed the regulation and for the reasons stated determined that the regulation should not be amended or repealed but retained in its current form.

Contact Information: Trisha Henshaw, Executive Director, Common Interest Community Board, 9960 Mayland Drive, Suite 400, Richmond, VA 23233, telephone (804) 367-8510, FAX (866) 490-2723, or email cic@dpor.virginia.gov.

Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Common Interest Community Board conducted a small business impact review of **18VAC48-70, Common Interest Community Ombudsman Regulations**, and determined that this regulation should be retained in its current form. The Common Interest Community Board is publishing its report of findings dated December 16, 2019, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

Sections 54.1-2349, 54.1-2351, and 54.1-2354.4 of the Code of Virginia mandate that the Common Interest Community Board promulgate regulations. Section 54.1-2354.4 specifically mandates that the board establish by regulation that common interest community associations establish procedures for the resolution of complaints. The continued need for the regulation is established in statute. Repeal of the regulation would remove the current public protections provided by the regulation.

Common interest community associations do not appear to be small businesses as contemplated under § 2.2-4007.1 of the Code of Virginia. The Common Interest Community Board provides protection to the public welfare of the citizens of the Commonwealth by ensuring common interest community associations establish procedures for the resolution of complaints from association members and other members of the public.

The regulation is clearly written and easily understandable and does not overlap, duplicate, or conflict with federal or state law or regulation. Based on the comment received during the public comment period, there does not appear to be a reason to repeal the regulation. There also does not appear to be a reason to amend the regulation at this time. However, the decision to retain a regulation in its current form does not prevent the board from conducting review or amendment of the regulation in the future.

The most recent periodic review of the regulation occurred in 2015. On December 5, 2019, the board discussed the regulation and for the reasons stated determined that the regulation should not be amended or repealed but retained in its current form.

Contact Information: Trisha Henshaw, Executive Director, Common Interest Community Board, 9960 Mayland Drive, Suite 400, Richmond, VA 23233, telephone (804) 367-8510, FAX (866) 490-2723, or email cic@dpor.virginia.gov.

FAIR HOUSING BOARD

Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Fair Housing Board conducted a small business impact review of **18VAC62-10, Public Participation Guidelines**, and determined that this regulation should be retained in its current form. The Fair Housing Board is publishing its report of findings dated December 4, 2019, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

Section 2.2-4007.02 of the Code of Virginia mandates that the agency solicit the input of interested parties in the formation and development of its regulations. Therefore, the continued need for the regulation is established in statute. The regulation is necessary to protect public health, safety, and welfare by establishing public participation guidelines that promote public involvement in the development, amendment, or repeal of an agency's regulation. By soliciting the input of interested parties, the agency is better equipped to effectively regulate an occupation or profession.

No complaints or comments were received during the public comment period. The regulation is clearly written and easily understandable. The regulation does not overlap, duplicate, or conflict with federal or state law or regulation. The most recent periodic review of the regulation occurred in 2015. On December 4, 2019, the board discussed the regulation and for the reasons stated determined that the regulation should not be amended or repealed but retained in its current form.

Contact Information: Christine Martine, Executive Director, Fair Housing Board, 9960 Mayland Drive, Suite 400, Richmond, VA 23233, telephone (804) 367-8552, FAX (866) 826-8863, or email fairhousing@dpor.virginia.gov.

Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Fair Housing Board conducted a small business impact review of **18VAC62-20, Fair Housing Certification Regulations**, and determined that this regulation should be retained in its current form. The Fair Housing Board is publishing its report of findings dated December 4, 2019, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

Subdivision 5 of § 54.1-201 of the Code of Virginia mandates that the Fair Housing Board promulgate regulations. The continued need for the regulation is established in statute. Repeal of the regulation would remove the current public protections provided by the regulation. The Fair Housing Board provides protection to the safety and welfare of the citizens of the Commonwealth by ensuring that only those individuals who meet specific criteria set forth in the statutes and regulations are eligible to receive a fair housing certificate. The board is also tasked with ensuring that its regulants meet standards of practice that are set forth in the regulations.

No comments or complaints were received during the public comment period. The regulation is clearly written and easily understandable and does not overlap, duplicate, or conflict with federal or state law or regulation. The most recent periodic review of the regulation occurred in 2015. On December 4, 2019, the board discussed the regulation and for

the reasons stated determined that the regulation should not be amended or repealed but retained in its current form.

Contact Information: Christine Martine, Executive Director, Fair Housing Board, 9960 Mayland Drive, Suite 400, Richmond, VA 23233, telephone (804) 367-8552, FAX (866) 826-8863, or email fairhousing@dpor.virginia.gov.

BOARD FOR WATERWORKS AND WASTEWATER WORKS OPERATORS AND ONSITE SEWAGE SYSTEM PROFESSIONALS

Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Board for Waterworks and Wastewater Works Operators and Onsite Sewage System Professionals conducted a small business impact review of **18VAC160-11, Public Participation Guidelines**, and determined that this regulation should be retained in its current form. The Board for Waterworks and Wastewater Works Operators and Onsite Sewage System Professionals is publishing its report of findings dated October 31, 2019, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

Section 2.2-4007.02 of the Code of Virginia mandates that the agency solicit the input of interested parties in the formation and development of its regulations. Therefore, the continued need for the regulation is established in statute. The regulation is necessary to protect public health, safety, and welfare by establishing public participation guidelines that promote public involvement in the development, amendment, or repeal of the agency's regulation. By soliciting the input of interested parties, the agency is better equipped to effectively regulate an occupation or profession. Since no complaints or comments were received during the public comment period, there does not appear to be a reason to amend or repeal the regulation. The regulation is clearly written and easily understandable. The regulation does not overlap, duplicate, or conflict with federal or state law or regulation. The most recent periodic review of the regulation occurred in 2015. On October 24, 2019, the board discussed the regulation and for the reasons stated determined that the regulation should not be amended or repealed but retained in its current form.

Contact Information: Trisha Henshaw, Executive Director, Board for Waterworks and Wastewater Works Operators and Onsite Sewage System Professionals, 9960 Mayland Drive, Suite 400, Richmond, VA 23233, telephone (804) 367-8595, FAX (866) 350-5354, or email waterwasteoper@dpor.virginia.gov.

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TITLE 24. TRANSPORTATION AND MOTOR VEHICLES

DEPARTMENT OF TRANSPORTATION

Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Department of Transportation conducted a small business impact review of **24VAC30-41, Rules and Regulations Governing Relocation Assistance**, and determined that this regulation should be retained in its current form. The Department of Transportation is publishing its report of findings dated August 16, 2019, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

There is a continued need for this regulation because it is required to implement the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970, as amended (42 USC § 4601 et seq.) in order for the Virginia Department of Transportation to receive federal financial assistance. It provides a system of benefits with the following objectives: "To ensure that persons displaced as a direct result of federal or federally-assisted projects are treated fairly, consistently, and equitably so that such displaced persons will not suffer disproportionate injuries as a result of projects designed for the benefit of the public as a whole; and to ensure that Agencies implement these regulations in a manner that is efficient and cost effective." (49 CFR 24.1(b) and 49 CFR 24.1(c)).

This regulation is not overly complex and is consistent with the federal law codified at 42 USC § 4601 et seq. and the related federal regulations in 49 CFR Part 24. The regulation does not impact small businesses but does provide eligible relocation benefits and advisory assistance when small businesses are affected by a state project.

Contact Information: JoAnne P. Maxwell, Agency Regulatory Coordinator, Governance and Legislative Affairs Division, Department of Transportation, 1401 East Broad Street, Richmond, VA 23219, telephone (804) 786-1830, FAX (804) 225-4700, or email joanne.maxwell@vdot.virginia.gov.

Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Department of Transportation conducted a small business impact review of **24VAC30-401, Change of Limited Access Control**, and determined that this regulation should be retained in its current form. The Department of Transportation is publishing its report of findings dated August 1, 2019, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

The regulation is needed for purposes of complying with state and federal laws and regulations regarding changes of limited access control on all limited access control roadways. The regulation is not overly complex, complements state and

federal laws and regulations, and is structured to support their policy goals and objectives. The last substantive review of the regulation was in 2006.

Contact Information: JoAnne P. Maxwell, Agency Regulatory Coordinator, Governance and Legislative Affairs Division, Department of Transportation, 1401 East Broad Street, Richmond, VA 23219, telephone (804) 786-1830, FAX (804) 225-4700, or email joanne.maxwell@vdot.virginia.gov.

TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF NURSING

Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the Board of Nursing intends to consider amending **18VAC90-40, Regulations for Prescriptive Authority for Nurse Practitioners.** The purpose of the proposed action is to add a section to 18VAC90-40 to (i) include in regulation the statutory requirement that takes effect on July 1, 2020, that a prescription for a controlled substance that contains an opioid must be issued as an electronic prescription and (ii) provide for a one-year waiver from the requirement if a practitioner can demonstrate economic hardship or technological limitations beyond the practitioner's control or for other exceptional circumstances.

The agency intends to hold a public hearing on the proposed action after publication in the Virginia Register.

Statutory Authority: §§ 54.1-2400 and 54.1-3408.02 of the Code of Virginia.

Public Comment Deadline: February 5, 2020.

Agency Contact: Jay P. Douglas, R.N., Executive Director, Board of Nursing, 9960 Mayland Drive, Suite 300, Richmond, VA 23233-1463, telephone (804) 367-4520, FAX (804) 527-4455, or email jay.douglas@dhp.virginia.gov.

VA.R. Doc. No. R20-6115; Filed December 23, 2019, 3:38 p.m.

BOARD OF PHARMACY

Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the Board of Pharmacy intends to consider amending **18VAC110-60, Regulations Governing Pharmaceutical Processors**. The purpose of the proposed action is to adopt the requirements of Chapter 690 of the 2019 Acts of Assembly regarding (i) registration of agents for patients certified to receive cannabidiol oil or THC-A oil; (ii) who may be employed to cultivate and extract chemicals from Cannabis plants; and (iii) wholesale distribution of oils between processors.

The agency intends to hold a public hearing on the proposed action after publication in the Virginia Register.

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

Public Comment Deadline: February 5, 2020.

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.

VA.R. Doc. No. R20-6129; Filed December 20, 2019, 1:22 p.m.

