



VIRGINIA

REGISTER OF REGULATIONS

VOL. 39 ISS. 10

PUBLISHED EVERY OTHER WEEK BY THE VIRGINIA CODE COMMISSION

January 2, 2023

TABLE OF CONTENTS

Register Information Page	1291
Publication Schedule and Deadlines	1292
Petitions for Rulemaking	1293
Periodic Reviews and Small Business Impact Reviews	1296
Regulations	1301
1VAC30-150. Regulations for Public Use of Robert E. Lee Monument, Richmond, VA (Fast-Track)	1301
4VAC20-720. Pertaining to Restrictions on Oyster Harvest (Final)	1302
4VAC20-1270. Pertaining to Atlantic Menhaden (Final)	1303
6VAC15-26. Regulations for Human Subject Research (Fast-Track)	1305
6VAC16-20. Regulations for Human Subject Research (Fast-Track)	1306
9VAC5-40. Existing Stationary Sources (Action Withdrawn)	1314
9VAC5-80. Permits for Stationary Sources (Action Withdrawn)	1315
9VAC5-170. Regulation for General Administration (Action Withdrawn)	1315
9VAC25-191. Virginia Pollutant Discharge Elimination System (VPDES) General Permit for Concentrated Animal Feeding Operations (Action Withdrawn)	1315
12VAC5-431. Sanitary Regulations for Hotels (Final)	1315
14VAC5-120. Rules Governing the Implementation of the Individual Accident and Sickness Insurance Minimum Standards Act with Respect to Specified Disease Policies (Final)	1316
14VAC5-135. Rules Governing Individual and Small Group Market Health Benefit Plans (Final)	1316
14VAC5-140. Rules Governing the Implementation of the Individual Accident and Sickness Insurance Minimum Standards Act (Final)	1316
14VAC5-141. Rules Governing Accident and Sickness Excepted Benefits Policies; Short-Term Limited Duration Insurance (Final)	1316
14VAC5-341. Rules Governing Standards for the Content of Dwelling Property Insurance Policies (Final)	1327
14VAC5-342. Rules Governing Standards for the Content of Homeowners Insurance Policies (Final)	1327
18VAC110-20. Regulations Governing the Practice of Pharmacy (Final)	1329
18VAC110-20. Regulations Governing the Practice of Pharmacy (Final)	1330
Governor	1332
Guidance Documents	1333
General Notices	1335

THE VIRGINIA REGISTER INFORMATION PAGE

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

ADOPTION, AMENDMENT, AND REPEAL OF REGULATIONS

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

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

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

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

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

If the Governor finds that the final regulation contains changes made after publication of the proposed regulation that have substantial impact, he may require the agency to provide an additional 30-day public comment period on the changes. Notice of the additional public comment period required by the Governor will be published in the *Virginia Register*. Pursuant to § 2.2-4007.06 of the Code of Virginia, any person may request that the agency solicit additional public comment on certain changes made after publication of the proposed regulation. The agency shall suspend the regulatory process for 30 days upon such request from 25 or more individuals, unless the agency determines that the changes have minor or 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 alternative to the standard process set forth in the Administrative Process Act for regulations deemed by the Governor to be noncontroversial. To use this process, the Governor's concurrence is required and advance notice must be provided to certain legislative committees. Fast-track regulations become effective on the date noted in the regulatory action if fewer than 10 persons object to using the process in accordance with § 2.2-4012.1.

EMERGENCY REGULATIONS

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

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

STATEMENT

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

CITATION TO THE VIRGINIA REGISTER

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

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

Members of the Virginia Code Commission: John S. Edwards, Chair; James A. Leftwich, Jr., Vice-Chair; Ward L. Armstrong; Nicole Cheuk; Richard E. Gardiner; Jennifer L. McClellan; Christopher R. Nolen; Steven Popps; Charles S. Sharp; Malfourd W. Trumbo; Amigo R. Wade; Wren M. Williams.

Staff of the Virginia Register: Holly Trice, Registrar of Regulations; Anne Bloomsburg, Assistant Registrar; Nikki Clemons, Regulations Analyst; Rhonda Dyer, Publications Assistant; Terri Edwards, Senior Operations Staff Assistant.

PUBLICATION SCHEDULE AND DEADLINES

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

January 2023 through January 2024

<u>Volume: Issue</u>	<u>Material Submitted By Noon*</u>	<u>Will Be Published On</u>
39:11	December 27, 2022 (Tuesday)	January 16, 2023
39:12	January 11, 2023	January 30, 2023
39:13	January 25, 2023	February 13, 2023
39:14	February 8, 2023	February 27, 2023
39:15	February 22, 2023	March 13, 2023
39:16	March 8, 2023	March 27, 2023
39:17	March 22, 2023	April 10, 2023
39:18	April 5, 2023	April 24, 2023
39:19	April 19, 2023	May 8, 2023
39:20	May 3, 2023	May 22, 2023
39:21	May 17, 2023	June 5, 2023
39:22	May 31, 2023	June 19, 2023
39:23	June 14, 2023	July 3, 2023
39:24	June 28, 2023	July 17, 2023
39:25	July 12, 2023	July 31, 2023
39:26	July 26, 2023	August 14, 2023
40:1	August 9, 2023	August 28, 2023
40:2	August 23, 2023	September 11, 2023
40:3	September 6, 2023	September 25, 2023
40:4	September 20, 2023	October 9, 2023
40:5	October 4, 2023	October 23, 2023
40:6	October 18, 2023	November 6, 2023
40:7	November 1, 2023	November 20, 2023
40:8	November 14, 2023 (Tuesday)	December 4, 2023
40:9	November 29, 2023	December 18, 2023
40:10	December 13, 2023	January 1, 2024
40:11	December 27, 2023	January 15, 2024
40:12	January 10, 2024	January 29, 2024

*Filing deadlines are Wednesdays unless otherwise specified.

PETITIONS FOR RULEMAKING

TITLE 9. ENVIRONMENT

DEPARTMENT OF ENVIRONMENTAL QUALITY

Initial Agency Notice

Title of Regulation: 9VAC15-60. Small Renewable Energy Projects (Solar) Permit by Rule.

Statutory Authority: § 10.1-1197.6 of the Code of Virginia.

Name of Petitioner: Joni Lam.

Nature of Petitioner's Request: The following facts and deficiencies are submitted in response to Energix Renewable Energies 30-day comment period notice for the period November 9, 2022, through December 9, 2022, for a 15.68-megawatt Endless Caverns North Project utility scale solar site in Endless Caverns (and related Endless Caverns South). This comment period forms part and parcel of Energix's Permit by Rule (PBR) application to the Department of Environmental Quality (DEQ) dated October 2022. Because of Energix Renewable Energies' systematic abuse of the PBR process, this document is also a petition for DEQ to amend its existing regulation of solar project notices of intent (NOI). A copy of this PBR deficiency filing and included § 2.2-4007 of the Administrative Process Act petitions for new or amended regulations; opportunity for public comment has been filed with the DEQ, Governor of Virginia, the State Attorney General, and the petitioner's state and local representatives, as well as other interested parties.

Energix subverted community stakeholder interests and did not properly notify DEQ by its filing of a NOI until five months after its simultaneous December 8, 2021, preliminary site plan filing and the special use permit (SUP) vote. DEQ should mandate that all notices of intent for solar utilities under PBR be filed at least three months before the mandatory public meeting or six months before any county board of supervisor vote is taken on a special use permit. "As early in the project development process as practicable" should be further defined as "and at least three months before the mandatory public meeting or six months before any county board of supervisor vote." Any refile of notices of intent after a special use permit is issued should trigger a restart of the public meeting and SUP vote, or DEQ will not consider the SUP submitted with PBRs as valid.

Energix has faced denial of permits or has been forced to withdraw its applications in New Kent County (New Kent Solar LLC, November 2022), Pulaski County (Energix Helios Solar LLC, October 2022), Caroline County (Energix Racehorse Solar, September 2022), Dinwiddie County (Energix Lily Pond Solar, October 2021), and Franklin County. It appears that Energix is trying to mislead communities about its record by filing materially misleading NOIs or filing them too late in the process to have any impact on permitting. DEQ should mandate that all notices of intent

list the name of the owner-operator and the address of the official headquarters of the owner-operator, as opposed to misleading shared office space addresses.

As in Endless Caverns, Energix appears to be inundating counties and DEQ with proposed solar sites and with misleading NOIs in order to avoid HB206 environmental protections, which are to commence in 2024. DEQ should flag for extra scrutiny Energix PBR applications that have misleading NOIs or that have "out of sequence" document chronologies in order to protect communities from environmental harm.

Rockingham County stakeholders value the contribution of their farmers and property owners too much to allow Energix to hurt farmers who support repairs that DEQ has mandated. This PBR must fail because Energix appears to weaponize DEQ-mandated repair actions against innocent parties, and DEQ has no policies in place to protect landowners. DEQ should amend its administrative procedures so that operators of solar utilities are not allowed to financially jeopardize landowners cooperating with DEQ-mandated repairs.

Agency Plan for Disposition of Request: The Department of Environmental Quality, as required by Virginia law, is submitting notice of the petition for publication in the Virginia Register of Regulations and announcing a public comment period. Following receipt of comments on the petition, the department will consider whether to grant or deny the petition for rulemaking.

Public Comment Deadline: January 23, 2023.

Agency Contact: Susan Tripp, Renewable Energy Permit-by-Rule Coordinator, Department of Environmental Quality, 1111 East Main Street, Suite 1400, P.O. Box 1105, Richmond, VA 23218, telephone (804) 664-3470, or email susan.tripp@deq.virginia.gov.

V.A.R. Doc. No. PFR23-16; Filed December 9, 2022, 11:43 a.m.

TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF AUDIOLOGY AND SPEECH-LANGUAGE PATHOLOGY

Initial Agency Notice

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

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

Name of Petitioner: Suzanne Dailey.

Nature of Petitioner's Request: The petitioner requests that the Board of Audiology and Speech-Language Pathology amend

Petitions for Rulemaking

18VAC30-21-60 A 1 to eliminate the requirement that initial licensure applicants hold a Certificate of Clinical Competence issued by the American Speech-Language-Hearing Association and replace that requirement with a requirement to hold a master's degree in speech-language pathology, communication disorders, speech and hearing science, or equivalent.

Agency Plan for Disposition of Request: The petition for rulemaking will be published in the Virginia Register of Regulations on January 2, 2023. The petition will also be published on the Virginia Regulatory Town Hall at www.townhall.virginia.gov to receive public comment, which will open on January 2, 2023, and will close on February 1, 2023. The board will consider the petition and all comments in support or opposition at the next meeting after the close of public comment, currently scheduled for March 14, 2023. The petitioner will be notified of the board's decision after that meeting.

Public Comment Deadline: February 1, 2023.

Agency Contact: Leslie L. Knachel, Executive Director, Board of Audiology and Speech-Language Pathology, 9960 Mayland Drive, Suite 300, Henrico, VA 23233, telephone (804) 597-4130, or email audbd@dhp.virginia.gov.

VA.R. Doc. No. PFR23-15; Filed December 8, 2022, 2:38 p.m.

BOARD OF DENTISTRY

Initial Agency Notice

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

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

Name of Petitioner: Suzanne Williams.

Nature of Petitioner's Request: The petitioner requests that the Board of Dentistry amend 18VAC60-21-250 C 8 to include Pacific Medical Training as an approved continuing education sponsor for the topics required in 18VAC60-21-250 B.

Agency Plan for Disposition of Request: The petition for rulemaking will be published in the Virginia Register of Regulations on January 2, 2023. The petition will also be published on the Virginia Regulatory Town Hall at www.townhall.virginia.gov to receive public comment, which will open on January 2, 2023, and will close on February 1, 2023. The board will consider the petition and all comments in support or opposition at the next meeting after the close of public comment, currently scheduled for March 3, 2023. The petitioner will be notified of the board's decision after that meeting.

Public Comment Deadline: February 1, 2023.

Agency Contact: Jamie Sacksteder, Executive Director, Board of Dentistry, 9960 Mayland Drive, Suite 300, Henrico, VA

23233, telephone (804) 367-4581, or email jamie.sacksteder@dhp.virginia.gov.

VA.R. Doc. No. PFR23-14; Filed December 6, 2022, 8:24 a.m.

TITLE 24. TRANSPORTATION AND MOTOR VEHICLES

COMMISSION ON THE VIRGINIA ALCOHOL SAFETY ACTION PROGRAM

Agency Decision

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

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

Name of Petitioner: Cynthia Hites.

Nature of Petitioner's Request: "I, Cynthia Hites, a citizen of the Commonwealth of Virginia, pursuant to § 2.2-4007 of the Code of Virginia, do humbly submit this petition for verbiage removal to Virginia Administrative Code 24VAC35-60-20, Definitions., "Violations".

July 1, 2012: VASAP Interlock Inception. Paradoxically, the Virginia interlock performance standard was set as "alcohol specific", and the design standard was set as the fuel cell. (24VAC35-60-70 "the machines shall be specific to alcohol", 24VAC35-60-20 "Alcohol is defined as ethanol (C₂H₅OH)")

November 26, 2019: The NHTSA recognizes the usage of the term "ethanol specific" published in "Ignition Interlock - What you need to know. A toolkit for policy makers, highway safety professionals and advocates" is in error and amends it immediately.

January 29, 2020: Randolph Atkins of the NHTSA states in writing "BAIDs are alcohol specific, but not ethanol specific."

January 21, 2021: Virginia Town Hall, Form TH-03 April 2020: "VASAP recognizes that ignition interlocks can detect alcohols other than ethanol..."

March 1, 2021: VASAP removes Virginia's interlock performance standard: "The term "alcohol specific" is being deleted to remove any suggested claim that interlocks will only detect ethanol", Virginia Register of Regulations Volume 37, Issue 14, page 674.

December 10, 2021: Minutes of Quarterly VASAP Meeting, Chief Legislative Officer for Lifesaver, "Mr. Ken Denton clarified that ignition interlocks are screening devices unlike evidentiary breath alcohol machines..."

With the full understanding that Virginia's interlock design standard could not meet Virginia's interlock performance standard, VASAP removed the performance standard of

"alcohol specific" for interlock devices in Virginia. The paradigm of the IID program has shifted, but VASAP administration has yet to adjust. The limited scope of this instrument renders it a screening tool, not evidential, and any "readings" stop at the pass or fail of the lockout device. This instrument is preliminary for the presence of ethanol and its results cannot be blanketly construed as drinking alcohol. The instrument can only corroborate sobriety. The interlock prevents a driver who has provided a failed breath test (>.02 BrAC) from starting a vehicle, and that is the end of its scope of functionality. An IID allows the car to either start or it locks the ignition, but IID readings do not meet the evidentiary standard of that of the Intox EC/IR II. The interlock is a lockout device, not an evidential breath test; its readings cannot be used in court, nor can they be used extrajudicially. The error lies in what VASAP considers a "violation". Defining a failed interlock reading as a "violation" for the presence of ethanol is not in accordance with the functionality of the fuel cell, as the instrument cannot distinguish between alcoholic compounds. Compliance should be defined as having the IID installed for the determined duration, regardless of the pass or fail of the machine. Failed readings are expected with non-alcohol specific instruments and should NOT constitute "violations" or VASAP program noncompliance. According to data received via FOIA requests and VASAP meeting materials, in 2021 there were 7889 interlock installations in Virginia and during that same timeframe 6,843 cases were received by VASAP for secondary interlock review. Non-alcohol-specific sensors generate high numbers of false positives. The solution to the non-alcohol-specific fuel cell is to stop considering failed interlock tests as "violations". The solution to alleviate the financial pressures felt by VASAP is to stop considering failed interlock tests as "violations". The solution to eliminate the punishment of false positives is to stop considering failed interlock tests as "violations". VASAP cannot continue to hold Virginians to a standard it has removed.

I hereby request the following underlined verbiage be omitted from 24VAC35-60-20: Definitions., "Violation" means an event such as "a breath test indicating a BAC reaching the fail point upon initial startup"; a refusal to provide a rolling retest deep lung breath sample, "a rolling retest with a BAC reaching the fail point"; altering, concealing, hiding or attempting to hide one's identity from the ignition interlock system's camera while providing a breath sample; or tampering, that breaches the guidelines for use of the interlock device.

Correcting the interlock system as outlined in this petition will be a solution to a host of current problems.

Thank you for your consideration in this matter."

Agency Decision: Request denied.

Statement of Reason for Decision: During its December 9, 2022, meeting, the Commission on the Virginia Alcohol Safety Action Program denied this petition, taking no action for the following reasons: The petitioner's recommendation to remove

"a breath test indicating a BAC reaching the fail point upon initial startup" and "a rolling retest with a BAC reaching the fail point" from the definition of a "violation" in 24VAC35-60-20 contradicts § 18.2-270.1 of the Code of Virginia, which requires a minimum of six consecutive months without alcohol-related violations of the interlock requirements. In addition, the petitioner's recommendation contradicts multiple court orders throughout the Commonwealth requiring alcohol-related events on an ignition interlock device to be returned to the court as violations.

Agency Contact: Christopher Morris, Special Programs Coordinator, Commission on the Virginia Alcohol Safety Action Program, 1111 East Main Street, Suite 801, Richmond, VA 23219, telephone (804) 786-5895, or email chris.morris@vasap.virginia.gov.

VA.R. Doc. No. PFR23-08; Filed December 9, 2022, 1:37 p.m.

PERIODIC REVIEWS AND SMALL BUSINESS IMPACT REVIEWS

TITLE 12. HEALTH

STATE BOARD OF HEALTH

Report of Findings

Pursuant to §§ 2.2-4007.1 and 2.2-4017 of **the** Code of Virginia, **the** State Board of Health conducted a periodic review and a small business impact review of **12VAC5-410, Regulations for the Licensure of Hospitals in Virginia**, and determined that this regulation should be amended. **The** board is publishing its report of findings dated October 28, 2022, to support this decision.

This regulation is necessary for **the** protection of public health, safety, and welfare because it requires hospitals to meet minimum standards for personnel, clinical and nonclinical services, treatment of patients, and facility safety. These standards protect members of **the** public who utilize hospital services. There is room for improvement on **the** clarity and understandability of **the** regulation.

In **the** short term, **the** board has decided to amend **the** regulation to (i) incorporate statutory and legislative mandates that have been inadvertently omitted; (ii) update regulatory provisions to include current clinical and industry practices; and (iii) update licensing processes and procedures. In **the** mid-term to long-term, **the** board intends to repeal 12VAC5-410 and replace it with at least two regulations. One regulation will focus on hospitals that only provide outpatient services and one will regulate hospitals that may provide inpatient and outpatient services. Through this repeal-and-replace effort, **the** board hopes to more closely align **the** hospital licensure program with **the** federal certification program to reduce confusion for both regulants and **the** public.

A continued need for **the** regulation exists as **the** board is mandated to regulate hospitals. **The** board did not receive complaints or comments concerning **the** regulation from **the** public during **the** comment period. **The** regulation is of moderate complexity, which is not an unexpected outcome given **the** overall complexity of **the** health care industry. **The** regulation does not conflict with federal law or regulation, though it currently does not meet all state mandates, which prompted **the** board to decide to amend **the** regulation to remedy this. **The** regulation has been incrementally amended as changes to **the** Code of Virginia occurred; however, more comprehensive changes to **the** regulation are needed to reflect changes in **the** health care industry, technology, and economic conditions, including those that impact small businesses. **The** board is not aware of any general hospital that would meet **the** definition of "small business"; to **the** extent that outpatient surgical hospitals meet this definition, hospitals of such classification already have fewer regulatory requirements in comparison to general hospitals.

Contact Information: Rebekah E. Allen, Senior Policy Analyst, Virginia Department of Health, 9960 Mayland Drive, Suite 401, Richmond, VA 23233, telephone (804) 367-2102.

STATE BOARD OF BEHAVIORAL HEALTH AND DEVELOPMENTAL SERVICES

Agency Notice

Pursuant to Executive Order 19 (2022) and §§ 2.2-4007.1 and 2.2-4017 of **the** Code of Virginia, this regulation is undergoing a periodic review and a small business impact review: **12VAC35-250, Peer Recovery Specialists**. **The** review of this regulation will be guided by **the** principles in Executive Order 19 (2022). **The** purpose of a periodic review is to determine whether this regulation should be repealed, amended, or retained in its current form. Public comment is sought on **the** review of any issue relating to this regulation, including whether **the** regulation (i) is necessary for **the** protection of public health, safety, and welfare or for **the** economical performance of important governmental functions; (ii) minimizes **the** economic impact on small businesses in a manner consistent with **the** stated objectives of applicable law; and (iii) is clearly written and easily understandable.

Public comment period begins January 2, 2023, and ends February 1, 2023.

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

Contact Information: Ruth Anne Walker, Director of Regulatory Affairs, Department of Behavioral Health and Developmental Services, Jefferson Building, 1220 Bank Street, 4th Floor, Richmond, VA 23219, telephone (804) 225-2252.



TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF DENTISTRY

Report of Findings

Pursuant to §§ 2.2-4007.1 and 2.2-4017 of **the** Code of Virginia, **the** Board of Dentistry conducted a periodic review and a small business impact review of **18VAC60-15, Regulations Governing the Disciplinary Process**, and determined that this regulation should be retained as is. **The** board is publishing its report of findings dated December 2, 2022, to support this decision.

This Board of Dentistry regulation is necessary for **the** protection of public health, safety, and welfare because it sets out **the** methods by which **the** board recovers disciplinary costs and **the** criteria by which **the** board may delegate informal fact-

Periodic Reviews and Small Business Impact Reviews

finding procedures to an agency subordinate. This regulation is necessary to continue to collect fees for disciplinary costs, when appropriate, and to allow the board to use agency subordinates to review certain cases. The Board of Dentistry has reviewed this chapter and determined that it is clearly written and understandable.

The board received no comments during the periodic review. The regulation is not complex and contains only two sections. The regulation does not overlap or duplicate state law or regulations. The regulation has not been amended since 2015, but there has been no change in law, practice, or standard disciplinary procedure that would require a change in the regulation. This regulation does not create an economic impact on small business. There are no compliance requirements. 18VAC60-15-10 only applies if a licensee is subject to discipline due to violations of laws or regulations. 18VAC60-15-20 does not apply to licensees of the board at all, but is a procedural section pertaining to how the board operates.

Contact Information: Jamie Sacksteder, Executive Director, Board of Dentistry, 9960 Mayland Drive, Suite 300, Henrico, VA 23233, telephone (804) 367-4581.



TITLE 24. TRANSPORTATION AND MOTOR VEHICLES

DEPARTMENT OF MOTOR VEHICLES

Report of Findings

Pursuant to §§ 2.2-4007.1 and 2.2-4017 of the Code of Virginia, the Department of Motor Vehicles conducted a periodic review and a small business impact review of 24VAC20-11, **Public Participation Guidelines**, and determined that this regulation should be retained as is. The department is publishing its report of findings to support this decision.

This regulation is required by § 2.2-4007.02 of the Code of Virginia and establishes the mechanisms by which the agency will advise the public of the agency's regulatory actions. Notice of the agency's regulatory actions assists in protecting the public's welfare. The regulation is clearly written and easily understandable.

Section 2.2-4007.02 was amended by Chapter 795 of the 2012 Acts of Assembly to allow for interested persons to be accompanied by and represented by counsel or other representative when submitting data, views, and information to an agency during the promulgation of regulations. The Department of Planning and Budget's model public participation guidelines were accordingly amended. As the sole potential amendment is already reflected within the statutory provision of the Code of Virginia, the Department of

Motor Vehicles determined any update to conform with the new version of the Department of Planning and Budget's model public participation guidelines would be duplicative and unnecessary. The regulation remain in effect without change because it is mandated by law and assists in notifying the public of the agency's regulatory actions.

The agency has not received any substantive comments or complaints regarding this regulation. The regulation is not complex and is easily understood. The regulation does not overlap, duplicate, or conflict with federal or state law or regulation. No factors have changed since the regulation was promulgated that necessitate amending this regulation. This regulation places no economic burden on any small business.

Contact Information: Patrick Harrison, Acting Legislative Services Manager, Department of Motor Vehicles, P.O. Box 27412, Richmond, VA 23269-0001, telephone (804) 249-5115.

COMMONWEALTH TRANSPORTATION BOARD

Report of Findings

Pursuant to §§ 2.2-4007.1 and 2.2-4017 of the Code of Virginia, the Commonwealth Transportation Board (CTB) conducted a periodic review and a small business impact review of 24VAC30-11, **Public Participation Guidelines**, and determined that this regulation should be retained as is. The board is publishing its report of findings dated October 25, 2022, to support this decision.

The CTB's public participation guidelines regulation mirrors the Department of Planning and Budget's (DPB's) model public participation guidelines regulation as that existed at the time the board's public participation regulation was last amended in 2021. The regulation is necessary to promote public involvement in the development, amendment, or repeal of regulations. Further, the regulation is clearly written and understandable.

There is a continued need for this regulation because it promotes public involvement in the development, amendment, or repeal of CTB regulations. There is no overlap, duplication, or conflict with federal or state law or regulation. There have been no complaints received from the public to date. Increased public participation is both an agency best practice and beneficial to the public, both to those who are interested in and choose to participate in a particular rulemaking as well as to those who decline to participate but may benefit from the participation of others. The last review of this regulation occurred in 2019, and the regulation was last amended in 2021 to align it with the most recent model public participation guidelines from DPB. The CTB does not believe that this regulation has a significant economic impact on small businesses.

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.

Periodic Reviews and Small Business Impact Reviews

Report of Findings

Pursuant to §§ 2.2-4007.1 and 2.2-4017 of **the** Code of Virginia, **the** Commonwealth Transportation Board (CTB) conducted a periodic review and a small business impact review of **24VAC30-41, Rules and Regulations Governing Relocation Assistance**, and determined that this regulation should be retained as is. **The** board is publishing its report of findings dated October 25, 2022, to support this decision.

This regulation is necessary for **the** protection of public health, safety, and welfare by providing relocation benefits and advisory assistance to persons displaced by a highway construction project and ensuring they are treated fairly and equitably. **The** regulation provides for relocation of displaced persons and personal property in a timely manner to meet **the** needs of those persons and to achieve project schedules. **The** regulation is clearly written and easily understandable.

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 (c)).

This regulation is not overly complex and is consistent with federal law and **the** related federal regulations in 49 CFR Part 24. **The** last review of this regulation occurred in 2019, and no amendments or public comments have occurred since then. **The** regulation provides eligible relocation benefits and advisory assistance to small businesses when affected by a state project, thereby minimizing **the** economic impact of these projects on small businesses.

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.

Report of Findings

Pursuant to §§ 2.2-4007.1 and 2.2-4017 of **the** Code of Virginia, **the** Commonwealth Transportation Board (CTB) conducted a periodic review and a small business impact review of **24VAC30-91, Subdivision Street Requirements**, and determined that this regulation should be retained as is. **The** board is publishing its report of findings dated October 25, 2022, to support this decision.

The subdivision street requirements (SSR) establish **the** conditions and standards that must be met before certain

subdivision streets constructed by entities other than **the** Virginia Department of Transportation (VDOT) will be accepted into **the** state secondary system for maintenance by VDOT. Proposed developments that include roads to be accepted into **the** secondary system and that were initially received by VDOT prior to July 1, 2009, may be grandfathered under these requirements. **The** consistent construction, review, and acceptance of streets that meet specified requirements promotes **the** protection of public health, safety, and welfare. **The** standards ensure access by emergency response vehicles, reduce congestion, and ensure **the** safe, efficient movement of people and goods. **The** SSR regulation is written in a manner that is clear and easily understandable.

The SSR regulation has a positive impact on state resources as well as small businesses. This regulation helps reduce long-term traffic congestion and supports and promotes more economic activity and better transportation systems. VDOT believes **the** regulation is not overly complex, and no overlap, duplication, or conflict with federal or state laws or regulations exists. **The** SSR regulation was originally adopted in 1949. In 2005, VDOT worked with external stakeholders to complete a comprehensive revision of **the** SSR regulation. There have been no complaints received from **the** public, and **the** one public comment received during **the** periodic review was supportive of changes which were included in **the** 2011 Secondary Street Acceptance Requirements (24VAC30-92), which follows **the** SSR regulation. There have been no amendments to **the** regulation since it was last reviewed in 2019.

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.

Report of Findings

Pursuant to §§ 2.2-4007.1 and 2.2-4017 of **the** Code of Virginia, **the** Commonwealth Transportation Board (CTB) conducted a periodic review and a small business impact review of **24VAC30-92, Secondary Street Acceptance Requirements**, and determined that this regulation should be retained as is. **The** board is publishing its report of findings dated October 25, 2022, to support this decision.

The secondary street acceptance requirements (SSAR) establish **the** conditions and standards that must be met before secondary streets constructed by developers, localities, and entities other than **the** Virginia Department of Transportation (VDOT) will be accepted into **the** state secondary system for maintenance by VDOT. All proposed developments that include roads to be accepted into VDOT's Secondary System of Highways, which were initially received by **the** agency on or after July 1, 2009, must meet **the** requirements of **the** SSAR regulation. **The** consistent construction, review, and acceptance of streets that meet specified requirements

Periodic Reviews and Small Business Impact Reviews

promotes the protection of public health, safety, and welfare. The standards ensure access by emergency response vehicles, reduce congestion, and ensure the safe, efficient movement of people and goods. The SSAR regulation is written in a manner that is clear and easily understandable.

Legislation passed during the 2022 General Assembly session requires VDOT to convene a stakeholder advisory group to provide recommended amendments to the SSAR regulation regarding flexibility to limit the number of connections to adjacent property or highway networks, as deemed appropriate. Any amendments to the SSAR regulation as a result of this legislation will be addressed separately upon completion of the stakeholder advisory group's review.

The SSAR regulation has a positive impact on state resources as well as small businesses. This regulation is needed to reduce long-term traffic congestion and support and promote more economic activity and better transportation systems. VDOT believes the regulation is not overly complex, and no overlap, duplication, or conflict with federal or state laws or regulations exists. No complaints were received from the public, and no amendments to the regulation have been made since it was last reviewed in 2019.

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.

Report of Findings

Pursuant to §§ 2.2-4007.1 and 2.2-4017 of the Code of Virginia, the Commonwealth Transportation Board (CTB) conducted a periodic review and a small business impact review of **24VAC30-155, Traffic Impact Analysis Regulations**, and determined that this regulation should be retained as is. The board is publishing its report of findings dated October 25, 2022, to support this decision.

The regulation establishes procedures by which localities submit proposals that will affect the state controlled transportation network to the Virginia Department of Transportation (VDOT) for review and comment. With that in mind, VDOT believes this regulation is necessary for the protection of the public health, safety, and welfare, as its administration intends to improve the manner in which land use and transportation planning decisions are coordinated and executed throughout the Commonwealth by establishing standardized methodologies and procedures for analyzing transportation impacts.

VDOT believes the regulation is not overly complex and should be easily understood by the regulated community and the public.

There is a continued need for the regulation, as it provides the most cost-effective means of analyzing and developing plans mitigating potential adverse impacts on state-controlled

highways with regard to comprehensive plans, amendments to comprehensive plans, and rezoning proposals. There have been no complaints received from the public to date. VDOT believes the regulation is not overly complex, and no overlap, duplication, or conflict with federal or state laws or regulations exists. There have been no amendments to the regulation since it was last reviewed in 2019. Pursuant to its examination of the regulation, especially the reasonable site trip generation thresholds that have been established for determining a substantial impact that triggers the requirement for a submission, VDOT has determined that the regulatory requirements currently minimize the economic impact of the regulation 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: 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.

Report of Findings

Pursuant to §§ 2.2-4007.1 and 2.2-4017 of the Code of Virginia, the Commonwealth Transportation Board (CTB) conducted a periodic review and a small business impact review of **24VAC30-325, Urban Maintenance and Construction Policy**, and determined that this regulation should be amended. The board is publishing its report of findings dated October 25, 2022, to support this decision.

The regulation is necessary for the protection of the public health, safety, and welfare as it specifies the appropriate design standards to which urban highways should be constructed and maintained in order for the cities and towns in which those urban highways are located to be eligible for certain state funds. The design standards ensure the safety of the public and facilitate the efficient movement of people and commercial goods on those highways. The regulation is clearly written and easily understandable.

The CTB is proposing to amend this regulation. The allocation of funding for urban construction has changed since the regulation was last amended, and amendments are now needed to conform the regulation to current requirements.

There is a continued need for this regulation because it provides certain details and conditions in order for urban streets to be eligible for maintenance payments as well as conditions for lane mile eligibility and calculations and further provides internal and external requirement for the administration of maintenance and construction payments for qualifying cities and towns. One comment was received during the public comment period for the periodic review, and the comment and agency response can be found on the Virginia Regulatory Town Hall at <https://townhall.virginia.gov/L/previews.cfm>.

Periodic Reviews and Small Business Impact Reviews

There have been no amendments to the regulation since it was last reviewed in 2019. The regulation is not overly complex. There is no overlap, duplication, or conflict with federal or state law or regulation. The regulation does not impact small businesses, other than by promoting the efficient movement of people and commercial goods on urban highways.

The regulation needs to be updated to reflect the elimination of formula funds, notably the urban construction allocation to localities referenced in the regulation. Chapter 684 of the 2015 Acts of Assembly amended § 33.2-358 of the Code of Virginia by changing the previous construction formula distribution – 40% to the primary system, 30% to the secondary system, and 30% to the urban system – to the current process that no longer utilizes an urban construction allocation. This change to the distribution formula applied to funds allocated for fiscal years beginning on and after July 1, 2020. Further, § 33.2-362 of the Code of Virginia, which outlined the allocation of construction funds for urban system highways, was repealed by Chapter 684 of the 2015 Acts of Assembly. The current programs for funding projects in the urban system of highways are outlined in Chapter 3.4 of the Urban Construction and Maintenance Manual. This Manual, adopted by VDOT, can be found by the public on the Virginia Regulatory Town Hall (www.townhall.virginia.gov) under VDOT's Guidance Documents and on the VDOT website (www.virginiadot.org) on the Local Assistance Division's Urban Highways page.

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.

Report of Findings

Pursuant to §§ 2.2-4007.1 and 2.2-4017 of the Code of Virginia, the Commonwealth Transportation Board (CTB) conducted a periodic review and a small business impact review of **24VAC30-380, Public Hearings for Location and Design of Highway Construction Projects**, and determined that this regulation should be retained as is. The board is publishing its report of findings dated October 25, 2022, to support this decision.

The origins of the regulation are nearly three decades old, and in the CTB's judgment, the regulation continues to be necessary to meet current federal and state laws and regulations regarding the requirements for public involvement in publicly funded transportation projects that will or are likely to affect the natural and human environments. Details of the public involvement process are typically coordinated and align with the level of involvement for state or federal environmental documents required by other sections of state and federal law and regulations. The regulation is clearly written and easily understandable.

The one public comment received during this periodic review was supportive of the regulation. The longevity of the

regulation and the general awareness of its nature and purpose lead the CTB to determine that it is sufficiently narrow and not overly complex. The regulation is seamlessly interwoven with federal and state laws and regulations and is structured to support their policy goals and objectives. The CTB does not believe that this regulation has a significant economic impact on small businesses.

In 2008, the regulation received a review resulting in significant substantive changes, but the most recent periodic review was conducted in 2019, and no amendments have been made to the regulation since then. Technology that impacts the implementation and execution of activities required to comply with this regulation is constantly evolving and, in turn, may sometimes modify discrete public involvement procedures. These technology changes and improvements can make public involvement processes and activities easier to administer and more accommodating and meaningful to the public constituency that participates in them. However, in and of themselves, technology changes do not and should not serve as substitutes for the requirement to conduct said public involvement activities for publicly funded transportation projects as required by underlying federal and state laws and regulations.

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.

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 1. ADMINISTRATION

DEPARTMENT OF GENERAL SERVICES

Fast-Track Regulation

Title of Regulation: 1VAC30-150. Regulations for Public Use of Robert E. Lee Monument, Richmond, VA (repealing 1VAC30-150-10 through 1VAC30-150-50).

Statutory Authority: § 2.2-4011 of the Code of Virginia.

Public Hearing Information: No public hearing is currently scheduled.

Public Comment Deadline: February 1, 2023.

Effective Date: February 17, 2023.

Agency Contact: Rhonda Bishton, Director's Executive Administrative Assistant, Department of General Services, 1100 Bank Street, Suite 420, Richmond, VA 23219, telephone (804) 786-3311, FAX (804) 371-8305, or email rhonda.bishton@dgs.virginia.gov.

Basis: Section 2.2-1102 of the Code of Virginia provides the legal authority for the Department of General Services (DGS) to repeal the regulation.

Purpose: DGS needs to repeal the regulation as the department no longer has authority to regulate the property, which is no longer owned by the Commonwealth. The rulemaking has no impact on public health, safety, or welfare.