REGULATIONS

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

Symbol Key

Roman type indicates existing text of regulations. Underscored language indicates proposed new text. Language that has been stricken indicates proposed text for deletion. Brackets are used in final regulations to indicate changes from the proposed regulation.

TITLE 3. ALCOHOLIC BEVERAGES

ALCOHOLIC BEVERAGE CONTROL AUTHORITY

Notice of Extension of Emergency Regulation

Title of Regulation: **3VAC5-50. Retail Operations (adding 3VAC5-50-250).**

Statutory Authority: §§ 4.1-103 and 4.1-111 of the Code of Virginia.

Effective Date Extended Through: June 29, 2020.

The Governor approved the request of the Alcoholic Beverage Control Authority Board of Directors to extend the expiration date of the emergency regulation for six months as provided by § 2.2-4011 D of the Code of Virginia. Therefore, the emergency regulation will continue in effect through June 29, 2020. The emergency regulation implements the confectionery license created by Chapters 173 and 334 of the 2018 Acts of Assembly, which authorizes a licensee to prepare and sell on licensed premises for off-premises consumption confectionery that contains 5% or less alcohol by volume. The agency has submitted the proposed stage of the permanent regulation for publication in the Virginia Register of Regulations. Active licenses are in place regulated by the emergency provisions. The emergency regulation was published in 34:23 VA.R. 2158-2159 July 9, 2018.

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

VA.R. Doc. No. R18-5486; Filed December 17, 2019, 4:33 p.m.

TITLE 4. CONSERVATION AND NATURAL RESOURCES

MARINE RESOURCES COMMISSION

Final Regulation

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

Title of Regulation: **4VAC20-1360. Pertaining to Commercial Electrofishing (adding 4VAC20-1360-10 through 4VAC20-1360-60).**

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

Effective Date: January 1, 2020.

Agency Contact: Jennifer Farmer, Regulatory Coordinator, Marine Resources Commission, 380 Fenwick Road, Fort Monroe, VA 23651, telephone (757) 247-2248, or email jennifer.farmer@mrc.virginia.gov.

Summary:

This action establishes a commercial electrofishing license and fishery, including definitions and provisions regarding licensing and entry requirements, prohibited actions, penalties, and sanctions.

CHAPTER 1360
PERTAINING TO COMMERCIAL ELECTROFISHING

4VAC20-1360-10. Purpose.

The purpose of this regulation is to sustainably manage populations of nonnative catfish species through the creation of a low-frequency electrofishing gear license.

4VAC20-1360-20. Definitions.

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

"Agent" means any individual who possesses the Commercial Fisherman Registration License, fishing gear license, or fishing permit of any registered commercial fisherman in order to fish that commercial fisherman's gear or sell that commercial fisherman's harvest.

"Blue catfish" means any fish of the nonnative species Ictalurus furcatus.

"Commercial electrofishing fishery" means low-frequency electrofishing and subsequent harvest by any individual where the harvest is for sale, barter, trade, or any commercial purpose or is intended for sale, barter, trade, or any commercial purpose.

"Electrofishing" means a method by which fish are immobilized by an electrical field created by pulsing direct current at a frequency not above 15 Hz.

"Flathead catfish" means any fish of the nonnative species Pylodictis olivaris.

"Harvest area" means the waters of (i) the mainstem of the James River, from the James River Bridge upstream to the southern point of Turkey Island; (ii) the mainstem of the Pamunkey River, from the Route 33 Eltham Bridge upstream to the mouth of Matadequin Creek; and (iii) the mainstem of the Rappahannock River, from the Route 360 Downing Bridge upstream to the Route 301 James Madison Memorial Bridge.

"Snout" means the most forward projection from a fish's head that includes the upper and lower jaw.

"Total length" means the length of a fish measured from the most forward projection of the snout, with the mouth closed, to the tip of the longer lobe of the tail (caudal) fin, measured with the tail compressed along the midline, using a straight-line measure, not measured over the curve of the body.

4VAC20-1360-30. Licensing and entry requirements.

A. The maximum number of Commercial Electrofishing Licenses issued in any calendar year shall be three.

B. Any individual who meets all of the following criteria shall be eligible for a Commercial Electrofishing License:

1. The individual shall possess a valid Commercial Fisherman Registration License.

2. The individual shall complete a Commercial Electrofishing Application that shall be received by the Marine Resources Commission by the first of February of the current calendar year.

3. The individual shall meet one of the following criteria:

a. The individual shall have operated electrofishing equipment as the applicant on a Virginia-issued Scientific Collection Permit.

b. The individual shall have possessed a Commercial Electrofishing License and reported harvest of at least 100 pounds by electrofishing gear to the Marine Resource Commission's Mandatory Harvest Reporting System in the previous calendar year.

C. If the number of individuals eligible for a Commercial Electrofishing License pursuant to subsection B of this section is fewer than three by the second of February in the current calendar year, a lottery will be conducted including any individual who meets all of the following criteria:

1. The individual shall possess a valid Commercial Fisherman Registration License.

2. The individual shall complete a Commercial Electrofishing Lottery Application that was received by the Marine Resources Commission on or before the last day of February of the current calendar year.

3. The individual shall have reported harvest to the Marine Resource Commission's Mandatory Harvest Reporting System of at least 1000 pounds of catfish per year in at least three of the previous 10 calendar years.

D. Any individual selected under subsection B or C of this section who fails to return a completed Commercial Electrofishing License Acceptance Form provided by the commission indicating acceptance within 14 days of selection shall forfeit eligibility for the current calendar year and another individual shall be selected from the list of eligible individuals pursuant to subsection C of this section.

E. A Commercial Electrofishing License shall not be issued to an eligible individual until the individual demonstrates to the Marine Resources Commission successful completion of an approved electrofishing operation safety training course.

F. The commission must approve all electrofishing gear prior to the issuance of a Commercial Electrofishing License.

G. Using agents or transferring any Commercial Electrofishing License shall be prohibited.

H. The commissioner or the commissioner's designee may grant exceptions to subsection G of this section.

4VAC20-1360-40. Prohibitions.

A. It shall be unlawful for any individual to harvest any fish immobilized by commercial electrofishing gear without possessing a Commercial Fisherman Registration License and Fish Dip Net License or a Commercial Electrofishing License.

B. It shall be unlawful for any individual in the commercial electrofishing fishery to:

1. Take, harvest, or possess any species other than blue catfish or flathead catfish.

2. Take, harvest, or possess any blue catfish greater than 25 inches in total length, except that up to 12 blue catfish per trip may be between 25 and 28 inches in total length.

C. It shall be unlawful for any individual licensed under the provisions of 4VAC20-1360-30 to:

1. Fail to be onboard the electrofishing vessel when conducting commercial electrofishing.

2. Conduct commercial electrofishing from October 16 through April 30.

3. Conduct commercial electrofishing between 11:59 a.m. Friday and 12:01 a.m. Monday.

4. Conduct commercial electrofishing within 100 yards of any marked commercial fishing gear.

5. Conduct commercial electrofishing within the week prior to or during any local sampling conducted by the Virginia Department of Game and Inland Fisheries. The dates and locations of such sampling will be provided to licensees.

6. Fail to contact the Virginia Marine Resources Commission Operations Station toll free line at 1-800-541-4646 when intending to conduct commercial electrofishing within the following 24-hour period to report the specific location and estimated time of fishing.

7. Conduct commercial electrofishing in Virginia waters except in the harvest area specified on the individual's Commercial Electrofishing License.

8. Conduct commercial electrofishing within 100 yards of any public boat ramp, fishing pier, or where people are in the water, including such activities as swimming and diving.

4VAC20-1360-50. Penalty.

As set forth in § 28.2-903 of the Code of Virginia, any individual violating any provision of this chapter shall be guilty of a Class 3 misdemeanor, and a second or subsequent violation of any provision of this chapter committed by the same individual within 12 months of a prior violation is a Class 1 misdemeanor.

4VAC20-1360-60. Sanctions.

Any individual found guilty of violating any provision of this chapter may have his Commercial Electrofishing License revoked at any time upon review by the commission as provided for in § 28.2-232 of the Code of Virginia.

NOTICE: Forms used in administering the regulation have been filed by the agency. The forms are not being published; however, online users of this issue of the Virginia Register of Regulations may click on the name of a form with a hyperlink to access it. The forms are also available from the agency contact or may be viewed at the Office of the Registrar of Regulations, 900 East Main Street, 11th Floor, Richmond, Virginia 23219.

FORMS (4VAC20-1360)

VMRC Commercial Electrofishing Lottery Application Form (eff. 12/2019)

VMRC Commercial Electrofishing Application Form (eff. 12/2019)

VMRC Commercial Electrofishing License Acceptance Form (undated, filed 12/18/2019)

VA.R. Doc. No. R20-6267; Filed December 18, 2019, 11:26 a.m.

TITLE 8. EDUCATION

VIRGINIA COMMONWEALTH UNIVERSITY

Final Regulation

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

Title of Regulation: **8VAC90-80. Human Subjects Research Regulation (adding 8VAC90-80-10, 8VAC90-80-20).**

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

Effective Date: December 20, 2019.

Agency Contact: Jacqueline Kniska, Chief Ethics and Compliance Officer, Virginia Commonwealth University, P.O. Box 842503, 918 West Franklin Street, Richmond, VA 23284, telephone (804) 828-3976, or email jkniska@vcu.edu.

Summary:

This regulation adopts standards for human subjects research for Virginia Commonwealth University.

CHAPTER 80
HUMAN SUBJECTS RESEARCH REGULATION

8VAC90-80-10. Scope.

This chapter applies to research involving human subjects conducted by Virginia Commonwealth University.

8VAC90-80-20. Federal regulations adopted.

Research conducted by Virginia Commonwealth University involving human subjects shall be conducted in accordance with 21 CFR Parts 50 (May 30, 1980) and 56 (January 27, 1981); 45 CFR Part 46 (revised June 19, 2017, and amended January 22, 2018, and June 19, 2018); 45 CFR Parts 160 and 164 (December 28, 2000); and any other applicable federal law or regulation.

VA.R. Doc. No. R20-6265; Filed December 18, 2019, 12:29 p.m.

TITLE 12. HEALTH

DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

Final Regulation

Title of Regulation: **12VAC30-50. Amount, Duration, and Scope of Medical and Remedial Care Services (amending 12VAC30-50-165).**

Statutory Authority: § 32.1-325 of the Code of Virginia; 42 USC § 1396 et seq.