Rationale for Using Fast-Track Rulemaking Process: DGS believes repealing this regulation will be noncontroversial as the real property is no longer owned by the Commonwealth or within the regulatory authority of the department.

Substance: This action repeals the entire regulation, which outlined what was needed to procure a permit to use the Robert E. Lee Monument. There is no disadvantage of the rulemaking to the public.

Issues: The primary advantage of repealing this regulation for the public is that the regulatory burden on the public is eliminated as the monument is no longer owned by the Commonwealth, and the regulation is not needed. The primary advantage of repealing the regulation for the agency and Commonwealth is the elimination of a regulation that is unnecessary given that the Commonwealth no longer owns nor could permit activity on the property. There are no disadvantages for the agency or Commonwealth.

Department of Planning and Budget's Economic Impact Analysis:

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Code of Virginia (Code) and Executive Order 14 (as amended, July 16, 2018). The analysis presented represents DPB's best estimate of these economic impacts.¹

Summary of the Proposed Amendments to Regulation. This regulation pertains to the Robert E. Lee monument including Lee Circle, the roughly 25,000 square feet of land that contained the monument at the intersection of Monument Avenue and Allen Avenue in Richmond (1700 Monument Avenue). The Department of General Services (DGS) proposes to repeal this regulation in its entirety since this property is no longer owned by the Commonwealth of Virginia.

Background. DGS promulgated this regulation in 2017 at the direction of then Governor McAuliffe in order to govern the use of the property,² including the use of permits.³ The Robert E. Lee statue was removed in September 2021. In December 2021, Governor Northam announced that the parcel of land that comprised Lee Circle would be conveyed to the City of Richmond once the pedestal was removed.⁴ The pedestal was removed later that month.

Subsequently, Richmond City Council adopted an ordinance in December 2021 that "authorized the acquisition by gift of the property known as the Lee Circle" and another ordinance in January 2022 that authorized the city's Chief Administrative Officer to accept a donation of personal property including the Robert E. Lee statue, pedestal blocks, and associated artifacts formerly located at the Lee Circle from the Commonwealth of Virginia.⁵

Consequently, DGS proposes to repeal this regulation since the property that it governs no longer belongs to the Commonwealth, which removes any basis for the regulation.

Estimated Benefits and Costs. The proposed repeal of this regulation would benefit readers of the Virginia Administrative Code by removing a redundant chapter and keeping it up-to-date. The proposed repeal would not create any new costs for any entities since the regulation is redundant.

Businesses and Other Entities Affected. The proposed repeal of the regulation would not affect any businesses or other entities because it became redundant once the property was transferred from the Commonwealth of Virginia to the City of Richmond.

The Code of Virginia requires DPB to assess whether an adverse impact may result from the proposed regulation.⁶ An

Regulations

adverse impact is indicated if there is any increase in net cost or reduction in net revenue for any entity, even if the benefits exceed the costs for all entities combined. As noted, repealing this regulation would not increase net costs and serves only to keep the Administrative Code current. Thus, an adverse impact is not indicated.

Small Businesses⁷ Affected.⁸ The proposed repeal of this regulation does not appear to adversely affect small businesses.

Localities⁹ Affected.¹⁰ The proposed repeal of this regulation would not affect any localities. Even though the City of Richmond is affected by the transfer of the monument and underlying property, this regulation became redundant once the transfer was formalized. Thus repealing the regulation would have no effect on the city.

Projected Impact on Employment. The proposed amendments do not appear to affect total employment.

Effects on the Use and Value of Private Property. Although the removal of the monument and the subsequent transfer of property to the city may impact the use and value of private property in the vicinity of Lee Circle, repeal of the regulation itself will not have any effect because the monument has already been removed and the property transferred to the City of Richmond. Thus repealing this regulation would neither affect the use and value of private property nor affect real estate development costs.

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

²See McAuliffe's Executive Order 67 as archived in the Library of Virginia's digital collections: <http://digitool1.lva.lib.va.us:8881/R/SKE66JHT65J27T6Y5GVT43X6V9QHDBDPB96RRCYJ1SF5U5SB5-02157?func=results-full>.

³DGS reports that no permits have been issued under this regulation since it went into effect. DPB-DGS meeting, May 20, 2022.

⁴An archived copy of the press release, dated December 5, 2021, can be found at <https://www.governor.virginia.gov/newsroom/all-releases/2021/december/headline-914623-en.html>.

⁵See ORD. 2021-351 regarding the transfer of the plot of land: <https://richmondva.legistar.com/LegislationDetail.aspx?ID=5360791&GUID=507EA78B-D3A9-445D-8785-5AC773B95F5F>; and ORD. 2022-001 regarding the monument, pedestal, and other property: <https://richmondva.legistar.com/LegislationDetail.aspx?ID=5373262&GUID=F1CA40D4-71E2-4B8F-A59F-AA6CB328DB10>

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

⁷Pursuant to § 2.2-4007.04, small business is defined as "a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million."

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

⁹"Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulatory change are most likely to occur.

¹⁰Section 2.2-4007.04 defines "particularly affected" as bearing disproportionate material impact.

Agency's Response to the Economic Impact Analysis: The agency has reviewed the economic impact analysis prepared by the Department of Planning and Budget and has no comment.

Summary:

The amendments repeal Regulations for Public Use of Robert E. Lee Monument, Richmond, VA (1VAC30-150), as the Commonwealth no longer owns the real property regulated by this chapter, and therefore the Department of General Services no longer has regulatory authority over it.

VA.R. Doc. No. R23-7141; Filed December 1, 2022, 9:06 a.m.



TITLE 4. CONSERVATION AND NATURAL RESOURCES

MARINE RESOURCES COMMISSION

Final Regulation

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

Title of Regulation: 4VAC20-720. Pertaining to Restrictions on Oyster Harvest (amending 4VAC20-720-15).

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

Effective Date: January 1, 2023.

Agency Contact: Jennifer Farmer, Regulatory Coordinator, Marine Resources Commission, 380 Fenwick Road, Building 96, Fort Monroe, VA 23651, telephone (757) 247-2248, FAX (757) 247-2002, or email jennifer.farmer@mrc.virginia.gov.

Summary:

The amendments (i) allow a person who has paid the oyster resource user fee for the previous five consecutive calendar years to transfer eligibility to pay the oyster resource user fee to a non-family member if the person has oyster harvest documented by the Marine Resources Commission's mandatory harvest reporting system and buyers' reports in a minimum of three of the previous five calendar years, has a Commissioner of the Marine Resources-approved documented medical hardship, or is deceased; and (ii) clarify that the Commissioner of the Marine Resources has final authority to approve or deny medical hardship or active military service as exceptions to paying the oyster resource fee for all five consecutive calendar years.

4VAC20-720-15. Control date, license moratorium, transferability, and agents.

A. The Marine Resources Commission (commission) hereby establishes July 1, 2014, as the control date for management of all public oyster fisheries in Virginia. Participation by any individual in any public oyster fishery after the control date may not be considered in the calculation or distribution of oyster fishing rights should entry limitations be established. Any individual entering the public oyster fishery after the control date will forfeit any right to future participation in the public oyster fishery should further entry limitations be established by the commission.

B. Only individuals who have paid the oyster resource user fee described in clause (ii) of subsection A of § 28.2-541 of the Code of Virginia in any year from 2013 through 2016 may pay that fee in 2017 for harvest of oysters from public ground in that year. In any year following 2017, eligibility to pay the oyster resource user fee described in clause (ii) of subsection A of § 28.2-541 of the Code of Virginia shall be limited to those individuals who paid the oyster resource user fee for harvest of oysters from public ground in the previous year.

C. Should the number of people eligible to pay the oyster resource user fee described in clause (ii) of subsection A of § 28.2-541 of the Code of Virginia in any given year fall below 600, a random drawing shall be held to award eligibility to pay that oyster resource user fee to individuals who were not previously eligible until the number of persons eligible to pay the fee reaches 600. Any Commercial Fisherman Registration Licensee may apply for the random drawing.

D. Any person eligible to pay the oyster resource user fee described in clause (ii) of subsection A of § 28.2-541 of the Code of Virginia, or such person's legal representative, may transfer the eligibility to pay such user fee to:

1. A transferee who is the transferor's spouse, sibling, parent, child, grandparent, or grandchild and who possesses a current Commercial Fisherman Registration License and intends to participate in the public oyster fishery.

2. A transferee other than a person described in subdivision 1 of this subsection if the transferor has documented by mandatory reporting and buyers reports 40 days or more of public oyster harvest during the previous calendar year, paid the oyster resource user fee described in clause (ii) of subsection A of § 28.2-541 of the Code of Virginia for the previous five consecutive calendar years and has satisfied one of the following conditions:

- a. Has oyster harvest documented by the Marine Resources Commission's mandatory harvest reporting system and buyers' reports in a minimum of three of the previous five calendar years; or
- b. Has a Commissioner of the Marine Resources-approved documented medical hardship or is deceased.

All transfers under this subsection shall be documented on a form provided by the Marine Resources Commission.

E. Exceptions to subsection B of this section shall only apply to those individuals who previously paid the oyster resource user fee described in clause (ii) of subsection A of § 28.2-541 of the Code of Virginia and shall be based on documented medical hardships or active military leave that prevented the fisherman from fully satisfying the requirements of subsection B of this section. The Commissioner of the Marine Resources, in consultation with the Shellfish Management Division, shall have final authority of approval or denial concerning such medical hardship or active military leave exception requests.

F. No person shall serve as an agent for any public oyster gear licensee.

VA.R. Doc. No. R23-7428; Filed December 15, 2022, 11:19 a.m.

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: 4VAC20-1270. Pertaining to Atlantic Menhaden (amending 4VAC20-1270-30).

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

Effective Date: December 31, 2022.

Agency Contact: Jennifer Farmer, Regulatory Coordinator, Marine Resources Commission, 380 Fenwick Road, Building 96, Fort Monroe, VA 23651, telephone (757) 247-2248, FAX (757) 247-2002, or email jennifer.farmer@mrc.virginia.gov.

Summary:

The amendment removes the limit of the year 2022 from the establishment of a reciprocal quota transfer system between the purse seine menhaden reduction sector and the purse seine menhaden bait sector of the fishery.

Regulations

4VAC20-1270-30. Total allowable landings for menhaden; allocation, accountability, overages, restrictions, closures, state-to-state transfers, and transfers between sectors.

A. Total allowable commercial landings for menhaden in 2022 shall be equivalent to 334,781,533 pounds or 78.66% of the annual total allowable catch (TAC) set by the Atlantic States Marine Fisheries Commission.

B. Total amount of allowable commercial landings in subsection A of this section shall be allocated as quotas among three sectors of the menhaden fishery in proportion to each sector's share of average landings from 2002 through 2011, as described in subdivisions 1, 2, and 3 of this subsection.

1. The purse seine menhaden reduction sector shall be allocated a quota of 301,437,292 pounds or 90.04% of allowable commercial menhaden landings.
2. The purse seine menhaden bait sector shall be allocated a quota of 28,054,692 pounds or 8.38% of allowable commercial menhaden landings.
3. The non-purse seine menhaden bait sector shall be allocated a quota of 5,289,548 pounds or 1.58% of allowable commercial menhaden landings.

C. If the total allowable commercial landings specified in subsection A of this section are exceeded in any calendar year, the total allowable commercial landings for the subsequent calendar year shall be reduced by the amount of the overage. Such overage shall be deducted from the sector of the menhaden fishery that exceeded the allocation specified in subsection B of this section, with the exception of the non-purse seine menhaden bait sector, which shall move into the incidental catch provision outlined in subdivision F 3 of this section.

D. Any portion of the 1.0% of the coastwide total allowable catch set aside by the Atlantic States Marine Fisheries Commission for episodic events that is unused as of September 1 of any calendar year shall be returned to Virginia and other states according to allocation guidelines established by the Atlantic States Marine Fisheries Commission. Any such return of this portion of the coastwide total allowable catch to Virginia shall increase the total allowable commercial landings for that year.

E. It shall be unlawful for any person to take or catch menhaden using a purse seine net except in accordance with the seasons, areas, and gear restrictions as set forth in §§ 28.2-409 and 28.2-410 of the Code of Virginia.

F. It shall be unlawful to harvest or land in Virginia any menhaden after the Commissioner of the Marine Resources Commission (commissioner) projects and announces that 100% of the total allowable landings for any sector has been taken. The commissioner may reopen a fishery sector if, after all reports as described in 4VAC20-1270-60 have been

received, the portion of the total allowable catch has not been harvested by that sector.

1. The commissioner shall announce the date of closure when the total allowable landings for the purse seine menhaden reduction sector is projected to be taken.
2. The commissioner shall announce the date of closure when the total allowable landings for the purse seine menhaden bait sector is projected to be taken.
3. The commissioner shall announce the date of closure when the total allowable commercial landings for the non-purse seine menhaden bait sector is projected to be taken. Once this closure is announced, any person licensed in the non-purse seine menhaden bait sector may possess and land up to 6,000 pounds of menhaden per calendar day as bycatch. Any two persons licensed in the non-purse seine menhaden bait sector may possess and land up to 12,000 pounds of menhaden bycatch when working together from the same vessel using stationary multi-species gear per the Atlantic States Marine Fisheries Commission incidental catch provision.

G. The commissioner may request a transfer of menhaden quota from any other state that is a member of the Atlantic States Marine Fisheries Commission. If Virginia receives a transfer of menhaden quota in any calendar year from another state, the total allowable commercial landings for that calendar year shall increase by the amount of transferred quota. It shall be unlawful for this quota transfer to be applied to the Bay Cap quota as described in 4VAC20-1270-35. The commissioner may transfer menhaden quota to another state only if there is unused menhaden quota at the end of the calendar year.

H. For 2022, the The Marine Resources Commission shall establish a reciprocal temporary transferable quota system between the purse seine menhaden reduction sector and the purse seine menhaden bait sector. Any transfer of menhaden quota between these sectors shall be limited by the following conditions:

1. A transfer of quota to the purse seine menhaden bait sector from the purse seine reduction sector shall be allocated to each qualified licensee's percentage share of the purse seine menhaden bait sector quota.
2. No transfer of quota to the purse seine menhaden bait sector shall be authorized by the Marine Resources Commission unless all qualified individuals of the purse seine menhaden bait sector and the purse seine menhaden reduction sector agree to the transfer and document the transfer on a form provided by the Marine Resources Commission, notarized by a lawful notary public, and approved by the commissioner.
3. No transfer of quota to the purse seine reduction sector shall be authorized by the Marine Resources Commission unless at least one qualified individual of the purse seine

menhaden bait sector and the purse seine menhaden reduction sector agree to the transfer and document the transfer on a form provided by the Marine Resources Commission, notarized by a lawful notary public, and approved by the commissioner.

4. No transfer shall be authorized by the Marine Resources Commission unless the transferring qualified individuals of the purse seine menhaden bait sector and the purse seine menhaden reduction sector have submitted up-to-date records of all commercial landings of menhaden to the Marine Resources Commission prior to such transfer.

5. Quota transfers between the purse seine menhaden reduction sector and purse seine menhaden bait sector shall be effective only during the calendar year in which the transfer is approved.

V.A.R. Doc. No. R23-7426; Filed December 7, 2022, 8:44 a.m.

TITLE 6. CRIMINAL JUSTICE AND CORRECTIONS

STATE BOARD OF LOCAL AND REGIONAL JAILS

Fast-Track Regulation

Title of Regulation: 6VAC15-26. Regulations for Human Subject Research (repealing 6VAC15-26-10 through 6VAC15-26-130).

Statutory Authority: § 53.1-5 of the Code of Virginia.

Public Hearing Information: No public hearing is currently scheduled.

Public Comment Deadline: February 1, 2023.

Effective Date: March 1, 2023.

Agency Contact: Colleen Maxwell, Policy Analyst, Department of Corrections, 6900 Atmore Drive, Richmond, VA 23225, telephone (804) 887-8445, or email colleen.maxwell@vadoc.virginia.gov.

Basis: Section 53.1-5.1 of the Code of Virginia authorizes the State Board of Local and Regional Jails to make, adopt, and promulgate such rules and regulations as may be necessary to carry out the provisions of Title 53.1 of the Code of Virginia. However, Chapter 759 of the 2020 Acts of Assembly moved authority to regulate human subject research from the board to the Department of Corrections.

Purpose: The regulation directly impacts the health, safety, and welfare of citizens who may be subject to research projects. It is essential to their protection that the Virginia Administrative Code accurately reflects the appropriate promulgating authority. Therefore, 6VAC15-26 must be repealed as the regulation is being adopted by the Department of Corrections at 6VAC16-20.

Rationale for Using Fast-Track Rulemaking Process: The regulation is for the protection of a group of individuals who may be part of a research project. These projects are prevalent in agencies responsible for services and supervision, as well as universities. The regulation protects those involved in the research and provides those conducting the research with clarity and guidance. Having the regulation at 6VAC15-26 under the State Board of Local and Regional Jails, which no longer has regulatory authority to enforce the regulation, creates a problem for the public seeking to conduct research and for the individuals who may be subject to such research. To place the regulation under the Department of Corrections at 6VAC16-20 requires 6VAC15-26 be repealed.

Due to the changes in the Code of Virginia pursuant to Chapter 759 of the 2020 Acts of Assembly regarding regulatory authority for certain Department of Corrections responsibilities, the regulation must be repealed under 6VAC15-26 and promulgated under 6VAC16-20. As there will be no substantive changes to the content of the regulation, and the agency has no discretion in the action, the regulatory action will likely be noncontroversial.

Substance: This action repeals 6VAC15-26 in entirety so that the regulation may be promulgated under the Department of Corrections at 6VAC16-20.

Issues: The regulation is for the protection of a group of individuals who may be part of a research project. These projects are prevalent in agencies responsible for services and supervision, as well as universities. The regulation protects those involved in the research and provides those conducting the research with clarity and guidance. The primary advantage to the public of the amendments is that users will be able to find the regulation easily because having this regulation under 6VAC15, with no regulatory authority for the board to issues them, creates a problem for the public seeking to conduct research, and for the individuals who may be subject to such research. There is no disadvantage to the public.

The primary advantage of this regulatory change to for the agency is that it accurately reflects the appropriate promulgating authority. There is no disadvantage to the agency or Commonwealth.

Department of Planning and Budget's Economic Impact Analysis:

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

Summary of the Proposed Amendments to Regulation. The State Board of Local and Regional Jails (Board) proposes to repeal this regulation, which has become obsolete following a legislative change in the authority for the regulation.