Effective Date: February 21, 2020.

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

Summary:

The amendments update coverage and documentation requirements for durable medical equipment (DME) by (i) eliminating the requirement that enteral nutrition be the Medicaid beneficiary's primary or sole source of nutrition and redundant language and requirements regarding enteral nutrition, (ii) permitting the use of implantable pumps for delivering home infusion therapy, (iii) streamlining the delivery ticket requirements to enhance flexibility and provide an alternative option of using an individual's medical record number on the ticket, and (iv) identifying the process and requirements for providing replacement DME to Medicaid beneficiaries who have lost DME or had DME destroyed as a result of a disaster.

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

12VAC30-50-165. Durable medical equipment ~~(DME) and supplies~~ suitable for use in the home.

A. Definitions. The following words and terms when used in ~~these regulations~~ this section shall have the following meanings unless the context clearly indicates otherwise:

"Affirmative contact" means speaking, either face-to-face or by phone, with either the individual or caregiver in order to ascertain that the DME ~~and supplies are~~ is still needed and appropriate. Such contacts shall be documented in the individual's medical record.

"Certificate of Medical Necessity" or "CMN" means the DMAS-352 form required to be completed and submitted in order for DMAS to provide reimbursement.

"Designated agent" means an entity with whom DMAS has contracted to perform ~~contracted~~ functions such as provider audits and prior authorizations of services.

"DMAS" means the Department of Medical Assistance Services.

"DME provider" means those entities enrolled with DMAS to render DME services.

"Durable medical equipment" or "DME" means medical equipment, supplies, and appliances suitable for use in the home consistent with 42 CFR 440.70(b)(3) that treat a diagnosed condition or assist the individual with functional limitations.

"Enteral nutrition" refers to any method of feeding that uses the gastrointestinal tract to deliver part or all of an individual's caloric requirements. "Enteral nutrition" may include a routine oral diet, the use of liquid supplements, or delivery of part or all of the daily requirements by use of a tube, which is called tube feeding.

"Expendable supply" means an item that is used and then disposed of.

"Frequency of use" means the rate of use by the individual as documented by the number of times per ~~day/week/month~~ day, week, or month, as appropriate, a supply is used by the individual. Frequency of use must be recorded on the face of the CMN in such a way that reflects whether a supply is used by the individual on a daily, weekly, or monthly basis. Frequency of use may be documented on the CMN as a range of the rate of use. By way of example and not limitation, the frequency of use of a supply may be expressed as a range, such as four to six adult diapers per day. However, large ranges shall not be acceptable documentation of frequency of use ~~(for~~, for example, the range of one to six adult diapers per day shall not be acceptable.~~)~~ The frequency of use provides the justification for the total quantity of supplies ordered on the CMN.

"Functional limitation" means the inability to perform a normal activity.

"Practitioner" means a licensed provider of physician services as defined in 42 CFR 440.50.

"Prior authorization" or "PA" ~~(also "service authorization")~~ means the process of approving either by DMAS or its prior authorization ~~(or service authorization)~~ contractor for the purposes of DMAS reimbursement for the service for the individual before it is rendered or reimbursed.

"Quantity" means the total number of supplies ordered on a monthly basis as reflected on the CMN. The monthly quantity of supplies ordered for the individual shall be dependent upon the individual's frequency of use.

~~"Sole source of nutrition" means that the individual is unable to tolerate (swallow or absorb) any other form of oral nutrition in instances when more than 75% of the individual's daily caloric intake is received from nutritional supplements.~~

B. General requirements and conditions.

1. a. All medically necessary supplies and equipment shall be covered. Unusual amounts, types, and duration of usage must be authorized by DMAS in accordance with published policies and procedures. When determined to be cost effective by DMAS, payment may be made for rental of the equipment in lieu of purchase.

b. No provider shall have a claim of ownership on DME reimbursed by Virginia Medicaid once it has been delivered to the Medicaid individual. Providers shall only

be permitted to recover DME, for example, when DMAS determines that it does not fulfill the required medically necessary purpose as set out in the Certificate of Medical Necessity, when there is an error in the ordering practitioner's CMN, or when the equipment was rented.

2. DME providers shall adhere to all applicable federal and state laws and regulations and DMAS policies for DME ~~and supplies~~. DME providers shall comply with all other applicable Virginia laws and regulations requiring licensing, registration, or permitting. Failure to comply with such laws and regulations that are required by ~~such~~ a licensing agency ~~or agencies~~ shall result in denial of coverage for DME ~~or supplies~~.

3. DME ~~products or supplies~~ must be furnished pursuant to a properly completed Certificate of Medical Necessity (CMN) (DMAS-352). In order to obtain Medicaid reimbursement, specific fields of the DMAS-352 form shall be completed as specified in 12VAC30-60-75.

4. DME ~~and supplies~~ shall be ordered by the licensed practitioner and shall be related to medical treatment of the Medicaid individual. The complete DME order shall be recorded on the CMN for Medicaid individuals to receive such services. In the absence of a different effective period determined by DMAS or its designated agent, the CMN shall be valid for a maximum period of six months for Medicaid individuals younger than 21 years of age. In the absence of a different effective period determined by DMAS or its designated agent, the maximum valid time period for CMNs for Medicaid individuals 21 years of age and older shall be 12 months. The validity of the CMN shall terminate when the individual's medical need for the prescribed DME ~~or supplies~~ no longer exists as determined by the licensed practitioner.

5. DME shall be furnished exactly as ordered by the licensed practitioner who signed the CMN. The CMN and any supporting verifiable documentation shall be fully completed, signed, and dated by the licensed practitioner, and in the DME provider's possession within 60 days from the time the ordered DME ~~and supplies are~~ is initially furnished by the DME provider. Each component of the DME ~~items~~ shall be specifically ordered on the CMN by the licensed practitioner.

6. The CMN shall not be changed, altered, or amended after the licensed practitioner has signed it. If the individual's condition indicates that changes in the ordered DME ~~or supplies are~~ is necessary, the DME provider shall obtain a new CMN. All new CMNs shall be signed and dated by the licensed practitioner within 60 days from the time the ordered supplies are furnished by the DME provider.

7. DMAS or its designated agent shall have the authority to determine a different ~~(from those specified above)~~ length of time from those specified in subdivisions 4, 5, and 6 of this subsection that a CMN may be valid based on medical documentation submitted on the CMN. The CMN may be completed by the DME provider or other appropriate health care professionals, but it shall be signed and dated by the licensed practitioner, as specified in subdivision 5 of this subsection. Supporting documentation may be attached to the CMN but the licensed practitioner's entire order for DME ~~and supplies~~ shall be on the CMN.

8. The DME provider shall retain a copy of the CMN and all supporting verifiable documentation on file for ~~DMAS'~~ purposes of the DMAS post payment audit review ~~purposes~~. DME providers shall not create or revise CMNs or supporting documentation for this service after the initiation of the post payment review audit process. Licensed practitioners shall not complete, sign, or date CMNs once the post payment audit review has begun.

9. The DME provider shall be responsible for knowledge of items requiring prior authorization and the limitation on the provision of certain items as described in the Virginia Medicaid Durable Medical Equipment and Supplies Manual, Appendix B. ~~The~~ Appendix B shall be the official listing of all items covered through the Virginia Medicaid DME program and ~~lists~~ list the service limits, items that require prior authorization, billing units, and reimbursement rates.

10. The DME provider shall be required to make affirmative contact with the individual or his caregiver and document the interaction prior to the next month's delivery and prior to the recertification CMN to assure that the appropriate quantity, frequency, and product are provided to the individual.

11. Supporting documentation, added to a completed CMN, shall be allowed to further justify the medical need for DME. Supporting documentation shall not replace the requirement for a properly completed CMN. The dates of the supporting documentation shall coincide with the dates of service on the CMN, and the supporting documentation shall be ~~fully~~ signed and dated by the licensed practitioner.

C. ~~Effective July 1, 2010, the~~ The billing unit for incontinence supplies (such as diapers, pull-ups, and panty liners) shall be by each product. For example, if the incontinence supply being provided is diapers, the billing unit would be by individual diaper, rather than a case of diapers. Prior authorization shall be required for incontinence supplies provided in quantities greater than the allowable service limit per month.

D. Supplies, equipment, or appliances that are not covered include~~, but shall not be limited to,~~ the following:

1. Space conditioning equipment, such as room humidifiers, air cleaners, and air conditioners;

2. DME ~~and supplies~~ for any hospital or nursing facility resident, except ventilators and associated supplies or specialty beds for the treatment of wounds consistent with DME criteria for nursing facility residents that have been prior approved by ~~the~~ DMAS ~~central office~~ or designated agent;

3. Furniture or appliances not defined as medical equipment (such as blenders, bedside tables, mattresses other than for a hospital bed, pillows, blankets or other bedding, special reading lamps, chairs with special lift seats, hand-held shower devices, exercise bicycles, and bathroom scales);

4. Items that are only for the individual's comfort and convenience or for the convenience of those caring for the individual (e.g., a hospital bed or mattress because the individual does not have a bed; wheelchair trays used as a desk surface); mobility items used in addition to primary assistive mobility aide for ~~caregiver's or individual's~~ the convenience of the individual or his caregiver (e.g., an electric wheelchair plus a manual chair); and cleansing wipes;

5. Prosthesis, except for artificial arms, legs, and their supportive devices, which shall be prior authorized by ~~the~~ DMAS ~~central office~~ or designated agent;

6. Items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (e.g., dentifrices; toilet articles; shampoos that do not require a licensed practitioner's prescription; dental adhesives; electric toothbrushes; cosmetic items, soaps, and lotions that do not require a licensed practitioner's prescription; sugar and salt substitutes; and support stockings);

7. Orthotics, including braces, diabetic shoe inserts, splints, and supports;

8. Home or vehicle modifications;

9. Items not suitable for or not used primarily in the home setting (e.g., car seats, equipment to be used while at school, etc.);

10. Equipment for which the primary function is vocationally or educationally related (e.g., computers, environmental control devices, speech devices, etc.);

11. Diapers for routine use by children younger than three years of age who have not yet been toilet trained;

12. Equipment or items that are not suitable for use in the home; and

13. Equipment or items that the Medicaid individual or his caregiver is unwilling or unable to use in the home.

E. For coverage of blood glucose meters for pregnant women, refer to 12VAC30-50-510.

F. Coverage of home infusion therapy.

1. Home infusion therapy shall be defined as the ~~intravenous (I.V.)~~ administration of fluids, drugs, chemical agents, or nutritional substances to ~~recipients~~ individuals through intravenous (I.V.) therapy or an implantable pump in the home setting. DMAS shall reimburse for these services, supplies, and drugs on a service day rate methodology established in 12VAC30-80-30. The therapies to be covered under this policy shall be: hydration therapy, chemotherapy, pain management therapy, drug therapy, and total parenteral nutrition (TPN). All the therapies that meet criteria shall be covered and do not require prior authorization. The established service day rate shall reimburse for all services delivered in a single day. There shall be no additional reimbursement for special or extraordinary services. In the event of incompatible drug administration, a separate HCPCS code shall be used to allow for rental of a second infusion pump and purchase of an extra administration tubing. When applicable, this code may be billed in addition to the other service day rate codes. There shall be documentation to support the use of this code on the I.V. Implementation Form. Proper documentation shall include the need for pump administration of the medications ordered, frequency of administration to support that they are ordered simultaneously, and indication of incompatibility.

2. The service day rate payment methodology shall be mandatory for reimbursement of all I.V. therapy services except for the individual who is enrolled in the Technology Assisted Waiver.

3. The following limitations shall apply to this service:

a. This service must be medically necessary to treat an individual's medical condition. The service must be ordered and provided in accordance with accepted medical practice. The service must not be desired solely for the convenience of the individual or the individual's caregiver.

b. In order for Medicaid to reimburse for this service, the individual shall:

(1) Reside in either a private home or a domiciliary care facility, such as an assisted living facility. Because the reimbursement for DME is already provided under institutional reimbursement, individuals in hospitals, nursing facilities, rehabilitation centers, and other institutional settings shall not be covered for this service;

(2) Be under the care of a licensed practitioner who prescribes the home infusion therapy and monitors the progress of the therapy;

(3) Have body sites available for peripheral intravenous catheter or needle placement or have a central venous access; and

(4) Be capable of either self-administering such therapy or have a caregiver who can be adequately trained, is capable of administering the therapy, and is willing to safely and efficiently administer and monitor the home infusion therapy. The caregiver must be willing to and be capable of following appropriate teaching and adequate monitoring. In cases where the individual is incapable of administering or monitoring the prescribed therapy and there is no adequate or trained caregiver, it may be appropriate for a home health agency to administer the therapy.

G. The DME ~~and supply~~ vendor shall provide the equipment and supplies as prescribed by the licensed practitioner on the CMN. Orders shall not be changed unless the vendor obtains a new CMN, which includes the licensed practitioner's signature, prior to ordering the equipment or supplies or providing the equipment or supplies to the individual.

H. Medicaid shall not provide reimbursement to the DME ~~and supply~~ vendor for services that are provided ~~either:~~ (i) prior to the date prescribed by the licensed practitioner; (ii) prior to the date of the delivery; or (iii) when services are not provided in accordance with ~~DMAS'~~ DMAS published regulations and guidance documents. If reimbursement is denied for one or all of these reasons, the DME ~~and supply~~ vendor shall not bill the Medicaid individual for the service that was provided.

I. The following criteria shall be satisfied through the submission of adequate and verifiable documentation on the CMN satisfactory to DMAS. Medically necessary DME ~~and supplies~~ shall be:

1. Ordered by the licensed practitioner on the CMN;

2. A reasonable and necessary part of the individual's treatment plan;

3. Consistent with the individual's diagnosis and medical condition, particularly the functional limitations and symptoms exhibited by the individual;

4. Not furnished solely for the convenience, safety, or restraint of the individual, the family or caregiver, the licensed practitioner, or other licensed practitioner or supplier;

5. Consistent with generally accepted professional medical standards (i.e., not experimental or investigational); and

6. Furnished at a safe, effective, and cost-effective level suitable for use in the individual's home environment.

J. Medical documentation shall provide DMAS or the designated agent with evidence of the individual's DME needs. Medical documentation may be recorded on the CMN or evidenced in the supporting documentation attached to the CMN. The following applies to the medical justification necessary for all DME services regardless of whether prior authorization is required. The documentation is necessary to identify:

1. The medical need for the requested DME;

2. The diagnosis related to the reason for the DME request;

3. The individual's functional limitation and its relationship to the requested DME;

4. How the DME service will treat the individual's medical condition;

5. For expendable supplies, the quantity needed and the medical reason the requested amount is needed;

6. The frequency of use to describe how often the DME is used by the individual;

7. The estimated duration of use of the equipment (rental and purchased);

8. Any other treatment being rendered to the individual relative to the use of DME ~~or supplies~~;

9. How the needs were previously met, identifying changes that have occurred that necessitate the DME;

10. Other alternatives tried or explored and a description of the success or failure of these alternatives;

11. How the DME service is required in the individual's home environment; and

12. The individual's or his caregiver's ability, willingness, and motivation to use the DME.

K. DME provider responsibilities. To receive reimbursement, the DME provider shall, at a minimum, perform the following:

1. Verify the individual's current Medicaid eligibility;

2. Determine whether the ordered ~~item or~~ items are a covered service and require prior authorization;

3. Deliver all ~~of the item or~~ items ordered by the licensed practitioner;

4. Deliver only the quantities ordered by the licensed practitioner on the CMN and prior authorized by DMAS if required;

5. Deliver only the ~~item or~~ items for the periods of service covered by the licensed practitioner's order and prior authorized, if required, by DMAS;

6. Maintain a copy of the licensed practitioner's signed CMN and all verifiable supporting documentation for all DME ~~and supplies~~ ordered;

7. Document and justify the description of services (i.e., labor, repairs, maintenance of equipment);

8. Document and justify the medical necessity, frequency, and duration for all items and supplies as set out in the Medicaid DME guidance documents;

9. Document all DME ~~and supplies~~ provided to an individual in accordance with the licensed practitioner's orders. The delivery ~~ticket/proof~~ ticket or proof of delivery shall document the requirements as stated in subsection L of this section~~.~~; and

10. ~~Documentation~~ Meet documentation requirements for the use of DME billing codes that have Individual Consideration (IC) indicated as the reimbursement fee ~~shall~~ to include a complete description of the ~~item or~~ items, a copy of the ~~supply invoice or~~ supplies invoices or the manufacturer's cost information, and all discounts that were received by the DME provider. Additional information regarding requirements for the IC reimbursement process can be found in the relevant agency guidance document.

L. Proof of delivery.

1. The delivery ticket shall contain the following information:

a. The Medicaid individual's name and Medicaid number or date of birth or a unique identifier (e.g., an individual's medical record number);

b. A detailed description of the ~~item or~~ items being delivered, including the product ~~name or~~ names and ~~brand or~~ brands;

c. The serial ~~number or~~ numbers or the product numbers of the DME ~~or supplies~~, if available;

d. The quantity delivered; and

e. The dated signature of either the individual or his caregiver.

2. If a commercial shipping service is used, the DME provider's records shall reference, in addition to the information required in subdivision 1 of this subsection, the delivery service's package identification ~~number or~~ numbers with a copy of the delivery service's delivery ticket, which may be printed from the online record on the delivery service's website.

a. The delivery service's ticket identification ~~number or~~ numbers shall be recorded on the DME provider's delivery documentation.

b. The service delivery documentation may be substituted for the individual's signature as proof of delivery.

c. In the absence of a delivery service's ticket, the DME provider shall obtain the individual's or his caregiver's dated signature on the DME provider's delivery ticket as proof of delivery.

3. Providers may use a postage-paid delivery invoice from the individual or his caregiver as a form of proof of delivery. The descriptive information concerning the ~~item or~~ items delivered, as described in subdivisions 1 and 2 of this subsection, as well as the required signature and date from either the individual or his caregiver, shall be included on this invoice.

4. DME providers shall make affirmative contact with the individual or his caregiver and document the interaction prior to dispensing repeat orders or refills to ensure that:

a. The item is ~~still~~ needed;

b. The quantity, frequency, and product are ~~still~~ appropriate; and

c. The individual ~~still~~ resides at the address in the provider's records.

5. The DME provider shall contact the individual prior to each delivery. This contact shall not occur any sooner than seven days prior to the delivery or shipping date and shall be documented in the individual's record.

6. DME providers shall not deliver refill orders sooner than five days prior to the end of the usage period.

7. Providers shall not bill for dates of service prior to delivery. The provider shall confirm receipt of the DME ~~or supplies~~ via the shipping service record showing the item was delivered prior to billing. Claims for refill orders shall be the start of the new usage period and shall not overlap with the previous usage period.

8. The purchase prices listed in the Virginia Medicaid Durable Medical Equipment and Supplies Manual, Appendix B, represent the amount DMAS shall pay for newly purchased equipment. Unless otherwise approved by DMAS or its designated agent, documentation on the delivery ticket shall reflect that the purchased equipment is new upon the date of the service billed. Any warranties associated with new equipment shall be effective from the date of the service billed. Since Medicaid is the payer of last resort, the DME provider shall explore coverage available under the warranty prior to requesting coverage of repairs from DMAS.

9. DME ~~and supplies~~ for home use for an individual being discharged from a hospital or nursing facility may be delivered to the hospital or nursing facility one day prior to the discharge. However, the DME provider's claim date of service shall not begin prior to the date of the individual's discharge from the hospital or nursing facility.

M. Enteral nutrition products. Coverage of enteral nutrition (EN) that does not include a legend drug shall be limited to when the nutritional supplement ~~is the sole source form of~~

~~nutrition,~~ is administered orally or through a nasogastric or gastrostomy tube~~,~~ and is necessary to treat a medical condition. DMAS shall provide coverage for nutritional supplements for enteral feeding only if the nutritional supplements are not available over the counter. Additionally, DMAS shall cover medical foods that are (i) specific to inherited diseases [~~,~~ and] metabolic disorders [~~, PKU, etc.~~]; (ii) not generally available in grocery stores, health food stores, or the retail section of a pharmacy; and (iii) not used as food by the general population. Coverage of EN shall not include the provision of routine infant formula or feedings as meal replacement only. Coverage of medical foods shall not extend to regular foods prepared to meet particular dietary restrictions, limitations, or needs, such as meals designed to address the situation of individuals with diabetes or heart disease. A nutritional assessment shall be required for all ~~recipients~~ individuals for whom nutritional supplements are ordered.