Background. This action would repeal rules governing human research for the Board. Chapter 759 of the 2020 Acts of

Regulations

Assembly, renamed **the** Board of Corrections as **the** State Board of Local and Regional Jails and changed **the** authority for this regulation from **the** prior Board of Corrections to **the** Director of **the** Department of Corrections (DOC).² Hence, **the** Registrar assigned a new location for DOC regulations within Title 6 of **the** VAC (6VAC16). Consequently, **the** Director proposed to establish substantially **the** same human research rules for replacement under **the** new Virginia Administrative Code 6VAC16 for DOC in a separate regulatory action.³ This action would repeal this regulation which has become obsolete after **the** enactment of Chapter 759 by operation of law.

Estimated Benefits and Costs. **The** primary effect of this action is to repeal regulatory language that has become obsolete. As a result, no economic impact is expected other than improving **the** accuracy of **the** administrative code.

Businesses and Other Entities Affected. No businesses or other entities are expected to be affected as this regulation is obsolete.

The Code of Virginia requires DPB to assess whether an adverse impact may result from **the** proposed regulation.⁴ An adverse impact is indicated if there is any increase in net cost or reduction in net revenue for any entity, even if **the** benefits exceed **the** costs for all entities combined. Repealing obsolete regulatory language with this action does not indicate an adverse impact on any entity.

Small Businesses⁵ Affected.⁶ **The** proposed repeal does not adversely affect small businesses.

Localities⁷ Affected.⁸ **The** proposed repeal does not disproportionately affect any particular localities or introduce costs for local governments.

Projected Impact on Employment. **The** proposed repeal does not affect total employment.

Effects on **the Use and Value of Private Property.** **The** proposed repeal does not affect **the** use and value of private property or **the** real estate development costs.

should be considered, nor indicate whether an adverse impact results from regulatory requirements mandated by legislation.

⁵Pursuant to § 2.2-4007.04, small business is defined as "a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million."

⁶If **the** proposed regulatory action may have an adverse effect on small businesses, § 2.2-4007.04 requires that such economic impact analyses include: (1) an identification and estimate of **the** number of small businesses subject to **the** proposed regulation, (2) **the** projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with **the** proposed regulation, including **the** type of professional skills necessary for preparing required reports and other documents, (3) a statement of **the** probable effect of **the** proposed regulation on affected small businesses, and (4) a description of any less intrusive or less costly alternative methods of achieving **the** purpose of **the** proposed regulation. Additionally, pursuant to § 2.2-4007.1 of **the** Code of Virginia, if there is a finding that a proposed regulation may have an adverse impact on small business, **the** Joint Commission on Administrative Rules shall be notified.

⁷"Locality" can refer to either local governments or **the** locations in **the** Commonwealth where **the** activities relevant to **the** regulatory change are most likely to occur.

⁸Section 2.2-4007.04 defines "particularly affected" as bearing disproportionate material impact.

Agency's Response to **the Economic Impact Analysis:** **The** State Board of Local and Regional Jails concurs with **the** economic impact analysis performed by **the** Department of Planning and Budget.

Summary:

The amendments repeal Regulations for Human Subject Research (6VAC15-26) under **the** State Board of Local and Regional Jails, which no longer has regulatory authority over human subject research pursuant to Chapter 759 of **the** 2020 Acts of Assembly, so that **the** regulation can be added at 6VAC16-20 under **the** Department of Corrections.

V.A.R. Doc. No. R22-7154; Filed December 7, 2022, 1:59 p.m.

DEPARTMENT OF CORRECTIONS

Fast-Track Regulation

Title of Regulation: 6VAC16-20. Regulations for Human Subject Research (adding 6VAC16-20-10 through 6VAC16-20-120).

Statutory Authority: § 53.1-10 of **the** Code of Virginia.

Public Hearing Information: No public hearing is currently scheduled.

Public Comment Deadline: February 1, 2023.

Effective Date: March 1, 2023.

Agency Contact: Annie Morgan, Hearing Legal Services Officer II, Department of Corrections, 6900 Atmore Drive, Richmond, VA 23225, telephone (804) 887-8436, or email annie.morgan@vadoc.virginia.gov.

Basis: Section 53.1-10 of **the** Code of Virginia specifies that **the** Director of **the** Department of Corrections shall promulgate regulations for human research, as defined in § 32.1-162.16 of

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

²<https://lis.virginia.gov/cgi-bin/legp604.exe?201+ful+CHAP0759>

³<https://townhall.virginia.gov/L/viewstage.cfm?stageid=9697>

⁴Pursuant to § 2.2-4007.04 D: In **the** event this economic impact analysis reveals that **the** proposed regulation would have an adverse economic impact on businesses or would impose a significant adverse economic impact on a locality, business, or entity particularly affected, **the** Department of Planning and Budget shall advise **the** Joint Commission on Administrative Rules, **the** House Committee on Appropriations, and **the** Senate Committee on Finance. Statute does not define "adverse impact," state whether only Virginia entities

the Code of Virginia, to be conducted or authorized by the department.

Purpose: The regulation regarding human research exists for the protection of individuals participating in any sort of research that may expose such human subjects to physical or psychological injury as a consequence of participation as subjects and that departs from the application of established and accepted therapeutic methods appropriate to meet the subject's needs. Moving the regulation to the agency with regulatory authority to enforce the regulation protects the public health, safety, or welfare.

Rationale for Using Fast-Track Rulemaking Process: Due to the changes in the Code of Virginia regarding regulatory authority for certain Department of Corrections responsibilities, the regulation must be moved from the State Board for Local and Regional Jails (6VAC15) to the Department of Corrections (6VAC16). The regulation must be promulgated under 6VAC16 and repealed under 6VAC15. No substantial changes have been made in the regulation beyond corrections to the regulatory authority, clarification in the prior use of offenders, and removal of an agency incorporated document (to comply with current regulatory guidance). For these reasons, the action is expected to be noncontroversial and the fast-track rulemaking process has been determined as the best approach to ensure that the regulation is put in place under the correct agency and available for use as quickly as possible.

Substance: The primary purpose of the change is to move the regulation from 6VAC15, regulations for the State Board of Local and Regional Jails, to 6VAC16, regulations for the Department of Corrections. No substantial changes are made to the regulation, except to move the chapter. Nonsubstantive changes to the regulation being added at 6VAC16-20 include (i) removing references to the Board of Corrections; (ii) changing "offenders" to a more specific term of "inmate," "probationer," "parolee," or "other individual" under supervision of the Department of Corrections; (iii) removing internal documents unnecessarily incorporated by reference; (iv) requiring training to comply with the federal Prison Rape Elimination Act of 2003; and (v) updating forms.

Issues: The primary advantage to the public of the regulation is for the protection of a group of individuals who may be part of a research project. These are prevalent in agencies responsible for services and supervision, as well as universities. The regulation protects those involved in the research and provides those conducting the research with clarity and guidance. There is no disadvantage to the public.

The primary advantage to the agency of placing this regulation under 6VAC16 is to ensure the regulation is in effect and in the appropriate regulatory authority. Having the regulation under 6VAC15, where the board has no regulatory authority to enforce the regulation, creates a problem for the public seeking to conduct research and for the individuals who may be subject to such research. There is no disadvantage to the agency or Commonwealth.

Department of Planning and Budget's Economic Impact Analysis: The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Code of Virginia (Code) and Executive Order 19. The analysis presented represents DPB's best estimate of these economic impacts.¹

Summary of the Proposed Amendments to Regulation. Following a legislative change in the authority for this regulation, the Director of the Department of Corrections (DOC) proposes to establish rules governing human research, which are substantially the same as prior regulations, under a new Virginia Administrative Code (VAC) Chapter for DOC.

Background. This action would establish rules governing human research for DOC. Regulations regarding human research are for the protection of individuals participating in any sort of research which may expose such human subjects to physical or psychological injury as a consequence of participation as subjects, and which departs from the application of established and accepted therapeutic methods appropriate to meet the subjects' needs.

Chapter 759 of the 2020 Acts of Assembly, renamed the Board of Corrections as the State Board of Local and Regional Jails.² As a result, the location in Title 6 of the VAC where the Board of Corrections resided (6VAC15) was renamed for the State Board of Local and Regional Jails. This regulation currently exists under 6VAC15. Chapter 759 also changed the authority for this regulation from the prior Board of Corrections to the Director of DOC. Hence, the Registrar assigned a new location for DOC regulations within Title 6 of the VAC (6VAC16). This action would establish substantially the same human research rules under the new Virginia Administrative Code 6VAC16 for DOC.³

Estimated Benefits and Costs. The prior rules for human research and the proposed new rules are substantially the same, except for adding the training requirement mandated by the federal Prison Rape Elimination Act (PREA) National Standards.⁴ According to DOC, the new regulation addresses PREA training which is required for all DOC personnel and its contractors, including entities authorized to conduct human research. DOC notes, however, that the training is free and takes limited time to complete. Furthermore, DOC is currently enforcing this training requirement as mandated by federal law. Thus, the primary effect of this action is to change the Virginia Administrative Code to reflect the statutory change in authority for this regulation and an existing requirement for PREA training under federal law. As a result, no economic impact is expected.

Businesses and Other Entities Affected. The regulations governing human subject research apply to any entity (private, public, nonprofit) that would propose research involving inmates, probationers, parolees, or other individuals under the supervision of DOC or its employees. DOC receives approximately eight proposals on average per year, and issues

Regulations

approximately three approvals which may include extensions of ongoing projects.

The Code of Virginia requires DPB to assess whether an adverse impact may result from the proposed regulation.⁵ An adverse impact is indicated if there is any increase in net cost or reduction in net revenue for any entity, even if the benefits exceed the costs for all entities combined. As noted above, the proposed regulation is substantially the same as the prior regulation. Thus, no adverse impact is indicated on any entity. Small Businesses⁶ Affected.⁷ The proposed regulation does not adversely affect small businesses.

Localities⁸ Affected.⁹ The proposed regulation does not introduce costs for local governments.

Projected Impact on Employment. The proposed regulation does not affect total employment.

Effects on the Use and Value of Private Property. The proposed regulation does not affect the use and value of private property or the real estate development costs.

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

²<https://lis.virginia.gov/cgi-bin/legp604.exe?201+ful+CHAP0759>

³This action does not repeal existing rules from the Virginia Administrative Code. According to DOC staff, the repeal will be done through a separate regulatory action.

⁴Title 28, Chapter I, Part 115; 5 USC 301; 28 USC 509, 510; 42 USC 15601-15609.

⁵Pursuant to § 2.2-4007.04 D: In the event this economic impact analysis reveals that the proposed regulation would have an adverse economic impact on businesses or would impose a significant adverse economic impact on a locality, business, or entity particularly affected, the Department of Planning and Budget shall advise the Joint Commission on Administrative Rules, the House Committee on Appropriations, and the Senate Committee on Finance. Statute does not define "adverse impact," state whether only Virginia entities should be considered, nor indicate whether an adverse impact results from regulatory requirements mandated by legislation.

⁶Pursuant to § 2.2-4007.04, small business is defined as "a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million."

⁷If the proposed regulatory action may have an adverse effect on small businesses, § 2.2-4007.04 requires that such economic impact analyses include: (1) an identification and estimate of the number of small businesses subject to the proposed regulation, (2) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the proposed regulation, including the type of professional skills necessary for preparing required reports and other documents, (3) a statement of the probable effect of the proposed regulation on affected small businesses, and (4) a description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation. Additionally, pursuant to § 2.2-4007.1 of the Code of Virginia, if there is a finding that a proposed regulation may have an adverse impact on small business, the Joint Commission on Administrative Rules shall be notified.

⁸"Locality" can refer to either local governments or the locations in the Commonwealth where the activities relevant to the regulatory change are most likely to occur.

⁹Section 2.2-4007.04 defines "particularly affected" as bearing disproportionate material impact.

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

Summary:

The amendments establish Regulations for Human Subject Research (6VAC16-20) under the Department of Corrections as a replacement for Regulations for Human Subject Research (6VAC15-26) under the State Board of Local and Regional Jails, which is being repealed because of a change in regulatory authority. No substantive changes are being made to the regulation. Nonsubstantive changes include (i) corrections to the regulatory authority; (ii) clarification in the use of the term "offender"; (iii) removal of a document incorporated by reference; (iv) requirement of training to comply with federal law; and (v) updating forms required by the regulation.

Chapter 20

Regulations for Human Subject Research

Part I

General provisions

6VAC16-20-10. Definitions.

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

"Department" means the Department of Corrections.

"Director" means the Director of the Department of Corrections.

"Human research" means any systematic investigation utilizing human subjects that may expose such human subjects to physical or psychological injury as a consequence of participation as subjects and that departs from the application of established and accepted therapeutic methods appropriate to meet the subject's needs.

"Human Subject Research Review Committee" or "HSRRC" means the Department of Corrections committee responsible for (i) reviewing all submitted research projects for completeness and compliance with the Regulations for Human Subject Research, with all applicable Department of Corrections operating procedures, and with all applicable state and federal regulations pertaining to human subject research; (ii) approving or denying submitted research proposals; (iii) monitoring all approved research projects for adherence to the scope of the research that was approved; and (iv) reporting on all research projects approved, all research projects denied, and the findings of all approved research projects. The composition

of the HSRRC and its responsibilities shall be as stated in Part II (6VAC16-20-40 et seq.) of this chapter.

"Legally authorized representative" means (i) any parent having custody of a prospective subject, (ii) the legal guardian of a prospective subject, or (iii) any person or judicial body authorized by law or regulation to consent on behalf of a prospective subject to such subject's participation in the particular human research. For the purposes of this definition, any person authorized by law or regulation to consent on behalf of a prospective participant to the prospective participant's participation in the particular human research shall include an attorney-in-fact appointed under a durable power of attorney, to the extent the power grants the authority to make such a decision. The attorney-in-fact shall not be employed by the person, organizational unit, or agency conducting the human research and shall not be authorized to consent to nontherapeutic medical research. No official or employee of the organizational unit or agency conducting or authorizing the research shall be qualified to act as a legally authorized representative.

"Minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

"Nontherapeutic research" means human research in which there is no reasonable expectation of direct benefit to the physical or mental condition of the human subject.

"Organizational work unit" means any unit, facility, office, or district within the Department of Corrections, such as prisons, correctional centers, correctional field units, correctional work centers, probation and parole districts or offices, community corrections alternative programs, or units supervised by a manager who reports directly to a deputy director. Each organizational work unit is managed by an organizational unit head such as a warden, superintendent, chief probation and parole officer, or manager.

"Participant" or "human participant" means a living individual whether employee, inmate, probationer, parolee, or other individual under supervision of the Department of Corrections, about whom a researcher, whether professional or student, conducting research obtains (i) data through intervention or interaction with the individual or (ii) identifiable private information. "Intervention" includes both physical procedures by which data are gathered and manipulations of the participant or the participant's environment that are performed for research purposes. "Interaction" includes communication or interpersonal contact between researcher and participant.

"Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and

information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public. Private information must be individually identifiable in order for obtaining the information to constitute research involving human participants.

"Research" means the systematic development of knowledge essential to effective planning and rational decision making. It involves the assessment of current knowledge on conceptual problems selected, statement of those problems in researchable format, design of methodologies appropriate to the problems, and the application of appropriate analytical techniques to the data. Research findings should provide valuable information to management for policy options.

"Research agreement" means the document signed by the principal researcher, research project supervisor, or advisor and the HSRRC indicating the principal researcher and research project supervisor or advisor agree to conduct their research project in the manner in which the research project was approved by the HSRRC, including compliance with this chapter, all applicable Department of Corrections operating procedures, all applicable state and federal laws and regulations, the research project timeline, and any conditions imposed by the HSRRC. The research agreement is governed by and must comply with the provisions of this chapter.

"Researcher" means an individual who has professional standing in the pertinent field or is supervised directly by such an individual.

"Research project" means the systematic collection of information, analysis of data, and preparation of a report of findings.

"Research proposal" means the document completed by the principal researcher outlining (i) information about the researchers, including contact information, affiliations, and funding sources; (ii) the human research to be performed, including purpose, methodology, informed consent, timeframe, and Department of Corrections resources required; and (iii) any endorsements. The research proposal must be submitted to and approved by the HSRRC. Research proposals are to be limited to 20 pages, not including bibliographies, curriculum vitae, letters of endorsement, copies of surveys or instruments to be used, copies of external institutional review board approvals, and voluntary informed consent forms.

"Voluntary informed consent" means the knowing consent of an individual so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. Voluntary informed consent forms shall not include any language through which the human subject waives or appears to waive any of the human subject's legal rights, including any release of any individual, facility, agency, or agents thereof, from liability or negligence. The human participant shall sign all voluntary informed consent forms confirmed by an

Regulations

acceptable witness. With regard to the conduct of human research, the basic elements of information necessary to such voluntary informed consent shall include:

1. A fair explanation to the individual of any procedures to be followed and their purposes, including identification of any procedures which are experimental;
2. A description of any attendant discomforts and risks reasonably to be expected;
3. A description of any benefits reasonably to be expected;
4. A disclosure of any appropriate alternative procedures that might be advantageous for the individual;
5. An offer to answer any inquiries by the individual concerning the procedure; and
6. An instruction that the individual is free to withdraw the individual's voluntary informed consent and to discontinue participation in the human research at any time without prejudice.

6VAC16-20-20. Applicability.

This chapter shall apply to any individual, group, or agency conducting research that uses human participants within the Virginia Department of Corrections, including any facility, program or organization owned, operated, funded, or licensed by the department.

6VAC16-20-30. Policy.

A. No human research may be conducted without informing the participant or the participant's legally authorized representative in writing of the risks, procedures, and discomforts of the research. The voluntary informed consent of the participant or the participant's legally authorized representative to participate in the research must be documented in writing and supported by signature of a witness not involved in the conduct of the research, except as provided in 6VAC16-20-100. Arrangements shall be made for those who need special assistance in understanding the consequences of participating in the research.

B. No inmate, probationer, parolee, or other individual under the supervision of the Department of Corrections shall be subjected to experimentation or participation in research against his will.

C. Nontherapeutic research using institutionalized participants is prohibited unless it is determined by the HSRRC that such nontherapeutic research will not present greater than minimal risk.

D. Research involving known and substantive physical, mental, or emotional risk to the participants, including the withholding of any prescribed program or treatment, is specifically prohibited.

E. Research shall not interfere with the rights of inmates, probationers, parolees, and other individuals under the supervision of the Department of Corrections or employees of the Department of Corrections.