1. General requirements and conditions.

a. Enteral nutrition products shall only be provided by enrolled DME providers.

b. DME providers shall adhere to all applicable DMAS policies, laws, and regulations. DME providers shall also comply with all other applicable Virginia laws and regulations requiring licensing, registration, or permitting. Failure to comply with such laws and regulations shall result in denial of coverage for enteral nutrition that is regulated by such licensing agency ~~or agencies~~.

2. Service units and service limitations.

a. DME ~~and supplies~~ shall be furnished pursuant to the Certificate of Medical Necessity ~~(CMN)~~ (DMAS-352).

b. The DME provider shall include documentation related to the nutritional evaluation findings on the CMN and may include supplemental information on any supportive documentation submitted with the CMN.

c. DMAS shall reimburse for medically necessary formulae and medical foods when used under a licensed practitioner's direction to augment dietary limitations or provide primary nutrition to individuals via enteral or oral feeding methods.

d. The CMN shall contain a licensed practitioner's order for the enteral nutrition products that are medically necessary to treat the diagnosed condition and the individual's functional limitation. The justification for enteral nutrition products shall be demonstrated in the written documentation either on the CMN or on the attached supporting documentation. The CMN shall be valid for a maximum period of six months.

e. Regardless of the amount of time that may be left on a six-month approval period, the validity of the CMN shall terminate when the individual's medical need for the prescribed enteral nutrition products ~~either~~ ends, as determined by the licensed practitioner~~, or when the enteral nutrition products are no longer the primary source of nutrition~~.

f. A face-to-face nutritional assessment completed by trained clinicians (e.g., physician, physician assistant, nurse practitioner, registered nurse, or a registered dietitian) shall be completed as required documentation of the need for enteral nutrition products.

~~g. The CMN shall not be changed, altered, or amended after the licensed practitioner has signed it. As indicated by the individual's condition, if changes are necessary in the ordered enteral nutrition products, the DME provider shall obtain a new CMN.~~

~~(1) New CMNs shall be signed and dated by the licensed practitioner within 60 days from the time the ordered enteral nutrition products are furnished by the DME provider.~~

~~(2) The order shall not be backdated to cover prior dispensing of enteral nutrition products. If the order is not signed within 60 days of the service initiation, then the date the order is signed becomes the effective date.~~

~~h.~~ g. Prior authorization of enteral nutrition products shall not be required. The DME provider shall assure that there is a valid CMN (i) completed every six months in accordance with subsection B of this section and (ii) on file for all Medicaid individuals for whom enteral nutrition products are provided.

(1) The DME provider is further responsible for assuring that enteral nutrition products are provided in accordance with DMAS reimbursement criteria in 12VAC30-80-30 A 6.

(2) Upon post payment review, DMAS or its designated contractor may deny reimbursement for any enteral nutrition products that have not been provided and billed in accordance with ~~these regulations~~ this section and DMAS policies.

~~i.~~ h. DMAS shall have the authority to determine that the CMN is valid for less than six months based on medical documentation submitted.

3. Provider responsibilities.

a. The DME provider shall provide the enteral nutrition products as prescribed by the licensed practitioner on the CMN. Physician orders shall not be changed unless the DME provider obtains a new CMN prior to ordering or providing the enteral nutrition products to the individual.

b. The licensed practitioner's order ~~(CMN)~~ on the CMN shall ~~state that the enteral nutrition products are the sole source of nutrition for the individual and~~ specify either a

brand name of the enteral nutrition product being ordered or the category of enteral nutrition products that must be provided. If a licensed practitioner orders a specific brand of enteral nutrition product, the DME provider shall supply the brand prescribed. The licensed practitioner order shall include the daily caloric intake and the route of administration for the enteral nutrition product. ~~Additional supporting~~ Supporting documentation may be attached to the CMN, but the entire licensed practitioner's order shall be on the CMN.

c. The CMN shall be signed and dated by the licensed practitioner within 60 days of the CMN begin service date. The order shall not be backdated to cover prior dispensing of enteral nutrition products. If the CMN is not signed and dated by the licensed practitioner within 60 days of the CMN begin service date, the CMN shall ~~not~~ become valid ~~until the~~ on the date of the licensed practitioner's signature.

d. The CMN shall include all of the following elements:

(1) Height of individual (or length for pediatric patients);

(2) Weight of individual. For initial assessments, indicate the individual's weight loss over time;

(3) Tolerance of enteral nutrition product (e.g., is the individual experiencing diarrhea, vomiting, constipation). This element is only required if the individual is already receiving enteral nutrition products;

~~(4) Indication of whether or not the enteral nutrition product is the primary or sole source of nutrition;~~

~~(5)~~ (4) Route of administration; and

~~(6)~~ (5) The daily caloric order and the number of calories per package or can~~; and~~.

~~(7) Extent to which the quantity of the enteral nutrition product is available through WIC, the Special Supplemental Nutrition Program for Women, Infants and Children.~~

~~e. The DME provider shall retain a copy of the CMN and all supporting verifiable documentation on file for DMAS' post payment review purposes. DME providers shall not create or revise CMNs or supporting documentation for this service after the initiation of the post payment review process. Licensed practitioners shall not complete or sign and date CMNs once the post payment review has begun.~~

~~f.~~ e. Medicaid reimbursement shall be recovered when the enteral nutrition products have not been ordered on the CMN. Supporting documentation is allowed to justify the medical need for enteral nutrition products. Supporting documentation shall not replace the requirement for a properly completed CMN. The dates of the supporting documentation shall coincide with the dates of service on the CMN, and the supporting documentation shall be ~~fully~~ signed and dated by the licensed practitioner.

~~g. To receive reimbursement, the DME provider shall:~~

~~(1) Deliver only the item or items and quantity or quantities ordered by the licensed practitioner and approved by DMAS or the designated prior or service authorization contractor;~~

~~(2) Deliver only the item or items for the periods of service covered by the licensed practitioner's order and approved by DMAS or the designated prior or service authorization contractor;~~

~~(3) Maintain a copy of the licensed practitioner's order and all verifiable supporting documentation for all DME ordered; and~~

~~(4) Document all supplies provided to an individual in accordance with the licensed practitioner's orders. The delivery ticket must document the individual's name and Medicaid number, the date of delivery, the item or items that were delivered, and the quantity delivered.~~

~~h.~~ N. Reimbursement denials.

1. DMAS shall deny payment to the DME provider if any of the following occur:

~~(1)~~ a. Absence of a current, fully completed CMN appropriately signed and dated by the licensed practitioner;

~~(2)~~ b. Documentation does not verify that the item was provided to the individual;

~~(3)~~ c. Lack of medical documentation, signed by the licensed practitioner to justify the ~~enteral nutrition products~~ DME; or

~~(4)~~ d. Item is noncovered or does not meet DMAS criteria for reimbursement.

~~i.~~ 2. If reimbursement is denied by Medicaid, the DME provider shall not bill the Medicaid individual for the service that was provided.

O. Replacement DME following [~~natural~~] a disaster.

1. Medicaid individuals who (i) live in [~~a disaster area, (ii) can prove they were present in the disaster area when the disaster occurred, or (iii) live in~~] areas that have been declared by the Governor [~~as a disaster or emergency area~~ to be subject to a state of emergency] in accordance with § 44-146.16 of the Code of Virginia, [(ii) live in Virginia and were present in an area of the state that has been declared by the Governor to be subject to a state of emergency in accordance with § 44-146.16 of the Code of Virginia, or (iii) live in Virginia and can prove they were present in a state or federally declared disaster or

emergency area in another state when the disaster occurred,] and who need to replace DME previously approved by Medicaid that were damaged as a result of the disaster or emergency, may contact a DME provider (either enrolled in fee-for-service Medicaid or a Medicaid health plan) of their choice to obtain a replacement.

a. If the individual's DME provider has gone out of business or is unable to provide replacement DME, the individual may choose another provider who is enrolled as a DME provider with Medicaid or the Medicaid health plan. The original authorization will be canceled or amended and a new authorization will be provided to the new DME provider.

b. The DME provider shall submit a signed statement from the Medicaid individual requesting a change in DME provider in accordance with the declaration by the Governor as a state of emergency due to a [~~natural~~] disaster and giving the Medicaid individual's current place of residence.

c. The individual can contact the state Medicaid office or the Medicaid health plan to get help finding a new DME provider.

2. For Medicaid enrolled providers, the provider shall make a request to the service authorization contractor; however, a new CMN and medical documentation is not required unless the DME is beyond the service limit (e.g., the individual has a wheelchair that is older than five years). The provider shall keep documentation in the individual's record that includes the individual's current place of residence and states that the original DME was lost due to the [~~natural~~] disaster.

VA.R. Doc. No. R17-5024; Filed December 10, 2019, 11:21 a.m.

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TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF NURSING

Emergency Regulation

Title of Regulation: **18VAC90-40. Regulations for Prescriptive Authority for Nurse Practitioners (adding 18VAC90-40-122).**

Statutory Authority: §§ 54.1-2400 and 54.1-3408.02 of the Code of Virginia.

Effective Dates: December 23, 2019, through June 22, 2021.

Agency Contact: Jay P. Douglas, R.N., Executive Director, Board of Nursing, 9960 Mayland Drive, Suite 300, Richmond, VA 23233-1463, telephone (804) 367-4520, FAX (804) 527-4455, or email jay.douglas@dhp.virginia.gov.

Preamble:

Section 2.2-4011 B of the Code of Virginia states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of § 2.2-4006 A 4 of the Code of Virginia.

The amendments add a section regarding electronic prescribing. Consistent with the Code of Virginia, beginning July 1, 2020, a prescription for a controlled substance that contains an opioid is required to be issued as an electronic prescription. The regulation also provides a one-time waiver of this requirement for a maximum of one year due to demonstrated economic hardship on the part of a prescriber, technological limitations beyond the prescriber's control, or other exceptional circumstances demonstrated by the prescriber.

18VAC90-40-122. Waiver for electronic prescribing.

A. Beginning July 1, 2020, a prescription for a controlled substance that contains an opioid shall be issued as an electronic prescription consistent with § 54.1-3408.02 of the Code of Virginia.

B. Upon written request, the boards may grant a one-time waiver of the requirement of subsection A of this section, for a period not to exceed one year, due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the prescriber, or other exceptional circumstances demonstrated by the prescriber.

VA.R. Doc. No. R20-6115; Filed December 23, 2019, 3:38 p.m.

BOARD OF PHARMACY

Emergency Regulation

Title of Regulation: **18VAC110-60. Regulations Governing Pharmaceutical Processors (amending 18VAC110-60-10, 18VAC110-60-20, 18VAC110-60-40 through 18VAC110-60-90, 18VAC110-60-130, 18VAC110-60-160, 18VAC110-60-170, 18VAC110-60-190 through 18VAC110-60-230, 18VAC110-60-300, 18VAC110-60-310, 18VAC110-60-320; adding 18VAC110-60-251).**

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

Effective Dates: December 30, 2019, through June 29, 2021.

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.

Preamble:

Section 2.2-4011 B of the Code of Virginia states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of § 2.2-4006 A 4 of the Code of Virginia.

Pursuant to Chapter 690 of the 2019 Acts of Assembly, the amendments provide for (i) registered agents for patients certified to receive cannabidiol oil or THC-A oil, (ii) changes to whom may be employed to cultivate and extract chemicals from Cannabis plants, and (iii) wholesale distribution of oils between 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.

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

"Board" means the Board of Pharmacy.

"Certification" means a written statement, consistent with requirements of § 54.1-3408.3 of the Code of Virginia, issued by a practitioner for the use of 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 registered agent or until the Cannabis, including the seeds, parts of plants, and extracts, are destroyed. The electronic tracking system shall include, at a minimum, a central inventory management system and standard and ad hoc reporting functions as required by the board and shall be capable of otherwise satisfying required recordkeeping.

"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, or registered agent.

"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, or registered agent.

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

D. Pharmaceutical processor permit.

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

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, or registered agent 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, or registered agent.

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 patient, or the patient's parent or legal guardian, may choose a registered agent to receive cannabidiol oil or THC-A oil on behalf of the patient. An individual may serve as a registered agent for no more than two registered patients. For a registration application to be approved, the following shall be submitted:

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

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

3. Payment of the applicable fee; and

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

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

~~C.~~ D. Patients, parents, ~~and~~ legal guardians, and registered agents 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, or registered agent registration application.

A. The board may deny an application or renewal of the registration of a qualifying patient, parent, ~~or~~ legal guardian, or registered agent 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, or registered agent 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, or registered agent applicant, the board shall provide the applicant with notice of the grounds for the denial and shall inform the applicant of the right to request a hearing pursuant to § 2.2-4019 of the Code of Virginia.

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

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

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

~~D.~~ E. If a patient, parent, ~~or~~ legal guardian, or registered agent becomes aware of the loss, theft, or destruction of the registration of such patient, parent, ~~or~~ legal guardian, or registered agent, the ~~patient, parent, or legal guardian~~ registrant shall notify the board not later than five business days after becoming aware of the loss, theft, or destruction, and submit the fee for a replacement registration. The board shall 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, or registered agents.

A. A registered patient, parent, or legal guardian or a registered agent shall exercise reasonable caution to transport and 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 or a registered agent shall dispose of all usable cannabidiol oil or THC-A oil in possession of the registered patient, parent, or legal ~~guardian's possession~~ guardian or registered agent 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 or a registered agent 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, or registered agent registration.

The board may revoke or suspend the registration of a registrant (i.e., a patient, parent, ~~or~~ legal guardian, or registered agent) under the following circumstances:

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

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

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

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

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

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

8. The registration of the ~~patient, parent, or legal guardian~~ registrant was lost, stolen, or destroyed, and the ~~patient, parent, or legal guardian~~ registrant 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~~ registrant failed to notify the board of a change in registration information or

notified the board of such change more than ~~14~~ 15 days after the change; or

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

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~~ the board's 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~~ a processor may begin cultivation of Cannabis. 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.

18VAC110-60-160. 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, or registered agent, except as required for a registered agent to act on behalf of a patient;

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 or the registered agent; 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 pharmaceutical processor may employ individuals who may have less than two years of experience to perform (i) cultivation-related duties under the supervision of an individual who has received a degree in horticulture or a certification recognized by the board or who has at least two years of experience cultivating plants and (ii) extraction-related duties under the supervision of an individual who has a degree in chemistry or pharmacology or at least two years of experience extracting chemicals from plants.

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

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

~~J.~~ K. 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.

18VAC110-60-190. 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, or registered agent 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 or registered agents:

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 only 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 or registered agent, 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, or to a patient's registered agent. 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 or a registered agent, 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~~ are 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 or registered agents 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 and registered agents 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, and registered agents if applicable, 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, except for the wholesale distribution of cannabidiol oil or THC-A oil products between pharmaceutical processors;

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; or a registered agent 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 or a registered agent or an agent of the processor may deliver cannabidiol oil or THC-A oil to the registered patient or in accordance with 18VAC110-60-310 A. Products may also be wholesale distributed between pharmaceutical processors.

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 or the registered agent 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 or the registered agent 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.

18VAC110-60-251. Wholesale distribution of cannabidiol oil and THC-A oil products.

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

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

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

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

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. After processing and before dispensing the cannabidiol oil or THC-A oil product, a pharmaceutical processor shall make a sample available from each batch of product for a laboratory to (i) test for microbiological contaminants, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue and (ii) conduct an active ingredient analysis and terpenes profile. The sample size shall be a statistically valid sample as determined by the board.

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

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

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

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

1. For purposes of the microbiological test, a 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 sample of cannabidiol oil or THC-A oil product shall be deemed to have passed if it meets the following standards:

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

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

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

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

5. For purposes of the active ingredient analysis, a sample of the cannabidiol oil or THC-A oil product shall be tested for:

a. Tetrahydrocannabinol (THC);

b. Tetrahydrocannabinol acid (THC-A);

c. Cannabidiols (CBD); and

d. Cannabidiolic acid (CBDA).

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

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

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

I. Each pharmaceutical processor shall have such laboratory results available upon request to registered patients, parents, or legal guardians or registered agents 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 or to a registered agent for a specific patient.

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, or registered agent. The pharmacist or pharmacy technician shall verify in the Virginia Prescription Monitoring Program of the Department of Health Professions or other program recognized by the board that 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 three years a paper or electronic copy of the current written certification that provides an exact image of the document that is clearly legible.

3. Prior to any subsequent dispensing, the pharmacist, pharmacy technician, or delivery agent shall view the current written certification and a current photo identification and current registration of the patient, parent, ~~or~~ legal guardian, or registered agent 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 or registered agent shall receive more than a 90-day supply of cannabidiol oil or THC-A oil for a patient 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 brand name of cannabidiol oil or THC-A oil that was registered with the board pursuant to 18VAC110-60-285 and its strength;

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

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

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

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

a. Tetrahydrocannabinol (THC);

b. Tetrahydrocannabinol acid (THC-A);

c. Cannabidiol (CBD); and

d. Cannabidiolic acid (CBDA);

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

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

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

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

11. The name or initials of the dispensing pharmacist;

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

13. Any necessary cautionary statement; and

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

D. 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.

E. 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).

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

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

H. A pharmacist shall document a registered patient's self-assessment of the effects of 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 three years from the date of dispensing and such documentation shall be made available in accordance with regulation.

I. A pharmacist shall exercise professional judgment to determine whether to dispense cannabidiol oil or THC-A oil to a registered patient, parent, or legal guardian or registered agent if the pharmacist suspects that dispensing cannabidiol oil or THC-A oil to the registered patient, parent, or legal guardian or registered agent 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, the patient's registered agent, or appropriate family member if the patient is deceased or is unable to fully comprehend the communication. The communication shall describe methods of correcting the dispensing error or reducing the negative impact of the error on the qualifying patient; and

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

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 or registered agent, where applicable, and the practitioner who certified the patient;

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

e. Recommended changes to pharmaceutical processor 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.

VA.R. Doc. No. R20-6129; Filed December 20, 2019, 1:22 p.m.

TITLE 21. SECURITIES AND RETAIL FRANCHISING

STATE CORPORATION COMMISSION

Final Regulation

REGISTRAR'S NOTICE: The State Corporation Commission is claiming an exemption from the Administrative Process Act in accordance with § 2.2-4002 A 2 of the Code of Virginia, which exempts courts, any agency of the Supreme Court, and any agency that by the Constitution is expressly granted any of the powers of a court of record.

Title of Regulation: **21VAC5-110. Retail Franchising Act Rules (amending 21VAC5-110-55).**

Statutory Authority: §§ 12.1-13 and 13.1-572 of the Code of Virginia.

Effective Date: January 3, 2020.

Agency Contact: Tim O'Brien, Manager, Divisions of Securities and Retail Franchising, State Corporation Commission, Tyler Building, 9th Floor, P.O. Box 1197, Richmond, VA 23218, telephone (804) 371-9415, FAX (804) 371-9911, or email tim.obrien@scc.virginia.gov.

Summary:

The amendment requires franchisors to include with the franchise disclosure document three "state cover sheets" and a "state effective dates page" in accordance with the requirements of Part III B of the 2008 Franchise Registration and Disclosure Guidelines, as adopted in 2019, by the North American Securities Administrators Association, Inc.

AT RICHMOND, DECEMBER 19, 2019

COMMONWEALTH OF VIRGINIA, ex rel.

STATE CORPORATION COMMISSION

CASE NO. SEC-2019-00052

Ex Parte: In the matter of
Adopting a Revision to the Rules
Governing the Virginia Retail Franchising Act

ORDER ADOPTING AMENDED RULES

By order entered November 1, 2019 ("Order to Take Notice"), all interested parties were ordered to take notice that the State Corporation Commission ("Commission") would consider the adoption of a revision to Chapter 110 of Title 21 of the Virginia Administrative Code ("Regulations") entitled "Retail Franchising Act Rules." On November 5 and 6, 2019, the Division of Securities and Retail Franchising ("Division") sent the Order to Take Notice of the proposed amendments to the Regulations to all interested parties pursuant to the Virginia Retail Franchising Act ("Act"), § 13.1-557 et seq. of the Code of Virginia.