F. Proper precautions must be exercised for the protection of the research participant's rights and for the overall safety and security of the public, the researcher, and the Department of Corrections.

G. Research shall not interfere significantly with ongoing programs or operations of the Department of Corrections.

H. The research findings shall not identify individual participants. The confidentiality and anonymity of all inmates, probationers, parolees, other individuals under the supervision of the Department of Corrections, and other parties engaged in the research will be maintained.

I. Researchers are required to notify all participants of risks caused by the research that are discovered after the research has concluded.

J. Each human research activity shall be reviewed and approved by the HSRRC.

K. No human research activity involving the Department of Corrections shall be initiated without a research proposal reviewed and approved by the HSRRC.

L. Each submitted research proposal must be accompanied by a research agreement signed by the principal researcher or research project supervisor or advisor.

M. All research proposals, research agreements, and accompanying documentation must be submitted to the HSRRC electronically via email.

N. The burden of proof for review by the HSRRC shall be with the principal researcher.

O. Research shall not commence until all procedural and applicable human research reviews and approvals are completed and the Director of the Department of Corrections or the director's designee signs an approval memorandum on behalf of the department. This approval memorandum and necessary information describing the project shall be sent to the appropriate organizational unit head, regional operations chief, and principal researcher at the Department of Corrections.

P. This chapter does not apply to Department of Corrections studies, program evaluations, and routine data analyses for management purposes.

Part II

Human subject research review committee

6VAC16-20-40. Composition.

A. The HSRRC shall have at least three members, appointed by the Director of the Department of Corrections or the

director's designee, with varying backgrounds to provide complete and adequate review of activities commonly conducted by researchers. The HSRRC shall be sufficiently qualified through the experience and diversity of its members.

1. The HSRRC shall not be comprised entirely of men or of women.
2. The HSRRC shall not be comprised entirely of members from one organizational work unit.
3. The HSRRC shall have at least one member who is not otherwise affiliated with the Department of Corrections and is not an immediate family member of a person who is affiliated with the department.

B. In addition to possessing the professional competence necessary to review research proposals, the HSRRC must be able to ascertain the acceptability of research proposals in terms of organizational work unit commitments, this chapter, applicable Department of Corrections operating procedures, any applicable state and federal law or regulation, standards of professional conduct and practice, and community attitudes.

C. No member of the HSRRC shall participate in the HSRRC's initial or continuing review of any research project in which the member has a conflict of interest, defined as having direct involvement in or department approval authority over the proposed human research or otherwise having a conflict of interest under applicable Virginia law. The HSRRC has responsibility for determining whether a member has a conflicting interest.

D. The HSRRC may, at its discretion, invite individuals with competence in special areas to assist in the review of complex issues that require expertise beyond or in addition to that available to the HSRRC. These individuals may not vote with the HSRRC.

E. A quorum of the HSRRC shall consist of a majority of its members. If a quorum cannot be established or cannot meet within the established timeframes from the existing HSRRC, the director or the director's designee may replace temporarily an active committee member with an alternate to the degree needed to establish a quorum.

6VAC16-20-50. Duties and responsibilities.

A. The HSRRC shall establish procedures and rules of operation necessary to fulfill the requirements of this chapter.

B. The HSRRC shall review all submitted research proposals for the following:

1. Completeness, including:
 - a. Researcher information:
 - (1) Name of principal researcher;
 - (2) Affiliation;
 - (3) Mailing address;

- (4) Telephone number;
- (5) Email address;
- (6) Names of all other researchers participating in the research project;
- (7) Name of research project supervisor or advisor, if different from principal researcher;
- (a) Telephone number;
- (b) Email address;
- (8) Funding source; and
- (9) Curriculum vitae of principal researcher, all persons named as researchers; and research project supervisor or advisor.

b. Research proposal information:

- (1) Date research proposal submitted to HSRRC;
- (2) Title of research proposal;
- (3) Purpose of research proposal;
- (4) Methodology;
- (a) Research design;
- (b) Sampling methods;
- (c) Methods of analysis;
- (5) Discussion of the research proposal in the context of relevant literature;
- (6) Discussion of the benefits to the Department of Corrections as well as the field of study;
- (7) Copies of any surveys or instruments to be used;
- (8) Voluntary informed consent forms;
- (9) Timeline for the research project;
- (10) Department of Corrections resources required (e.g., personnel, supplies, materials, equipment, workspace, access to participants, and files); and
- (11) External Institutional Review Board (IRB) approval, including academic IRBs, research group IRBs, and government IRBs; all external IRB approvals must be received before the HSRRC will initiate review of a submitted research proposal.

c. Letters of endorsement.

2. Compliance with this chapter, all applicable Department of Corrections operating procedures, and all applicable state and federal laws and regulations. Compliance includes:

- a. The researcher's ability to obtain the appropriate security clearances to enter an organizational work unit.
- b. The researcher's adherence to an organizational work unit's standards for appropriate attire, including dress or wardrobe, jewelry, hair, grooming, body piercings, and tattoos.
- c. The researcher's ability to pass an organizational work unit's security screening process for contraband, including weapons of any kind, alcohol, drugs of any kind, cellular

Regulations

phones, other electronic devices, tobacco products, including lighters and matches, and any other items deemed as potentially adversely impacting the safety and security of the Department of Corrections, organizational work unit, department staff, research participants or other inmates, probationers, parolees, and other individuals under the supervision of the Department of Corrections, the researchers, or the general public.

d. The researcher's completion of Prison Rape Elimination Act (PREA) training and any other Department of Corrections required training for vendors and volunteers.

3. Adherence to basic research standards, including:

a. Credentials. The principal researcher shall have academic or professional standing in the pertinent field or job-related experience in the areas of study or be directly supervised by such a person.

b. Ethics. The research shall conform to the appropriate standards of ethics of professional societies such as the American Psychological Association, the American Sociological Association, the National Association of Social Workers, or other equivalent society.

c. Protection of rights. The principal researcher is responsible for the conduct of the principal researcher's staff and assumes responsibility for the protection of the rights of participants involved in the research project.

d. Confidentiality or anonymity. Research project information given by participants to the researcher shall be confidential or anonymous depending on the study design. This does not preclude the reporting of results in aggregated form that protects the identity of individuals, or the giving of raw data to the Department of Corrections for further analysis. The confidentiality of any such raw data shall be monitored by the department. Persons who breach confidentiality or anonymity shall be subject to sanctions in accordance with applicable laws, policies, and procedures.

e. Participant incentives. The opportunity to participate in research is considered sufficient incentive for participation. The offering of additional incentives is prohibited without specific written approval from the Director of the Department of Corrections or designee. Sentence reduction or pecuniary compensation are always prohibited as incentives.

4. Determination if the research proposal is subject to the human research review requirements of §§ 32.1-162.16 through 32.1-162.20 of the Code of Virginia.

5. Agreement with Department of Corrections research procedures.

a. The principal researcher and research project supervisor or advisor must submit a separate, signed written research agreement when submitting the research proposal indicating that the principal researcher, research project

supervisor or advisor, and all other researchers and staff under their supervision who are associated with the research project have read, understand, and agree to abide by Department of Corrections research procedures.

b. The research agreement shall establish a timeline for the research project and the specific date when the principal researcher shall submit the final report to the HSRRC.

c. In the case of student research, the student's academic advisor must sign the research agreement indicating endorsement of the research project.

C. After reviewing each submitted, complete research proposal, research agreement, and accompanying documentation, the HSRRC will vote to approve or deny the research proposal.

D. A research proposal shall be approved by the HSRRC when a majority of the quorum of the HSRRC votes to approve the research proposal.

E. If a research proposal is denied, the HSRRC shall notify the principal researcher of all reasons for denial and any requested clarifications, edits, updates, or additions that can be made to the research proposal. The principal researcher may resubmit a revised research proposal with these requested clarifications, edits, updates, or additions. The HSRRC will then review the resubmitted revised, complete research proposal in accordance with 6VAC16-20-50 B.

F. Upon approval of a research proposal by the HSRRC, the HSRRC shall prepare a research brief summarizing the research proposal with any comments. The research brief will be provided to the Director of the Department of Corrections or the director's designee for review and approval.

G. Upon approval of the research brief by the Director of the Department of Corrections or the director's designee, the HSRRC shall provide an approval memorandum and necessary information describing the research project to the organizational work unit head, regional operations chief, and principal researcher.

H. The HSRRC shall retain a separate electronic file for each submitted research proposal. Each electronic file shall contain:

1. The original submitted research proposal;
2. The research agreement;
3. Any accompanying documentation;
4. Any resubmitted revised research proposals;
5. The research brief;
6. The approval memorandum;
7. Any progress reports;
8. The final report; and

9. All communication between the HSRRC, principal researcher, research project supervisor or advisor, the Director of the Department of Corrections or the director's designee, regional operations chief, and organizational unit head pertaining to the research project.

I. At the time the research agreement is signed, the HSRRC shall establish due dates for progress reports to be provided by the principal researcher. These progress reports will inform the HSRRC of the status of the research project and any difficulties encountered that might delay or preclude completion of the research project.

J. The HSRRC shall establish research priorities consistent with the needs of the Department of Corrections.

K. The HSRRC shall regulate the number and timetable of research projects so as to not disrupt the normal functioning of any Department of Corrections operational work unit.

L. Upon receipt of a complaint from an organizational unit head or participant, the HSRRC will investigate to determine if there has been a violation of this chapter, Department of Corrections operating procedures, the research proposal, the research agreement, or any applicable state or federal laws or regulations.

M. If the HSRRC determines that a principal researcher, researcher, research project supervisor or advisor, or staff supervised by them has violated any provisions of this chapter, Department of Corrections operating procedures, the research proposal, the research agreement, or any applicable state or federal laws or regulations, the HSRRC may terminate the research project at any time.

N. The HSRRC shall submit to the Governor, the General Assembly, and the Director of the Department of Corrections or the director's designee, at least annually, a report on the human research projects reviewed and approved by the HSRRC, including any significant deviations from the approved research projects.

6VAC16-20-60. Reports.

A. The principal researcher must submit progress reports to the HSRRC by the dates agreed upon in the research agreement. These progress reports must be submitted electronically via email.

B. The principal researcher must submit a final report to the HSRRC. The final report must be submitted electronically via email.

C. The HSRRC reserves the right to reproduce the final report for official Department of Corrections use only.

6VAC16-20-70. Records maintenance.

A. The principal researcher shall maintain records adequate to enable the Department of Corrections to ascertain the status of the research project at any given time.

B. The principal researcher shall maintain completed voluntary informed consent forms in a secure location for at least three years.

6VAC16-20-80. Publication rights.

A. Researchers are not permitted to publish beyond the approved research proposal without further review and approval from the HSRRC.

B. The researcher shall furnish the HSRRC with an electronic copy of the published research findings.

C. The Department of Corrections shall be permitted to use the data collected in the research project and to reproduce the materials as the materials are published.

D. Without the explicit written approval of the researcher, the Department of Corrections should not publicly distribute any dissertation or thesis material that the researcher has not published or presented publicly or professionally.

E. Without prior approval from the HSRRC, research conducted by employees or agents, including interns, volunteers, contractors, and vendors, of the Department of Corrections is the property of the department and cannot be published without the approval of the Director of the Department of Corrections or the director's designee.

6VAC16-20-90. Research exempt from HSRRC review.

The following are exempt from HSRRC review:

1. Department of Corrections studies, program evaluations, and routine data analyses for management purposes.

2. Research conducted by the Department of Corrections and any of its organizational units in established or commonly accepted educational settings, involving commonly used educational practices, such as:

a. Research on regular and special education instructional strategies.

b. Research on the effectiveness of, or the comparison among, instructional techniques, curriculum, or classroom management methods.

3. Research involving required department survey procedures, unless responses are recorded in such a manner that participants can be identified, directly or through identifiers linked to the participants, and either:

a. Participant responses, if they become known outside the research, could reasonably place a participant at risk of criminal or civil liability or be damaging to a participant's financial standing, employability, or reputation; or

b. The research deals with sensitive aspects of a participant's own behavior, such as sexual behavior, drug or alcohol use, illegal conduct, or family planning.

4. Research involving solely the collection or study of existing data, documents, records, or pathological or

Regulations

diagnostic specimens if these sources are publically available or if the information taken from these sources is recorded in such a manner that participants cannot be identified, either directly or through identifiers linked to the participants.

6VAC16-20-100. Waiver of signed voluntary informed consent form.

A. The HSRRC may waive the requirement for the researcher to obtain a signed voluntary informed consent form for some or all participants in a research project if it finds that the only record linking the participant and the research would be the consent form and that the principal risk would be potentially harmful resulting from a breach of confidentiality.

B. Each participant will be asked whether the participant wants documentation linking the participant to the research, and the participant's wishes will govern.

C. In cases where the documentation requirement is waived, the HSRRC shall require the researcher to provide participants with a written statement explaining the research.

Part III

Role of the department and director

6VAC16-20-110. Role of the department and director.

A. The Director of the Department of Corrections or the director's designee shall establish and maintain records of the HSRRC assurances, annual reports, and summary descriptions of research projects.

B. The Director of the Department of Corrections or the director's designee shall review communications from the HSRRC reporting violations of research protocols that led to suspension or termination of the research to ensure that appropriate steps have been taken for the protection of rights of human research participants.

C. The Director of the Department of Corrections shall arrange for the printing and dissemination of copies of this chapter.

Part IV

Applicability of state and federal policies

6VAC16-20-120. Applicability of state and federal policies.

A. No statement in this chapter shall be construed as limiting in any way the rights of participants in research under regulations promulgated by the director pursuant to § 53.1-10 of the Code of Virginia.

B. Human research that is subject to policies and regulations for the protection of human participants promulgated by any agency of the federal government shall be exempted from this chapter. Annual certification shall be made to the Director of the Department of Corrections that exempted projects have complied with the policies and regulations of federal agencies.

NOTICE: The following forms used in administering the regulation have been filed by the agency. Amended or added forms are reflected in the listing and are published following the listing. Online users of this issue of the Virginia Register of Regulations may also click on the name to access a form. The forms are also available from the agency contact or may be viewed at the Office of Registrar of Regulations, 900 East Main Street, 11th Floor, Richmond, Virginia 23219.

FORMS (6VAC16-20)

[Research Agreement, Form 020_F2_5-22 \(rev. 5/2022\)](#)

[Research Proposal, Form 020_F14_9-21 \(rev. 9/2021\)](#)

[Voluntary Informed Consent to Participate in Research, Form 020_F3_9-21 \(rev. 9/2021\)](#)

VA.R. Doc. No. R23-7297; Filed December 5, 2022, 4:19 p.m.

TITLE 9. ENVIRONMENT

STATE AIR POLLUTION CONTROL BOARD

Action Withdrawn

Title of Regulation: **9VAC5-40. Existing Stationary Sources.**

Statutory Authority: § 10.1-1308 of the Code of Virginia; Clean Air Act (§§ 110, 111, 123, 129, 171, 172 and 182); 40 CFR Parts 51 and 60.

The State Air Pollution Control Board has WITHDRAWN the regulatory action for **9VAC5-40, Existing Stationary Sources**, which was published as a Notice of Intended Regulatory Action in [37:18 VA.R. 2639 April 26, 2021](#). This action is being withdrawn because the need for this regulatory action has been overtaken by other events. The primary focus of the regulatory action was on transmission and storage, including pipelines, compressor stations, and underground storage associated with the natural gas transmission and storage sector, and gathering/boosting compressors and gas processing plants associated with production and processing. Secondary focus was on production and processing, including drilling and well completion, producing wells, and gathering lines. The regulatory action panel for this action will be recalled and reorganized as an ad hoc group in order to assist with the report to the General Assembly due July 2023.

Agency Contact: Karen Sabasteanski, Department of Environmental Quality, 1111 East Main Street, Suite 1400, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4426, FAX (804) 698-4178, or email karen.sabasteanski@deq.virginia.gov.

VA.R. Doc. No. R21-6494; Filed December 2, 2022, 1:49 p.m.

Action Withdrawn

Titles of Regulations: 9VAC5-80. Permits for Stationary Sources.

9VAC5-170. Regulation for General Administration Permits for Stationary Sources.

Statutory Authority: § 10.1-1308 of the Code of Virginia; Clean Air Act §§ 110, 112, 165, 173, 182 and Title V; 40 CFR Parts 51, 61, 63, 70, and 72.

The State Air Pollution Control Board has WITHDRAWN the regulatory action for **9VAC5-80, Permits for Stationary Sources**, and **9VAC5-170, Regulation for General Administration**, which was published as a Notice of Intended Regulatory Action in 37:19 VA.R. 2761 May 10, 2021. This action is being withdrawn because the action was initiated in response to certain issues with § 10.1-1307 E of the Code of Virginia, which were subsequently addressed by the General Assembly in Chapter 356 of the 2022 Acts of Assembly. This regulatory action is no longer needed; therefore, it is being withdrawn.

Agency Contact: Karen G. Sabasteanski, Department of Environmental Quality, 1111 East Main Street, Suite 1400, P.O. Box 1105, Richmond, VA 23218, telephone (804) 659-1973, FAX (804) 698-4510, or email karen.sabasteanski@deq.virginia.gov.

VA.R. Doc. No. R21-6537; Filed December 2, 2022, 1:51 p.m.

STATE WATER CONTROL BOARD**Action Withdrawn**

Title of Regulation: 9VAC25-191, Virginia Pollutant Discharge Elimination System (VPDES) General Permit for Concentrated Animal Feeding Operations.

Statutory Authority: §§ 62.1-44.15 and 62.1-44.17:1 of the Code of Virginia; 40 CFR Parts 9, 122, 123, and 412.

The State Water Control Board has WITHDRAWN the regulatory action for **9VAC25-191, Virginia Pollutant Discharge Elimination System (VPDES) General Permit for Concentrated Animal Feeding Operations**, which was published as a Notice of Intended Regulatory Action in 26:11 VA.R. 1456 February 1, 2010. This action is being withdrawn because the regulation has been repealed; therefore the associated NOIRA to reissue this general permit is unnecessary as the general permit regulation is no longer needed.

Agency Contact: Betsy Bowles, Department of Environmental Quality, 1111 East Main Street, Suite 1400, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4059, FAX (804) 698-4116, or email betsy.bowles@deq.virginia.gov.

VA.R. Doc. No. R10-2297; Filed December 8, 2022, 4:11 p.m.

TITLE 12. HEALTH**STATE BOARD OF HEALTH****Final Regulation**

REGISTRAR'S NOTICE: The State Board of Health is claiming an exemption from Article 2 of the Administrative Process Act in accordance with § 2.2-4006 A 4 a of the Code of Virginia, which excludes regulations that are necessary to conform to changes in Virginia statutory law or the appropriation act where no agency discretion is involved. The board will receive, consider, and respond to petitions by any interested person at any time with respect to reconsideration or revision.

Title of Regulation: 12VAC5-431. Sanitary Regulations for Hotels (adding 12VAC5-431-490).

Statutory Authority: §§ 35.1-11, 35.1-13, and 35.1-15.1 of the Code of Virginia.

Effective Date: February 1, 2022.

Agency Contact: Briana Bill, Program Manager, Tourist Establishments and General Environmental Health Services, Virginia Department of Health, 109 Governor Street, Richmond, VA 23235, telephone (805) 584-6340, or email briana.bill@vdh.virginia.gov.

Summary:

Pursuant to Chapter 751 of the 2022 Acts of Assembly, the amendments add a new section that requires hotel employees to complete an approved training course, no later than June 30, 2023, on recognizing and reporting instances of suspected human trafficking. The Department of Criminal Justice shall develop and administer the approved training course, and the Virginia Department of Health shall enforce the new requirement.

12VAC5-431-490. Employee training.

A. Each employee, as defined in § 35.1-15.1 A of the Code of Virginia, shall by July 1, 2023, or within six months of being employed by a hotel and thereafter at least once per consecutive two-year period, complete a training course provided or approved by the Department of Criminal Justice Services pursuant to §§ 9.1-102 and 35.1-15.1 of the Code of Virginia on recognizing and reporting instances of suspected human trafficking.

B. The permit holder shall provide documentation, upon request by the department, that the hotel's employees have completed the required training.

VA.R. Doc. No. R23-7128; Filed November 30, 2022, 2:57 p.m.

TITLE 14. INSURANCE

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.

Titles of Regulations: 14VAC5-120. Rules Governing the Implementation of the Individual Accident and Sickness Insurance Minimum Standards Act with Respect to Specified Disease Policies (repealing 14VAC5-120-10 through 14VAC5-120-100).

14VAC5-135. Rules Governing Individual and Small Group Market Health Benefit Plans (adding 14VAC5-135-10 through 14VAC5-135-60).

14VAC5-140. Rules Governing the Implementation of the Individual Accident and Sickness Insurance Minimum Standards Act (repealing 14VAC5-140-10 through 14VAC5-140-100).

14VAC5-141. Rules Governing Accident and Sickness Excepted Benefits Policies; Short-Term Limited Duration Insurance (adding 14VAC5-141-10 through 14VAC5-141-160).

Statutory Authority: §§ 12.1-13 and 38.2-223 of the Code of Virginia.

Effective Date: January 1, 2023.

Agency Contact: Elsie Andy, Manager, Bureau of Insurance, State Corporation Commission, P.O. Box 1157, Richmond, VA 23218, telephone (804) 371-9072, or email elsie.andy@scc.virginia.gov.

Summary:

The amendments implement the provisions of Chapters 34 (§ 38.2-3400 et seq.) and 35 (§ 38.2-3500 et seq.) of Title 38.2 of the Code of Virginia by repealing 14VAC5-120 and 14VAC5-140 and adding two new chapters, Rules Governing Individual and Small Group Market Health Benefit Plans (14VAC5-135) and Rules Governing Accident and Sickness Excepted Benefits Policies; Short-Term Limited Duration Insurance (14VAC5-141). The new, separate chapters distinguish between two major categories of accident and sickness insurance to clearly identify the requirements for each category.

14VAC5-135 outlines minimum standards for those individual and small group market health benefit plans that are filed in accordance with Affordable Care Act, including general policy and form requirements and certain prohibitions, limitations, and disclosures as well as standards for student health insurance coverage.

14VAC5-141 outlines minimum standards for the types of accident and sickness "excepted benefits" policies that may be filed in Virginia, including accident, disability income, limited scope benefits, specified disease, hospital, or other fixed indemnity and similar supplemental coverage as well as standards for short-term limited-duration insurance, including general policy provisions, prohibitions, limitations and disclosures, and requirements for replacement of coverage.

Changes to the proposed regulation include (i) in 14VAC5-135, removing the requirement for policies to cover medically necessary services that arise from complications of contractually excluded services; and (ii) in 14VAC5-141, clarifying four definitions, clarifying language for some general policy provisions and requiring coverage for complications that arise from pregnancy, adding details on waiting periods for certain limited scope dental benefits, and clarifying payment of individual or group benefits for fixed indemnity policies.

AT RICHMOND, DECEMBER 8, 2022

COMMONWEALTH OF VIRGINIA, ex rel.

STATE CORPORATION COMMISSION

CASE NO. INS-2022-00073

Ex Parte: In the matter of Repealing and Adopting Rules Governing Individual and Small Group Market Health Benefit Plans and Excepted Benefits Policies

ORDER REPEALING AND ADOPTING REGULATIONS

On July 15, 2022, the State Corporation Commission ("Commission") entered an Order to Take Notice proposing to update its current rules regarding accident and sickness insurance following significant changes in this area. As part of this update, the Bureau of Insurance ("Bureau") submitted to the Commission a proposal to repeal two existing chapters and promulgate two new chapters of the Virginia Administrative Code.

Specifically, the order proposed to: (a) repeal Chapter 120 of Title 14 of the Virginia Administrative Code entitled "Rules Governing the Implementation of the Individual Accident and Sickness Insurance Minimum Standards Act with Respect to Specified Disease Policies," set out at 14VAC5-120-10 through 14VAC5-120-100; (b) repeal Chapter 140 of Title 14 of the Virginia Administrative Code entitled "Rules Governing the Implementation of the Individual Accident and Sickness Insurance Minimum Standards Act," set out at 14VAC5-140-10 through 14VAC5-140-100; (c) promulgate new Chapter 135 of Title 14 of the Virginia Administrative Code entitled "Rules Governing Individual and Small Group Market Health Benefit Plans," which sets forth new rules at 14VAC5-135-10 through 14VAC5-135-60; and (d) promulgate new Chapter 141 of Title 14 of the Virginia Administrative Code entitled "Rules Governing Accident and Sickness Excepted Benefits

Policies; Short-Term Limited Duration Insurance," which sets forth new rules at 14VAC5-141-10 through 14VAC5-141-160.

The Bureau has recommended the repeal of Chapters 120 and 140 as well as the adoption of Chapters 135 and 141 as necessary revisions because of significant changes in the regulation of individual and small group health benefit plans, excepted benefits policies, and short-term limited duration insurance in the last decade. The Bureau has noted that separate and distinct requirements for most health benefit plans now exist, and a bright line divides these types of plans and "excepted benefits" policies as defined in § 38.2-3431 of the Code of Virginia ("Code") as well as the federal Public Health Service Act, 42 U.S.C. § 201 et seq. In light of these changes, the Bureau recommends repealing outdated rules and implementing new, separate chapters to clearly identify the requirements for each category of policies. Furthermore, proposed Chapters 135 and 141 implement the provisions of Chapters 34 (§ 38.2-3400 et seq.) and 35 (§ 38.2-3500 et seq.) of Title 38.2 of the Code.

The Order to Take Notice and proposed rules were posted on the Commission's website, sent to all carriers licensed in Virginia to write accident and sickness insurance and to all interested persons known to the Bureau to have an interest in life and health insurance on July 22, 2022, sent to the Virginia Attorney General's Division of Consumer Counsel ("Consumer Counsel"), and published in the Virginia Register of Regulations on August 15, 2022. Licensees, Consumer Counsel and other interested persons were afforded the opportunity to file written comments or request a hearing on or before September 30, 2022.

The Bureau received six sets of comments to the proposed rules, which were filed by the following: Health Benefits Institute; Delta Dental of Virginia; Virginia Association of Health Plans; United Healthcare; American Council of Life Insurers; and William Schiffbauer on his own behalf. No request for a hearing was filed with the Clerk of the Commission ("Clerk").

The Bureau considered the comments filed and responded to them in its Response to Comments ("Response"), which the Bureau filed with the Clerk on November 10, 2022. In its Response, the Bureau addressed the comments and either recommended that various sections of the proposed rules be amended or indicated why it did not believe suggested revisions were authorized or warranted.

NOW THE COMMISSION, having considered the proposal to repeal and adopt rules, the comments filed, and the Bureau's Response, concludes that Chapters 120 and 140 of the Virginia Administrative Code should be repealed effective January 1, 2023, and that the proposed regulations should be adopted by the Commission, as modified and attached hereto effective January 1, 2023. The new rules shall be applicable to any new form submitted to the Bureau for review on or after the effective date.

Accordingly, IT IS ORDERED THAT:

(1) Chapter 120 of Title 14 of the Virginia Administrative Code entitled "Rules Governing the Implementation of the Individual Accident and Sickness Insurance Minimum Standards Act with Respect to Specified Disease Policies," set out at 14VAC5-120-10 through 14VAC5-120-100, and Chapter 140 of Title 14 of the Virginia Administrative Code entitled "Rules Governing the Implementation of the Individual Accident and Sickness Insurance Minimum Standards Act," set out at 14VAC5-140-10 through 14VAC5-140-100 are hereby REPEALED effective January 1, 2023.

(2) Chapter 135 of Title 14 of the Virginia Administrative Code entitled "Rules Governing Individual and Small Group Market Health Benefit Plans," set out at 14VAC5-135-10 through 14VAC5-135-60, and Chapter 141 of Title 14 of the Virginia Administrative Code entitled "Rules Governing Accident and Sickness Excepted Benefits Policies; Short-Term Limited Duration Insurance," set out at 14VAC5-141-10 through 14VAC5-141-160, as modified and attached hereto, are hereby ADOPTED effective January 1, 2023. The new rules shall be applicable to any new form submitted to the Bureau for review on or after the effective date.

(3) The Bureau shall provide notice of the repeal and adoption of rules to all carriers licensed in Virginia to write accident and sickness insurance and to all persons known to the Bureau to have an interest in life and health insurance.

(4) This Order and the attached regulations shall be made available on the Commission's website: scc.virginia.gov/pages/Case-Information.

(5) The Commission's Office of General Counsel shall provide a copy of this Order and the regulations to the Virginia Registrar of Regulations for publication in the Virginia Register of Regulations.

(6) The Bureau shall file with the Clerk an affidavit of compliance with the notice requirements of Ordering Paragraph (3) above.

(7) This case is dismissed.

A COPY hereof shall be sent by the Clerk of the Commission to: C. Meade Browder, Jr., Senior Assistant Attorney General, mbrowder@oag.state.va.us, Office of the Attorney General, Division of Consumer Counsel, 202 N. 9th Street, 8th Floor, Richmond, Virginia 23219-3424; and a copy hereof shall be delivered to the Commission's Office of General Counsel and the Bureau of Insurance in care of Deputy Commissioner Julie Blauvelt.

Regulations

Chapter 135

Rules Governing Individual and Small Group Market Health Benefit Plans

14VAC5-135-10. Applicability and scope.

A. This chapter (14VAC5-135) implements the provisions of Chapters 34 (§ 38.2-3400 et seq.) and 35 (§ 38.2-3500 et seq.) of Title 38.2 of the Code of Virginia and sets forth the standards for compliance with the federal Affordable Care Act.

B. This chapter shall apply to all individual and small group market health benefit plans delivered or issued for delivery in this Commonwealth.

C. Health benefit plans filed in this Commonwealth and approved for sale in a health benefit exchange pursuant to § 38.2-326 of the Code of Virginia shall comply with the provisions of this chapter.

D. This chapter shall not apply to a grandfathered health plan, as defined in § 38.2-3438 of the Code of Virginia, for as long as the plan maintains its status in accordance with federal regulations.

E. This chapter shall not apply to excepted benefits policies, as defined in § 38.2-3431 of the Code of Virginia.

F. This chapter shall not apply to a short-term limited-duration medical plan, as defined in § 38.2-3407.21 of the Code of Virginia.

14VAC5-135-20. Definitions.

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

"Affordable Care Act" or "ACA" means the Patient Protection and Affordable Care Act (P.L. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (P.L. 111-152) and any federal regulations issued pursuant thereto.

"Covered benefits" or "benefits" means those health care services to which an enrollee is entitled under the terms of a health benefit plan.

"Dependent" means the spouse, child, or other class of persons of an enrollee or eligible individual, subject to the applicable terms of the policy, contract, or plan.

"Eligible individual" means an employee of a small employer as shall be determined (i) in accordance with the terms of the group health benefit plan; (ii) as provided by the health carrier under rules of the health carrier that are uniformly applicable to employers in the small group market; and (iii) in accordance with all applicable laws of the Commonwealth.

"Enrollee" means a policyholder, subscriber, participant, member, insured, or other individual covered by a health benefit plan.

"Exchange" means either (i) the federal health benefit exchange established pursuant to § 1321 of the Affordable Care Act or (ii) the Virginia Health Benefit Exchange established pursuant to Chapter 65 (§ 38.2-6500 et seq.) of Title 38.2 of the Code of Virginia, through which qualified health plans and qualified dental plans are made available to qualified individuals.

"Group health plan" means an employee welfare benefit plan as defined in § 3(1) of the Employee Retirement Income Security Act of 1974 (ERISA) (29 USC § 1002(1)) to the extent that the plan provides medical care within the meaning of § 733(a) of ERISA (29 USC § 1191b(a)) to employees, including both current and former employees, or their dependents as defined under the terms of the plan directly or through insurance, reimbursement, or otherwise.

"Health benefit plan" means a policy, contract, certificate, or agreement offered by a health carrier to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services, except as otherwise specifically exempted. "Health benefit plan" does not include the "excepted benefits" as defined in § 38.2-3431 of the Code of Virginia.

"Health carrier" means an entity subject to the insurance laws and regulations of the Commonwealth and subject to the jurisdiction of the State Corporation Commission that contracts or offers to contract to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services, including a health carrier licensed to sell accident and sickness insurance, a health maintenance organization, a health services plan, or any other entity providing a plan of health insurance, health benefits, or health care services.

"Health insurance coverage" means benefits consisting of medical care (provided directly, through insurance or reimbursement, or otherwise) under any hospital or medical service policy or certificate, hospital or medical service plan contract, or health maintenance organization contract offered by a health carrier.

"Health status-related factor" means any of the following factors: health status; medical condition, including physical and mental illnesses; claims experience; receipt of health care services; medical history; genetic information; evidence of insurability, including conditions arising out of acts of domestic violence or extra-hazardous activities; disability; or any other health status-related factor as determined by federal regulation.

"Individual market" means the market for health insurance coverage offered to individuals other than in connection with a group health plan.

"Medical necessity" or "medically necessary" means appropriate and necessary health care services that are rendered for a condition that, according to generally accepted principles of good medical practice, requires the diagnosis or

direct care and treatment of an illness, injury, or pregnancy-related condition, and are not provided only as a convenience.

"Premium" means all moneys paid by an employer, eligible individual, or enrollee as a condition of coverage from a health carrier, including fees and other contributions associated with the health benefit plan.

"Small group market" means the health insurance market under which eligible individuals obtain health benefit plans directly or through any arrangement on behalf of themselves and their dependents through a group health plan maintained by a small employer.

14VAC5-135-30. General policy requirements.

A. Each health benefit plan shall contain a guaranteed renewability provision in accordance with § 38.2-3430.7 or 38.2-3432.1 of the Code of Virginia. The provision shall appear on the first page of the policy.

B. Each health benefit plan shall contain a termination, cancellation, or discontinuation of coverage policy provision in accordance with § 38.2-3430.7 or 38.2-3432.1 of the Code of Virginia.

C. Each health benefit plan shall contain a provision for grace periods:

1. An individual health benefit plan shall contain a grace period of not less than 31 days after the initial premium is paid. Further, in accordance with 45 CFR 156.270(d), an individual health benefit plan offered on the exchange shall also contain language that an enrollee receiving advance payments of the premium tax credit is instead subject to a grace period of three consecutive months, during which time the health carrier shall pay all appropriate claims for services rendered to the enrollee during the first month of the grace period and may pend claims for services rendered to the enrollee in the second and third months of the grace period. If the enrollee exhausts the three-month grace period, the health carrier shall terminate the policy effective the last day of the first month of the three-month grace period.

2. A group health benefit plan shall contain a grace period of not less than 31 days after the initial premium is paid.

D. A health benefit plan shall contain essential health benefits in accordance with § 38.2-3451 of the Code of Virginia. Benefits required by any applicable state or federal law shall also be covered.

E. The standard by which payment of benefits is made shall be clearly described in the policy. "Allowed amount" and other similar words shall be clearly defined.

14VAC5-135-40. Student health insurance coverage.

A. For purposes of this section, "student health insurance coverage" means a type of individual health insurance coverage offered in the individual market that (i) is provided

pursuant to a written agreement between an institution of higher education, as defined by the Higher Education Act of 1965 (P.L. 89-329), and a health carrier and provided to students enrolled in that institution of higher education and their covered dependents; (ii) does not make health insurance coverage available other than in connection with enrollment as a student or as a covered dependent of a student of the institution of higher education; and (iii) does not condition eligibility for health insurance coverage on any health status-related factor related to a student or a covered dependent of the student.

B. Student health insurance coverage is subject to the requirements of the ACA, including essential health benefits, mental health parity, and the requirements of this chapter, except as noted in this section.

C. Student health insurance coverage is exempt from the guaranteed availability requirements of § 38.2-3430.3 of the Code of Virginia and the guaranteed renewability requirements of § 38.2-3430.7 of the Code of Virginia.

D. Student health insurance coverage is not subject to the single risk pool requirement outlined in § 1312(c) of the ACA.

E. Student health insurance coverage premium rates may be based on a school-specific community rating.

14VAC5-135-50. Prohibitions, limitations, and disclosures.

A. A health carrier shall not discriminate on the basis of race, color, national origin, disability, age, sex, gender identity, gender expression, sexual orientation, or status as a transgender individual. Nothing in this section shall be construed to prevent a health carrier from appropriately utilizing reasonable medical management techniques including medical necessity.

~~[B. A policy shall not limit or exclude medically necessary services that arise out of complications from contractually excluded services.~~

~~C. B.]~~ If a health carrier offers an optional benefit to a health benefit plan, the health carrier may file a separate schedule that includes the additional benefit and identify the health benefit plan to which the schedule applies. A different plan identification is necessary to distinguish the health benefit plan with the additional benefit.