Section 55 of Chapter 110 of the Act's Rules sets forth the requirements for the content and format of a franchisor's Franchise Disclosure Document ("FDD"), which must be provided to a prospective franchisee and approved by the Division prior to the sale of a franchise in Virginia. The proposed amendments to the Regulations require franchisors to include with the FDD three "State Cover Sheets" and a "State Effective Dates Page" in accordance with the requirements of Part III B of the North American Securities Administrators Association, Inc. 2008 Franchise Registration and Disclosure Guidelines, as adopted in 2019.

The Order to Take Notice described the proposed amendments to Rule 21 VAC 5-110-55 (C) of the Act's Rules and afforded interested parties an opportunity to file written comments or requests for hearing by December 9, 2019.

On November 7, 2019, franchisor Precision Door Service filed a comment with the Commission supporting the adoption of the proposed amendments to the Regulations.[1] Precision Door Service did not request a hearing, and no other comments were filed, nor were any requests for hearing made in this matter.

NOW THE COMMISSION, upon consideration of the proposed amendment, the comments received, the recommendation of the Division, and the record in this case, finds that the proposed amendments to the Regulations should be adopted.

Accordingly, IT IS ORDERED THAT:

(1) The proposed Regulations are attached hereto, made a part hereof, and are hereby ADOPTED effective January 3, 2020.

(2) This matter is dismissed from the Commission's docket, and the papers herein shall be placed in the file for ended causes.

AN ATTESTED COPY of this Order shall be sent by regular mail by the Division to: George Payor, Esquire,

Precision Door Service, 2395 S. Washington Avenue, Suite 5, Titusville, Florida 32780; and copies also shall be sent to the Commission's Division of Information Resources and the Commission's Office of General Counsel.

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[1]Doc. Con. Cen. No. 191110287.

21VAC5-110-55. The Franchise Disclosure Document.

A. Format. The Franchise Disclosure Document must be prepared in accordance with §§ 436.3 through 436.5 of the Federal Trade Commission Franchise Rule (16 CFR 436.3 through 436.5), subject to the modifications set forth in subsections B and C of this section.

B. Financial statements. Notwithstanding § 436.5(u)(2) of the Federal Trade Commission Franchise Rule (16 CFR 436.5), a start-up franchisor in its first partial or full fiscal year selling franchises shall provide an opening balance sheet that has been audited by an independent certified public accountant using generally accepted United States auditing standards.

C. State cover ~~page~~ sheets and effective dates page. The Franchise Disclosure Document shall include the ~~following state cover page prepared in accordance with this subsection, which must immediately follow the Federal Trade Commission required cover page:~~

~~1. State the following legend:~~

~~STATE COVER PAGE~~

~~Your state may have a franchise law that requires a franchisor to register or file with a state franchise administrator before offering or selling in your state. REGISTRATION OF A FRANCHISE BY A STATE DOES NOT MEAN THAT THE STATE RECOMMENDS THE FRANCHISE OR HAS VERIFIED THE INFORMATION IN THIS DISCLOSURE DOCUMENT.~~

~~Call the state franchise administrator listed in Exhibit __ for information about the franchisor or about franchising in your state.~~

~~2. State the following:~~

~~MANY FRANCHISE AGREEMENTS DO NOT ALLOW YOU TO RENEW UNCONDITIONALLY AFTER THE INITIAL TERM EXPIRES. YOU MAY HAVE TO SIGN A NEW AGREEMENT WITH DIFFERENT TERMS AND CONDITIONS IN ORDER TO CONTINUE TO OPERATE YOUR BUSINESS. BEFORE YOU BUY, CONSIDER WHAT RIGHTS YOU HAVE TO RENEW YOUR FRANCHISE, IF ANY, AND WHAT TERMS YOU MIGHT HAVE TO ACCEPT IN ORDER TO RENEW.~~

~~3. If any of the following apply, state the following, using capital letters as shown:~~

~~Please consider the following RISK FACTORS before you buy this franchise:~~

~~THE FRANCHISE AGREEMENT REQUIRES YOU TO RESOLVE DISPUTES WITH US BY [LITIGATION/ARBITRATION/MEDIATION] ONLY IN [STATE]. OUT OF STATE [LITIGATION/ARBITRATION/MEDIATION] MAY FORCE YOU TO ACCEPT A LESS FAVORABLE SETTLEMENT FOR DISPUTES. IT MAY ALSO COST YOU MORE TO [LITIGATE/ARBITRATE/MEDIATE] WITH US IN [STATE] THAN IN YOUR OWN STATE.~~

~~THE FRANCHISE AGREEMENT STATES THAT [STATE] LAW GOVERNS THE AGREEMENT, AND THIS LAW MAY NOT PROVIDE THE SAME PROTECTIONS AND BENEFITS AS LOCAL LAW. YOU MAY WANT TO COMPARE THESE LAWS.~~

~~4. In addition to the above, disclose other risk factors required by the state administrator.~~

~~5. If one or more risk factors applies, also state:~~

~~THERE MAY BE OTHER RISKS CONCERNING THIS FRANCHISE.~~

~~6. If you use the services of a franchise broker or referral source, state the following:~~

~~We use the services of one or more FRANCHISE BROKERS or referral sources to assist us in selling our franchise. A franchise broker or referral source represents us, not you. We pay this person a fee for selling our franchise or referring you to us. You should be sure to do your own investigation of the franchise.~~

~~7. State the following:~~

~~Effective Date:~~

~~a. Leave the effective date blank until notified of effectiveness by the state administrator.~~

~~b. If an applicant is using a multistate disclosure document, the applicant may list multiple state effective dates together on a separate page that is to be inserted immediately following the state cover page.~~ state cover sheets and state effective dates page prepared in accordance with the requirements set forth in Part III B of the 2008 Franchise Registration and Disclosure Guidelines, as adopted May 19, 2019, by the North American Securities Administrators Association, Inc.

DOCUMENTS INCORPORATED BY REFERENCE (21VAC5-110)

2008 Franchise Registration and Disclosure Guidelines, adopted May 19, 2019, North American Securities Administrators Association, Inc.

VA.R. Doc. No. R20-6153; Filed December 19, 2019, 3:10 p.m.

TITLE 24. TRANSPORTATION AND MOTOR VEHICLES

COMMONWEALTH TRANSPORTATION BOARD

Final Regulation

REGISTRAR'S NOTICE: The Commonwealth Transportation Board is claiming an exemption from the Administrative Process Act in accordance with § 2.2-4002 B 2 of the Code of Virginia, which exempts regulations relating to the award or denial of state contracts, as well as decisions regarding compliance therewith.

Title of Regulation: **24VAC30-240. Certification Procedures for the Disadvantaged and Women-Owned Business Program (repealing 24VAC30-240-10).**

Statutory Authority: § 33.2-210 of the Code of Virginia.

Effective Date: February 5, 2020.

Agency Contact: Jo Anne P. Maxwell, Regulatory Coordinator, Policy Division, Department of Transportation, 11th Floor, 1401 East Broad Street, Richmond, VA 23219, telephone (804) 786-1830, FAX (804) 225-4700, or email joanne.maxwell@vdot.virginia.gov.

Summary:

The amendments repeal Certification Procedures for the Disadvantaged and Women-Owned Business Program, a regulation that sets out by description the requirements to be followed by firms seeking certification as a disadvantaged and women-owned business enterprise as a prerequisite for bidding on contracts awarded by the Commonwealth Transportation Board. The Department of Small Business and Supplier Diversity regulates this certification function, and 24VAC30-240 is not necessary and is therefore repealed.

VA.R. Doc. No. R20-6258; Filed December 20, 2019, 11:28 a.m.

EXECUTIVE ORDER NUMBER FORTY-SIX (2019)

Declaration of a State of Emergency for the Commonwealth of Virginia Due to Highway Damages from Flooding

Importance of the Issue

On this date, December 6, 2019, I declare a state of emergency to exist for the Commonwealth of Virginia due to flooding that affected roadways in the northern Virginia portions of the Commonwealth during July 5 to July 8, 2019.

The health and general welfare of the citizens require that state action be taken to help alleviate the conditions caused by this situation. The effects of this incident constitute a disaster wherein human life and public and private property are imperiled, as described in § 44-146.16 of the Code of Virginia.

Therefore, by virtue of the authority vested in me by § 44-146.17 of the Code of Virginia, as Governor and as Director of Emergency Management, and by virtue of the authority vested in me by Article V, Section 7 of the Constitution of Virginia and by § 44-75.1 of the Code of Virginia, as Governor and Commander-in-Chief of the armed forces of the Commonwealth, and subject always to my continuing and ultimate authority and responsibility to act in such matters, I declare that a state of emergency exists, and I am directing that appropriate assistance be rendered by agencies of both state and local governments to respond to the impacts of this severe weather event, alleviate any conditions resulting from the incident, and to implement recovery and mitigation operations and activities so as to return impacted areas to pre-event conditions in so far as possible.

In order to marshal all public resources and appropriate preparedness, response, and recovery measures to meet this threat and recover from its effects, and in accordance with my authority contained in § 44-146.17 of the Code of Virginia, I hereby order the following protective and restoration measures:

A. Implementation by state agencies of the Commonwealth of Virginia Emergency Operations Plan (COVEOP) along with other appropriate state agency plans.

B. Activation of the Virginia Emergency Operations Center (VEOC) and the Virginia Emergency Support Team (VEST), as directed by the State Coordinator of Emergency Management, to coordinate the provision of assistance to local governments and emergency services assignments of other agencies as necessary and determined by the State Coordinator of Emergency Management and other agencies as appropriate.

C. Implementation by public agencies of their emergency assignments under my supervision and control as directed in the COVEOP without regard to normal procedures pertaining to performance of public work, entering into contracts, incurring of obligations or other logistical and support measures of the Emergency Services and Disaster Laws, as provided in § 44-146.28(b) of the Code of Virginia. Section 44-146.24 of the Code of Virginia also applies to the disaster activities of state agencies.

Effective Date of this Executive Order

This Executive Order shall be effective July 5, 2019, and shall remain in full force and effect until December 20, 2019, unless sooner amended or rescinded by further executive order. Termination of this Executive Order is not intended to terminate any federal-type benefits granted or to be granted due to injury or death as a result of service under this Order.

Given under my hand and under the Seal of the Commonwealth of Virginia, this 6th day of December, 2019.

/s/ Ralph S. Northam
Governor

GUIDANCE DOCUMENTS

PUBLIC COMMENT OPPORTUNITY

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

The following guidance documents have been submitted for publication by the listed agencies for a public comment period. Online users of this issue of the Virginia Register of Regulations may click on the name of a guidance document to access it. Guidance documents are also available on the Virginia Regulatory Town Hall (http://www.townhall.virginia.gov) or from the agency contact or may be viewed at the Office of the Registrar of Regulations, 900 East Main Street, Richmond, Virginia 23219.

BOARD OF DENTISTRY

Titles of Documents:

Periodic Office Inspections for Administration of Sedation and Anesthesia.

Policy on Recovery of Disciplinary Costs.

Practice of Dental Hygienists under Remote Supervision.

Questions and Answers on Analgesia, Sedation and Anesthesia Practice.

Public Comment Deadline: February 5, 2020.

Effective Date: February 6, 2020.

Agency Contact: Elaine J. Yeatts, Agency 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.

STATE BOARD OF EDUCATION

Title of Document: Handbook for Educators of English Learners with Suspected Disabilities.

Public Comment Deadline: February 5, 2020.

Effective Date: February 6, 2020.

Agency Contact: Dr. Lynn Sodat, Director of ESEA Programs, Department of Education, 101 North 14th Street, Richmond, VA 23219, telephone (804) 225-2870, or email lynn.sodat@doe.virginia.gov.

DEPARTMENT OF ENVIRONMENTAL QUALITY

Title of Document: Virginia Environmental Excellence Program Operations Manual.

Public Comment Deadline: February 5, 2020.

Effective Date: February 6, 2020.

Agency Contact: Meghann Quinn, Manager, Office of Pollution Prevention, Department of Environmental Quality, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4021, or email meghann.quinn@deq.virginia.gov.

STATE BOARD OF HEALTH

Title of Document: Children with Special Health Care Needs Pool of Funds Guidelines.

Public Comment Deadline: February 5, 2020.

Effective Date: February 6, 2020.

Agency Contact: Robin Buskey, Policy Analyst, Virginia Department of Health, 109 Governor Street, Richmond, VA 23219, telephone (804) 864-7253, or email robin.buskey@vdh.virginia.gov.

DEPARTMENT OF HEALTH PROFESSIONS

Title of Document: Guidance Regarding Collaborative Practice Agreements.

Public Comment Deadline: February 5, 2020.

Effective Date: February 6, 2020.

Agency Contact: Elaine J. Yeatts, Agency 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.

DEPARTMENT OF MOTOR VEHICLES

Titles of Documents:

DMV Cognitive Impairment Policy at https://www.dmv.virginia.gov/drivers/#medical/cognitive.asp.

DMV Policy for Adaptive Equipment and Certified Driving Rehabilitation Specialist (CDRS) Referrals at https://www.dmv.virginia.gov/drivers/#medical/adaptive.asp.

DMV Policy for Drivers Experiencing a Crash Due to a Pedal Application Error at https://www.dmv.virginia.gov/drivers/#medical/pedal.asp.

Public Comment Deadline: February 5, 2020.

Effective Date: February 6, 2020.

Agency Contact: Melissa K. Velazquez, Senior Policy Analyst, Department of Motor Vehicles, 2300 West Broad Street, Richmond, VA 23220, telephone (804) 367-1844, or email melissa.velazquez@dmv.virginia.gov.

BOARD OF PHARMACY

Titles of Documents:

Delegation of Authority for Disciplinary Matters.

Manufacturer, Third-Party Logistics Provider, Warehouser, and Wholesale Distributor Licensure Guidance.

Pharmacist-In-Charge Responsibilities.

Practitioner of the Healing Arts Selling Controlled Substances Inspection Deficiency Monetary Penalty Guide.

Statistically Valid Sample Size for Pharmaceutical Processors.

Public Comment Deadline: February 5, 2020.

Effective Date: February 6, 2020.

Agency Contact: Elaine J. Yeatts, Agency 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.

STATE BOARD OF SOCIAL SERVICES

Title of Document: Administrative/Human Resources Manual of Local Departments of Social Services Chapter 2 Revisions - Classification and Compensation.

Public Comment Deadline: February 5, 2020.

Effective Date: June 1, 2020.

Agency Contact: Lori Schamerhorn, Associate Director, Department of Social Services, 801 East Main Street, Richmond, VA 23219, telephone (804) 726-7264, or email lori.schamerhorn@dss.virginia.gov.

DEPARTMENT OF TAXATION

Title of Document: Debt Buyer Apportionment Guidelines.

Public Comment Deadline: February 5, 2020.

Effective Date: February 6, 2020.

Agency Contact: James Savage, Tax Policy Analyst, Department of Taxation, P.O. Box 27185, Richmond, VA 23261-7185, telephone (804) 371-2301, or email james.savage@tax.virginia.gov.

DEPARTMENT OF ENVIRONMENTAL QUALITY

Maplewood Solar Notice of Intent for Small Renewable Energy Project (Solar) - Pittsylvania County

Virginia Electric and Power Company d/b/a Dominion Energy has provided the Department of Environmental Quality a notice of intent to submit the necessary documentation for a permit by rule for a small renewable energy project (solar) in Pittsylvania County. The project, Maplewood Solar, is an approximately 120-megawatt alternating current solar project located in the vicinity of the community of Climax on the east and west sides of Climax Road in Pittsylvania County. The project will be constructed on multiple parcels of land totaling approximately 1,850 acres and will use conventional solar panels to deliver up to 120 megawatts of alternating current electricity to an existing transmission line. The preliminary design of the project calls for the project to use approximately 475,000 to 500,000 solar panels.

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, FAX (804) 698-4319, or email mary.major@deq.virginia.gov.

M&R Development LLC Notice of Intent for Small Renewable Energy Project (Solar) - Lancaster County

M&R Development LLC has provided the Department of Environmental Quality a notice of intent to submit the necessary documentation for a permit by rule for a small renewable energy project (solar) in Lancaster County. The project, Moraticco Road Solar 1, will consist of approximately 40,000 solar modules (20-megawatt direct current) deployed in ground-mounted arrays on approximately 50 acres of land off Moraticco Road near Nuttsville, Virginia, which is currently being crop farmed.

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, FAX (804) 698-4319, or email mary.major@deq.virginia.gov.

Proposed Judicial Consent Decree for McCarthy Building Companies Inc. and Essex Solar Center LLC

The Commonwealth of Virginia is proposing to enter into a judicial consent decree with McCarthy Building Companies Inc. and Essex Solar Center LLC to settle certain alleged violations of the Commonwealth's environmental laws and regulations related to construction activities in Essex County, Virginia. The proposed consent decree is available at www.deq.virginia.gov or by submitting a request for the document to Kristen Sadtler via email at kristen.sadtler@deq.virginia.gov. Written comments will be accepted from January 1, 2020, through February 5, 2020, and should also be submitted via email to kristen.sadtler@deq.virginia.gov; by postal mail to Enforcement, Department of Environmental Quality, P.O. Box 1105, Richmond, VA 23218; or by hand-delivery by close of business to Enforcement, Department of Environmental Quality, 1111 East Main Street, Suite 1400, Richmond, VA 23219.

DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

Draft Hospital and Physician or Practitioner Provider Manuals for Stakeholder Input

Comment period: December 11, 2019, to January 10, 2020.

The updated Chapter IV of both the Hospital and Physician or Practitioner Provider Manuals are now available on the Department of Medical Assistance Services website at http://www.dmas.virginia.gov/#/manualdraft for public comment until January 10, 2020.

The update to the Medical Coverage for Nonresident Aliens section includes a 12-month certification period for dialysis services and additional documentation requirements.

Please refer to pages 23 through 32 of the hospital manual and pages 72 through 76 of the physician or practitioner manual for more details.

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.

STATE WATER CONTROL BOARD

Public Meeting and Public Comment for a Total Maximum Daily Load for Lewis Creek

Community informational meeting: A community meeting will be held Wednesday, January 15, 2020, at 5:30 p.m. at the Staunton Public Library, 1 Churchville Avenue, Staunton, VA 24401. This meeting will be open to the public and all are welcome. In the case of inclement weather, the meeting will be held on Wednesday, January 22, 2020, at the same time and location.

Purpose of notice: The Virginia Department of Environmental Quality (DEQ) will discuss polychlorinated biphenyls (PCBs) data collected from the creek in support of a water quality study known as a total maximum daily load (TMDL) to be developed for Lewis Creek. This is an opportunity for local residents to learn about the condition of the creek, share

information about the area, and become involved in the process of local water quality improvement. A 30-day public comment period will follow the meeting (January 16, 2020, through February 14, 2020) in order to collect community input on the study and planning process.

Meeting description: This meeting is intended to introduce the local community to the process used in Virginia to improve the quality of waterways, formally known as the TMDL process. DEQ will provide information on PCB monitoring efforts and sources in the Lewis Creek watershed, discuss next steps in the study process, and invite the local community to participate in the study through a technical advisory committee. Section 303(d) of the Clean Water Act and § 62.1-44.19:7 C of the Code of Virginia require DEQ to develop TMDLs for pollutants responsible for each impaired water contained in Virginia's § 303(d) TMDL Priority List and Report.

Description of study: A portion of Lewis Creek, located in Augusta County and the City of Staunton, Virginia, is listed as impaired for PCBs based on a Virginia Department of Health fish consumption advisory and violations of Virginia's Water Quality Standards. The PCB impairment begins approximately 0.65 miles upstream of the Route 262 bridge crossing and extends 10 miles downstream to Lewis Creek's confluence with Middle River. This water quality study will report on the sources of PCBs in the watershed and recommend reductions to meet the PCB TMDL. A TMDL is the total amount of a pollutant a waterbody can contain and still meet water quality standards. To restore water quality, PCB levels need to be reduced to the TMDL amount.

How to comment and participate: All meetings held in support of the TMDL process are open to the public and all interested parties are welcome. Written comments will be accepted through February 14, 2020, and should include the name, address, and telephone number of the person submitting the comments. For more information or to submit written comments, please contact Nesha McRae, Department of Environmental Quality, Valley Regional Office, 4411 Early Road, P.O. Box 3000, Harrisonburg, VA 22801, telephone (540) 574-7850, or email nesha.mcrae@deq.virginia.gov.

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.