~~[D. C.]~~ A health carrier may offer a health benefit plan that does not include pediatric oral health benefits if:

1. The health carrier is reasonably assured that pediatric oral health benefits are available to the purchaser of the health benefit plan in accordance with § 38.2-3451 B of the Code of Virginia, and

2. The plan contains the following statement on the first page of the policy and bold:

Regulations

"This policy does not provide **the** ACA-required pediatric oral health benefits."

[~~E~~. D.] If an individual policy contains a military service exclusion or a provision that suspends coverage during military service, **the** policy shall provide for a refund of unearned premium upon receipt of written notice of **the** military service.

[~~F~~. E.] A policy application shall not contain questions about any health-status related factors other than age and tobacco use.

[~~G~~. F.] A policy shall only be rated on age, tobacco use, geographic location, plan category, and whether **the** policy covers dependents in accordance with § 38.2-3447 of **the** Code of Virginia.

[~~H~~. G.] No policy shall contain a provision that allows for increase in premium or change in deductible except during renewal.

[~~I~~. H.] A health benefit plan shall not impose any preexisting condition exclusion.

[~~J~~. I.] Policy exclusions may be no more restrictive than allowed by **the** state-selected essential health benefits benchmark plan.

14VAC5-135-60. Severability.

If any provision of this chapter or its application to any person or circumstance is for any reason held to be invalid, **the** remainder of **the** chapter and **the** application of **the** provisions to other persons or circumstances shall not be affected.

Chapter 141

Rules Governing Accident and Sickness Excepted Benefits Policies; Short-Term Limited Duration Insurance

14VAC5-141-10. Applicability and scope.

A. This chapter implements **the** provisions of Chapters 34 (§ 38.2-3400 et seq.) and 35 (§ 38.2-3500 et seq.) of Title 38.2 of **the** Code of Virginia as it applies to excepted benefits as defined in § 38.2-3431 of **the** Code of Virginia, 45 CFR § 146.145, and 45 CFR 148.220, as well as short-term limited-duration insurance.

B. This chapter applies to all individual and group market insurance policies delivered or issued for delivery in Virginia that qualify as accident and sickness excepted benefits.

C. This chapter applies to all short-term limited-duration insurance delivered or issued for delivery in Virginia, including a certificate delivered in Virginia that is issued under a short-term limited-duration plan in any other jurisdiction.

D. This chapter outlines **the** types of accident and sickness excepted benefits policies and **the** allowable combinations of such policies that may be approved for use in Virginia. No other combinations or types of such policies may be filed without prior approval by **the** commission.

E. This chapter does not apply to Medicare Supplement policies, which are governed under Rules Governing Minimum Standards for Medicare Supplement Policies (14VAC5-170) and long-term care insurance, which is governed under Rules Governing Long-Term Care Insurance (14VAC5-200).

14VAC5-141-20. Definitions.

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

"Accident" means an unintentional or unexpected event or circumstance that results in injury.

"Accident only coverage" means a policy that provides benefits for accidental injury.

"Accidental injury" means bodily injury sustained by **the** insured that is **the** direct result of an accident independent of disease, infirmity, or any other cause. "Accidental injury" shall not include words that establish an accidental means test or use words such as "external," "violent," "visible wounds," or similar words of description or characterization.

"Commission" means **the** State Corporation Commission.

"Disability income insurance" means a policy that provides for weekly or monthly periodic payments for a specified period during **the** continuance of **the** insured's partial or total disability resulting from either sickness or injury or a combination of **the** two.

"Elimination period" means a period of time [after coverage begins and is] between **the** date of loss and when benefits commence. An elimination period may only be included in a disability income policy or a short-term convalescent care policy, unless otherwise specified in this chapter.

"Excepted benefits" has **the** same meaning as in § 38.2-3431 of **the** Code of Virginia. For purposes of this regulation:

1. **The** following benefits are excepted in all circumstances:
 - a. Coverage only for accident (including accidental death and dismemberment); or
 - b. Disability income insurance.
2. **The** following benefits are excepted if **the** benefits are provided under a separate individual or group policy, certificate, or contract of insurance, or are not an integral part of **the** group health plan:
 - a. Limited scope dental, limited scope vision, or limited scope hearing benefits; or
 - b. Other similar, limited benefits as may be filed and approved by **the** commission.
3. **The** following benefits are excepted if offered as independent, noncoordinated benefits:
 - a. Specified disease or critical illness; or
 - b. Hospital indemnity or other fixed indemnity insurance.

4. Similar supplemental coverage qualifies as excepted benefits if the coverage supplements and fills gaps in a group health plan and is provided in a separate policy.

"Hospital" means a facility licensed as a hospital under state law. The term "hospital" may be [further] defined with no [further more] restrictions than the applicable [state] licensure requirements.

"Major medical coverage" or "minimum essential coverage" as defined in 45 CFR 156.600 means any of the following:

1. Employer-sponsored coverage (including Consolidated Omnibus Budget Reconciliation Act (COBRA) coverage and retiree coverage);
2. Coverage purchased in the individual market, including a qualified health plan offered through the Health Insurance Marketplace (also known as the Health Benefit Exchange);
3. Coverage under a grandfathered health plan;
4. Medicare Part A coverage and Medicare Advantage plans;
5. Most Medicaid coverage, except for limited coverage plans;
6. Children's Health Insurance Program (CHIP) coverage;
7. Most student health plans;
8. Certain types of veterans' health coverage administered by the Department of Veterans Affairs;
9. TRICARE;
10. Coverage provided to Peace Corps volunteers;
11. Coverage under the Nonappropriated Fund Health Benefit Program;
12. Refugee Medical Assistance supported by the Administration for Children and Families; or
13. State high-risk pools for plan or policy years that started on or before December 31, 2014.

"Partial disability" or "residual disability," if such term is used in the policy or certificate, means the insured's inability to perform one or more but not all of the major or essential duties of employment or occupation or may be related to a percentage of time worked, a specified number of hours, or amount of compensation. Where a policy provides total and partial or residual disability benefits, no more than one elimination period may be required for any one period of disability.

"Policy" means an insurance policy, contract, certificate, evidence of coverage, or other agreement of insurance, including any attached rider, endorsement, or application.

"Preexisting condition" means a disease or physical condition [that, during a one-year period immediately preceding the effective date of coverage for which medical advice] or treatment was received [during a period not to exceed one year

immediately preceding the effective date of coverage]. "Preexisting condition" shall not include congenital anomalies of a covered dependent child.

A preexisting condition exclusion shall not exceed one year for individual policies, unless otherwise specified in this chapter.

A preexisting condition exclusion for group policies shall not apply to loss incurred or disability commencing after the earlier of (i) the end of a continuous period of 12 months commencing on or after the effective date of the person's coverage during which the person receives no medical advice or treatment in connection with the disease or physical condition, or (ii) the end of the two-year period commencing on the effective date of the person's coverage, unless otherwise specified in this chapter.

"Renewable" means the right of a policyholder to continue the policy in force by the timely payment of premiums, during which period the insurer shall not unilaterally make any change in any provision of the policy while the policy is in force; however, the insurer may adjust premium rates upon renewal in accordance with rate filing requirements.

"Short-term limited-duration insurance" means health insurance coverage in which the period of coverage or policy duration is three months or less and complies with the requirements of § 38.2-3407.21 of the Code of Virginia. "Short-term limited-duration insurance" is not individual health insurance coverage and is not excepted benefits as those terms are defined in § 38.2-3431 of the Code of Virginia.

"Sickness" means an illness, disease, condition, or disorder.

"Total disability" means the insured's inability to perform the substantial and material duties of the insured's regular occupation or the insured's inability to engage in an employment or occupation for which the insured is or becomes qualified by reason of education, training, or experience. Total disability shall not be based solely upon an insured's inability to (i) perform any occupation, any occupational duty, any and every duty of the insured's occupation, or words of similar meaning; or (ii) engage in any training or rehabilitation program.

"Waiting period" means the period of time commencing from the effective date of coverage during which no benefits are provided under the policy [but does not include an eligibility waiting period imposed by a group or employer before coverage begins].

14VAC5-141-30. General policy provisions.

A. Each excepted benefits policy shall contain a notice displayed prominently in advertising, application and plan materials and on the face of the policy in at least 14-point type the following language:

Regulations

"THIS IS AN EXCEPTED BENEFITS POLICY. IT PROVIDES COVERAGE ONLY FOR THE LIMITED BENEFITS OR SERVICES SPECIFIED IN THE POLICY."

B. A policy that [~~is intended to cover~~ covers] specific types of benefits or services may not then exclude the same or similar types of conditions, illnesses, or events, except for any preexisting condition limitations. Benefits shall be reasonable in relation to the premium charged [~~and specific~~. Specific] prohibitions [~~shall may~~] be limited as determined by the commission.

C. Each individual policy issued under this chapter may be renewable at the option of the insured, unless otherwise specified in this chapter. The renewability provisions shall appear on the first page of the policy and be appropriately captioned.

D. If covered, pregnancy, childbirth, or miscarriage shall be treated like any other sickness. [Complications that arise from pregnancy shall be covered.]

E. In the event an insurer cancels an individual policy in accordance with § 38.2-3504 of the Code of Virginia, any coverage for pregnancy shall provide for an extension of benefits for the duration of the pregnancy if the pregnancy commenced while the policy was in force and for which benefits would be payable had the policy remained in force.

F. A policy that provides for the payment of benefits based on standards described as "usual and customary," "reasonable and customary," or similar words shall include an explanation of these terms.

G. An individual policy that provides for dependent coverage shall provide that in the event of the insured's death, a covered spouse of the insured shall become the insured.

H. A policy may [~~only~~] exclude services performed by a member of the covered person's immediate family and services for which no charge is normally made in the absence of insurance.

I. If [~~a~~ an individual] policy contains a military service exclusion or a provision that suspends coverage during military service, the policy shall provide for a refund or credit of unearned premium upon receipt of written notice of the military service.

J. For any individual policy, if additional premium is charged for benefits provided in connection with a rider or endorsement, a separate premium amount shall be stated in the policy.

K. If a policy contains any preexisting condition limitations, these shall appear in a separate paragraph in the policy and labeled as "Preexisting Conditions Limitation."

L. If age is used to reduce the maximum aggregate benefits available in the policy, this shall be prominently stated in the policy.

M. If a policy contains a conversion provision, it shall appear in a separate paragraph and shall state eligibility requirements, limitations on the conversion, and the benefits provided.

14VAC5-141-40. Prohibitions, limitations and disclosures.

A. No excepted benefits policy or short-term limited-duration insurance policy may be advertised, offered for sale, or sold as minimum essential coverage.

B. A policy shall not have a waiting period that exceeds 30 days, unless otherwise specified in this chapter.

C. If a policy contains a preexisting condition exclusion, it shall conform to the requirements included in the definition of "preexisting condition" in this chapter, unless otherwise specified in this chapter.

D. Any limit or reduction of coverage or benefits for specifically named or described preexisting conditions that goes beyond the limitations in subsection C of this section or extrahazardous activity that is a condition of issuance, renewal, or reinstatement requires a signed acceptance by the policyholder and shall be attached to the policy.

E. Except for riders or endorsements by which the insurer fulfills a request made in writing by the policyholder, an insurer shall not reduce or eliminate benefits or coverage except at reinstatement or renewal. After the date of policy issue and during the policy term, any rider or endorsement that increases benefits or coverage with an increase in premium shall be agreed to in writing by the policyholder, except if the increased benefits or coverage is required by law.

14VAC5-141-50. Accident.

A. Accident only coverage is a benefit provided for accidental bodily injury sustained by the insured person. Accident only coverage shall not contain a waiting period.

B. Accident only coverage may be filed in combination with the following:

1. Accidental death and dismemberment;
2. Disability income; or
3. Hospital indemnity or fixed indemnity.

C. A policy that covers an accidental injury may provide that injuries shall not include:

1. Injuries for which benefits are provided under any workers' compensation, employer's liability or similar law, or motor vehicle no-fault plan, unless prohibited by law; or
2. Injuries incurred while the insured person is engaged in any activity pertaining to any trade, business, employment, or occupation for wage or profit.

D. Accidental death and dismemberment benefits shall be payable if the loss occurs within 180 days from the date of the

accident, the loss is a result of the accident, and the policy was in force at the time of the accident.

E. Specific dismemberment benefits shall not be payable in lieu of other benefits under the policy unless the specific dismemberment benefit equals or exceeds any other benefits contained in the policy.

F. An elimination period may be applied to an incidental benefit that is in addition to the accident benefit, such as a fixed or lump-sum payment for a coma resulting from an accident.

14VAC5-141-60. Disability income insurance.

A. Disability income insurance is a policy that provides for weekly or monthly periodic payments for a specified period during the continuance of partial or total disability resulting from either sickness or injury or a combination of the two.

B. Disability income insurance may be filed in combination with the following:

1. Accident only coverage;
2. Accidental death and dismemberment; or
3. Hospital indemnity or fixed indemnity.

C. A disability income policy may contain an elimination period no greater than:

1. 30 days in the case of coverage providing a benefit of one year or less, unless otherwise provided in subsection F of this section;
2. 90 days in the case of coverage providing a benefit of more than one year but not greater than two years; or
3. 180 days in all other cases during the continuance of disability resulting from sickness or injury.

D. A disability income policy shall allow at least 30 days after the date of an accident for a covered loss to start.

E. A disability policy shall cover complications arising out of pregnancy, childbirth, or miscarriage.

F. A disability income individual policy shall contain a minimum period of time for which benefits are paid that is not less than 180 days. A disability income group policy may contain a minimum period of time for which benefits are paid that is not less than 90 days. A policy that is 90 days but less than 180 days may have an elimination period of not more than seven days.

G. If a disability income policy contains a provision for recurrent disabilities, the period of time required between recurrent disabilities shall be no greater than six months.

H. If the insurer terminates a disability income policy, any claim for a covered loss that commenced while the policy was in force shall not be affected, subject to the terms and conditions of the policy.

I. If a disability income policy contains a return of premium or cash value benefit, it shall not be reduced by an amount greater than the aggregate of claims paid under the policy. The insurer shall also demonstrate that the reserve basis for the policy is adequate.

J. A rider or endorsement that provides a specific dollar payment to the employer or business that may suffer a financial loss in the event of the disability of a key person may be attached to a disability income policy.

K. If a disability income policy provides coverage for disability from childbirth, it shall provide for a payable benefit of at least 12 weeks immediately following childbirth in accordance with § 38.2-3407.11:4 of the Code of Virginia. No waiting or elimination period shall apply.

14VAC5-141-70. Limited scope benefits - dental, vision, and hearing.

A. Limited scope dental, limited scope vision, and limited scope hearing are plans that provide for benefits primarily for the treatment of the mouth, eyes, and ears, respectively.

B. Limited scope dental, limited scope vision, and limited scope hearing plans may be provided either as separate policies, certificates, or contracts of insurance, or not part of an integral group health plan. Benefits are not part of an integral group health plan if the participant has the right to opt-out of coverage, or if claims for the benefits are administered under a separate contract from the claims administration for any other benefits under the group health plan.

C. Except for [basic or diagnostic and] preventive benefits, a limited scope dental plan may apply waiting periods that exceed 30 days but no longer than 12 months to specific services or benefits. [A waiting period not to exceed 24 months may be applied to orthodontic services.]

D. For any limited scope dental plan to be recognized as meeting essential health benefits in accordance with § 38.2-3451 of the Code of Virginia and be treated as a qualified health plan in accordance with 45 CFR 155.1065, pediatric dental essential health benefits shall be included in the plan.

E. In addition to the notice required in 14VAC5-141-30 A, any limited scope dental plan that is not an exchange certified stand-alone dental plan shall include the following language on the face of the policy:

"THIS IS A STAND-ALONE DENTAL POLICY THAT IS NOT EXCHANGE CERTIFIED AND MAY NOT PROVIDE MINIMUM ESSENTIAL PEDIATRIC DENTAL BENEFITS."

14VAC5-141-80. Limited scope benefits - accident and sickness insurance while traveling.

A. Limited scope accident and sickness insurance while traveling is a separate policy providing accident and sickness benefits only for the limited duration of an insured's trip.

Regulations

B. A limited scope accident and sickness insurance while traveling policy:

1. Shall not contain preexisting condition exclusions;
2. Shall not contain a waiting period;
3. Shall not contain a deductible applied to benefits;
4. Shall not coordinate benefits with any other accident and sickness policy;
5. Shall not be renewable;
6. Shall not include benefits for trip interruption or trip cancellation; and
7. Shall provide accident and sickness benefits only for the limited duration of an insured's trip.

C. Travel insurance in which the primary purpose of the insurance is trip cancellation or interruption shall be reviewed as miscellaneous casualty insurance in accordance with § 38.2-111 of the Code of Virginia and is exempt from this chapter.

14VAC5-141-90. Limited scope benefits - short-term convalescent care.

A. A short-term convalescent care policy may include care provided in a nursing home, assisted living facility, hospice, adult day care center, or home. A short-term convalescent care policy is a policy with a maximum lifetime benefit period that does not exceed 364 days and that is provided under a separate policy, certificate, or contract of insurance.

B. There is no coordination of benefits with any other accident and sickness policy.

C. A short-term convalescent care policy shall contain the following provisions:

1. Eligibility for benefits shall be based on loss due to accident or sickness and loss of functional capacity or cognitive impairment.
2. Once the maximum benefit period under the policy has been exhausted, the policy may not be renewed.
3. If a policy contains a period in which benefits may be restored, the maximum period of time between benefit periods shall be no more than 180 days.
4. If a policy conditions benefits on an insured's inability to perform activities of daily living or on cognitive impairment, such requirements shall be defined.
5. Eligibility for benefits shall not be more restrictive than the presence of cognitive impairment or a deficiency of no more than two activities of daily living.
6. Reimbursement for any covered service that is legally performed by a person licensed to perform such services may not be denied.

D. If a policy provides short-term convalescent care or extended care benefits following hospitalization, qualification for benefits for the convalescent care or extended care facility shall not require admission less than 14 days after discharge from the hospital.

E. In addition to the provisions of 14VAC5-141-30 A, the following disclosure shall appear on the face of the policy:

"This is a policy that provides benefits for short-term convalescent care. THIS IS NOT A LONG-TERM CARE POLICY."

14VAC5-141-100. Limited scope benefits - group blanket policies.

A. A group blanket insurance policy is a policy of limited accident and sickness insurance that provides coverage for specified circumstances and a specific class of persons defined in the policy issued to a master policyholder. Such policy does not specifically name persons covered, by certificate or otherwise, although a statement of the coverage provided may be given, or required by the policy to be given, to eligible persons.

B. An individual application is not required from a person covered under a blanket insurance policy.

C. No insurer issuing a blanket insurance policy shall be required to furnish a certificate to each person covered by the policy.

D. A blanket insurance policy to be issued or issued for delivery in Virginia shall comply with the requirements of § 38.2-3521.2 of the Code of Virginia.

14VAC5-141-110. Specified disease insurance.

A. Specified disease insurance is a policy that pays benefits for the diagnosis or treatment of a specifically named disease or a critical illness.

B. Specified disease insurance benefits shall be provided under a separate policy, certificate, or contract of insurance.

C. Any policy provision that provides for the coordination or reduction of benefits because benefits are payable under any other health insurance coverage is prohibited.

D. A specified disease policy shall not exclude coverage for any subtype of disease or illness covered under the policy. The dollar value of benefits may only be limited based on the severity of the disease or illness where the insurer shows actuarial justification for the lower amount.

E. As a condition for eligibility for benefits under the policy, a clinical diagnosis shall be accepted if a pathological diagnosis cannot be reasonably obtained.

F. If a policy provides convalescent care or extended care benefits following hospitalization, qualification for benefits for

the convalescent care or extended care facility shall not require admission less than 14 days after discharge from the hospital.

G. Policy benefits shall begin with the first day of care or confinement if the care or confinement is for a covered disease or illness even though a diagnosis is made at a later date. The retroactive application of coverage may not be limited to less than 90 days prior to the diagnosis.

H. If a specified disease policy contains a return of premium or cash value benefit, it shall not be reduced by an amount greater than the aggregate of claims paid under the policy. The insurer shall also demonstrate that the reserve basis for the policy is adequate.

14VAC5-141-120. Hospital indemnity or other fixed indemnity insurance.

A. Hospital indemnity or other fixed indemnity insurance means a policy that provides supplementary benefits that are paid to the insured in a single lump sum or a fixed dollar amount per specified event, per day, or per other period of hospitalization or illness regardless of the amount of expenses incurred. The policy shall not be a substitute for major medical coverage.

B. Hospital indemnity or other fixed indemnity insurance that is offered in the individual market shall meet the following criteria:

1. Benefits shall be provided under a separate policy, certificate, or contract of insurance;
2. Benefits paid may be a single lump sum or a fixed dollar amount per service, per specified event, per day, or per other period of time. Benefits shall be determined based on the category of services and not the billed amount. Dollar amounts shall be expressed in the policy;
3. There is no coordination between the provision of benefits and an exclusion of benefits under any other health coverage;
4. A pregnancy that exists on the effective date of coverage may be considered a preexisting condition;
5. No waiting period shall be applied to loss due to accidental injury; and
6. In addition to the notice required in 14VAC5-141-30 A, the following notice shall be displayed prominently on the face of the policy: "THIS IS A SUPPLEMENT TO HEALTH INSURANCE AND IS NOT A SUBSTITUTE FOR MAJOR MEDICAL COVERAGE."

C. Hospital indemnity or other fixed indemnity insurance offered in the group market shall meet the following criteria:

1. There is no coordination between the provision of the benefits and an exclusion of benefits under any group health plan maintained by the same plan sponsor;

2. The benefits are paid with respect to an event without regard to whether benefits are provided with respect to the event under any group health plan maintained by the same plan sponsor; and

3. Benefits shall be paid in a single lump sum or a fixed dollar amount per day or other period of hospitalization or illness regardless of the amount of expenses incurred. [A group policy shall not pay benefits on a per service basis.] Benefits shall not be determined based on the billed amount. Dollar amounts shall be expressed in the policy.

14VAC5-141-130. Similar supplemental coverage.

A. Similar supplemental coverage that qualifies as excepted benefits is coverage that supplements and fills gaps in a group health plan. The supplemental coverage shall:

1. Cover benefits that are not covered by the primary coverage and are not essential health benefits as described in § 38.2-3451 of the Code of Virginia; or
2. Fill gaps in cost-sharing for primary coverage, including copayments, coinsurance, and deductibles.

B. Similar supplemental coverage shall be provided under a separate policy.

C. Similar supplemental coverage does not include coverage that becomes secondary or supplemental only under a coordination of benefits provision.

14VAC5-141-140. Short-term limited-duration insurance coverage.

A. Short-term limited-duration insurance is health insurance coverage in which the period of coverage or policy duration is three months or less. Based on the insured's eligibility, coverage may be renewed or extended so that coverage may not exceed six months in any 12-month period in accordance with § 38.2-3407.21 of the Code of Virginia. An application form shall include a question on whether the applicant had any short-term limited-duration coverage within 12 months of the application date.

B. A short-term limited-duration insurance policy issued by a health maintenance organization shall cover basic health care services as defined in § 38.2-4300 of the Code of Virginia. A short-term limited-duration insurance policy issued by any health carrier other than a health maintenance organization shall include at a minimum emergency services, hospital and physician care, outpatient medical services, surgical benefits, and radiology and laboratory benefits.

C. Short-term limited-duration insurance coverage may be nonrenewable or renewable, but not guaranteed renewable in accordance with § 38.2-3514.2 of the Code of Virginia.

1. A nonrenewable short-term limited-duration policy shall include all applicable state mandates that do not specifically exempt short-term nonrenewable policies.

Regulations

2. A renewable short-term limited-duration policy shall include all applicable state mandates, including those mandates that exempt short-term nonrenewable policies.

D. A policy shall not subject a person to a preexisting condition exclusion of more than three months in any 12-month period. Any preexisting condition exclusion shall credit for any prior creditable coverage.

E. A short-term limited-duration policy shall not contain any waiting period or elimination period prior to receiving benefits.

F. Any advertising, sales call, solicitation, or other marketing practices shall include a disclosure that a short-term limited-duration policy is not minimum essential coverage or major medical coverage.

G. Each short-term limited-duration policy shall contain the following notice displayed prominently in the application, plan materials and on the face of the policy in at least 14-point type:

"THIS COVERAGE IS NOT REQUIRED TO COMPLY WITH FEDERAL MARKET REQUIREMENTS FOR HEALTH INSURANCE, PRINCIPALLY THOSE CONTAINED IN THE AFFORDABLE CARE ACT. Be sure to check your policy carefully to make sure you are aware of any exclusions or limitations regarding coverage of preexisting conditions or health benefits (such as hospitalization, emergency services, maternity care, preventive care, prescription drugs, and mental health and substance use disorder services). Your policy might also have lifetime and/or annual dollar limits on health benefits. If this coverage expires or you lose eligibility for this coverage, you might have to wait until an open enrollment period to get other health insurance coverage."

H. Short-term limited-duration insurance forms and rates shall be filed with and approved by the commission in accordance with §§ 38.2-316 and 38.2-316.1 of the Code of Virginia.

I. A short-term limited-duration insurance policy shall be subject to internal appeal process requirements and external review requirements of Chapter 35.1 (§ 38.2-3556 et seq.) of Title 38.2 of the Code of Virginia.

J. An insurer shall not issue a short-term limited-duration policy during any open enrollment period. [~~No application for short-term limited-duration insurance may be accepted during any open enrollment period.~~]

14VAC5-141-150. Requirements for replacement of an individual policy.

A. The application form for an excepted benefits or short-term limited-duration policy shall include a question regarding whether the insurance to be issued is intended to replace any other insurance presently in force.

B. An insurer may not replace any policy that qualifies as minimum essential coverage with an excepted benefits or a

short-term limited-duration policy unless specifically requested in writing by the insured.

C. If the sale will involve replacement, an insurer or its agent shall furnish to the applicant prior to issuance or delivery of the policy the notice required in subsection D of this section. A direct response insurer shall deliver the notice to the applicant upon issuance of the policy. A copy signed by the applicant shall be retained by the insurer.

D. Notice to applicants shall be provided in substantially the following form:

"NOTICE TO APPLICANT REGARDING REPLACEMENT OF AN INSURANCE POLICY

According to your application, you intend to lapse or otherwise terminate an existing policy and replace it with an excepted benefits or short-term limited-duration policy issued by (insert Company Name). In accordance with the terms of your policy, you may have at least 10 days to decide without cost whether you desire to keep the policy. For your own protection you should consider certain factors that may affect the insurance provisions available to you under the new policy.

1. Preexisting conditions may not be immediately or fully covered under the new policy. This could result in denial or delay of a claim for benefits under the new policy, where a similar claim may have been payable under your present policy.

2. You may wish to consult with your present insurer or its agent regarding the proposed replacement of your present policy. It is your right and in your best interest to make sure you understand all the factors involved in replacing your present coverage.

3. If you still wish to terminate your present policy and replace it with new coverage, carefully check all the information in the application before you sign it.

The above "Notice to Applicant" was delivered to the applicant on (date).

(Applicant's signature _____)"

14VAC5-141-160. Severability.

If any provision of this chapter or the application thereof to any person or circumstance is for any reason held to be invalid, the remainder of the chapter and the application of such provision to other persons or circumstances shall not be affected.

VA.R. Doc. No. R22-4101; Filed December 9, 2022, 9:47 a.m.

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.

Titles of Regulations: 14VAC5-341. Rules Governing Standards for the Content of Dwelling Property Insurance Policies (amending 14VAC5-341-10).

14VAC5-342. Rules Governing Standards for the Content of Homeowners Insurance Policies (amending 14VAC5-342-10).

Statutory Authority: §§ 12.1-13 and 38.2-223 of the Code of Virginia.

Effective Date: December 31, 2022.

Agency Contact: Jackie Myers, Chief Insurance Market Examiner, Bureau of Insurance, State Corporation Commission, P.O. Box 1157, Richmond, VA 23218, telephone (804) 371-9630, or email jackie.myers@scc.virginia.gov.

Summary:

The amendments extend the deadline to submit filings for compliance to May 1, 2023, for policies delivered or issued for delivery in Virginia on and after December 31, 2023.

AT RICHMOND, DECEMBER 8, 2022

COMMONWEALTH OF VIRGINIA, ex rel.

STATE CORPORATION COMMISSION

CASE NO. INS-2022-00154

Ex Parte: In the matter of amending Rules Governing Standards for the Content of Dwelling Property Insurance Policies and Rules Governing Standards for the Content of Homeowners Insurance Policies

ORDER ADOPTING REGULATIONS

On October 27, 2022, the State Corporation Commission ("Commission") entered an Order to Take Notice to amend rules set forth in Chapter 341 of the Virginia Administrative Code, 14VAC5-341-10 et seq., entitled "Rules Governing Standards for the Content of Dwelling Property Insurance Policies," and Chapter 342 of the Virginia Administrative Code, 14VAC5-342-10 et seq., entitled "Rules Governing Standards for the Content of Homeowner Policies" ("Rules").

Specifically, and solely, the Commission's Bureau of Insurance ("Bureau") proposes changing the deadline to submit filings for compliance from December 31, 2022 to May 1, 2023; and proposes to require compliance for policies delivered or issued for delivery in Virginia from those with effective dates on and after July 1, 2023, to those with effective dates on and after December 31, 2023.1

The Order to Take Notice and proposed amendments to the Rules were posted on the Commission's website; sent to all carriers licensed in Virginia to write fire and homeowners insurance and to all interested persons on October 31, 2022; sent to the Office of the Virginia Attorney General's Division of Consumer Counsel ("Consumer Counsel"); and published in the Virginia Register of Regulations on November 21, 2022. Licensees, Consumer Counsel, and other interested parties were afforded the opportunity to file written comments and request a hearing on or before December 5, 2022.

The Bureau received four comments to the proposed amendments to the Rules, which were filed by the following: American Association of Insurance Services; Insurance Services Office, Inc.; National Association of Mutual Insurance Companies; and American Property and Casualty Insurance Association. The Commission received no request for a hearing.

The Bureau considered the comments filed and responded to such comments in its Response to Comments ("Response"), filed with the Clerk of the Commission on December 6, 2022. In its Response, the Bureau indicates why it does not believe that suggested revisions are warranted.

NOW THE COMMISSION, having considered the proposal to amend the Rules, the comments filed, and the recommendation of the Bureau to adopt the amendments to the Rules, concludes that the attached amendments to the Rules should be adopted, effective December 31, 2022.

Accordingly, IT IS ORDERED THAT:

(1) The amendments to "Rules Governing Standards for the Content of Dwelling Property Insurance Policies," 14VAC5 341-10 et seq. of the Virginia Administrative Code and "Rules Governing Standards for the Content of Homeowners Insurance Policies," 14VAC5-342-10 et seq. of the Virginia Administrative Code, which are attached hereto and made a part hereof, are hereby ADOPTED effective December 31, 2022.

(2) The Bureau shall provide notice of the adopted amendments to the Rules to all carriers licensed in Virginia to write fire and homeowners insurance and to all persons known to the Bureau to have an interest in fire and homeowners insurance.

(3) The Commission's Office of General Counsel shall cause a copy of this Order and the amendments to the Rules to be forwarded to the Virginia Registrar of Regulations for appropriate publication in the Virginia Register of Regulations.

(4) The Commission's Division of Information Resources shall make available this Order and the attached amendments on the Commission's website: scc.virginia.gov/pages/Case-Information.

Regulations

(5) The Bureau shall file with the Clerk of the Commission a certificate of compliance with the notice requirements of Ordering Paragraph (2) above.

(6) This case is dismissed.

A COPY hereof shall be sent electronically by the Clerk of the Commission to:

C. Meade Browder, Jr., Senior Assistant Attorney General, Office of the Attorney General, Division of Consumer Counsel, 202 North 9th Street, 8th Floor, Richmond, Virginia 23219-3424, at mbrowder@oag.state.va.us; and a copy hereof shall be delivered to the Commission's Office of General Counsel and the Bureau of Insurance in care of Deputy Commissioner Rebecca Nichols.

The Bureau proposed amendments to 14VAC5-341-10 B and 14VAC5-342-10 B that contain identical language.

14VAC5-341-10. Scope and applicability.

A. This chapter sets forth the standards of content for policies of dwelling property insurance covering solely owner-occupied dwellings, including condominium units. This chapter applies to insurers licensed to do business in Virginia and issuing policies of dwelling property insurance pursuant to the provisions of Chapter 21 (§ 38.2-2100 et seq.) of Title 38.2 of the Code of Virginia.

B. Compliance with this chapter is required for policies delivered or issued for delivery in Virginia with effective dates on and after ~~July 1~~ December 31, 2023. Insurers and rate service organizations shall submit filings for compliance with this chapter no later than ~~December 31, 2022~~ May 1, 2023.

C. No insurer shall represent to a prospective purchaser or a policyholder that a dwelling property policy subject to the provisions of this chapter is a homeowners policy as defined in § 38.2-130 of the Code of Virginia.

D. This chapter does not apply to policies that:

1. Are lender-placed;
2. Insure owner-occupied farms;
3. Insure manufactured homes as defined in § 46.2-100 of the Code of Virginia, except for policies insuring manufactured homes as defined in § 46.2-653.1 of the Code of Virginia;
4. Are issued pursuant to Chapter 27 (§ 38.2-2700 et seq.) of Title 38.2 of the Code of Virginia;
5. Are issued pursuant to Chapter 48 (§ 38.2-4800 et seq.) of Title 38.2 of the Code of Virginia; or
6. Primarily insure the personal property of renters.

E. Insurers shall file with the commission all policies or endorsements for approval before use.

F. Policies and endorsements shall not be less favorable than the provisions set forth in this chapter. Insurers may provide broader and more favorable coverages, terms, and conditions than those set forth in this chapter. Insurers may use any policy language that is not less favorable to the insured and complies with provisions of this chapter.

14VAC5-342-10. Scope and applicability.

A. This chapter sets forth the standards of content for policies of homeowners insurance, including policies insuring owner-occupied condominium units. This chapter applies to insurers licensed to do business in Virginia and issuing policies of homeowners insurance and condominium unit owners insurance pursuant to Chapter 21 (§ 38.2-2100 et seq.) of Title 38.2 of the Code of Virginia.

B. Compliance with this chapter is required for policies delivered or issued for delivery in Virginia with effective dates on and after ~~July 1~~ December 31, 2023. Insurers and rate service organizations shall submit filings for compliance with this chapter no later than ~~December 31, 2022~~ May 1, 2023.

C. Pursuant to § 38.2-130 of the Code of Virginia, homeowners insurance policies are indivisible package policies that insure owner-occupied dwellings.

D. This chapter does not apply to policies that:

1. Are lender-placed;
2. Insure owner-occupied farms;
3. Insure manufactured homes as defined in § 46.2-100 of the Code of Virginia, except for policies insuring manufactured homes as defined in § 46.2-653.1 of the Code of Virginia;
4. Primarily insure the personal property of renters;
5. Are issued pursuant to Chapter 27 (§ 38.2-2700 et seq.) of Title 38.2 of the Code of Virginia; or
6. Are issued pursuant to Chapter 48 (§ 38.2-4800 et seq.) of Title 38.2 of the Code of Virginia.

E. Insurers shall file with the commission all policies and endorsements for approval before use.

F. Policies and endorsements shall not be less favorable than the provisions set forth in this chapter. Insurers may provide broader and more favorable coverages, terms, and conditions than those set forth in this chapter. Insurers may use any policy language that is not less favorable to the insured and complies with provisions of this chapter.

V.A.R. Doc. No. R23-5997; Filed December 9, 2022, 10:14 a.m.



TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF PHARMACY

Final Regulation

REGISTRAR'S NOTICE: The Board of Pharmacy is claiming an exemption from Article 2 of the Administrative Process Act in accordance with § 2.2-4006 A 13 of the Code of Virginia, which exempts amendments to regulations of the board to schedule a substance in Schedule I or II pursuant to subsection D of § 54.1-3443 of the Code of Virginia. The board will receive, consider, and respond to petitions by any interested person at any time with respect to reconsideration or revision.

Title of Regulation: 18VAC110-20. Regulations Governing the Practice of Pharmacy (amending 18VAC110-20-322).

Statutory Authority: §§ 54.1-2400 and 54.1-3443 of the Code of Virginia.

Effective Date: February 1, 2023.

Agency Contact: Caroline Juran, RPh, Executive Director, Board of Pharmacy, 9960 Mayland Drive, Suite 300, Richmond, VA 23233-1463, telephone (804) 367-4456, FAX (804) 527-4472, or email caroline.juran@dhp.virginia.gov.

Summary:

The amendments add five compounds into Schedule I as recommended by the Department of Forensic Science pursuant to § 54.1-3443 of the Code of Virginia. These compounds added by regulatory action will remain in effect for 18 months or until the compounds are placed in Schedule I by legislative action of the General Assembly.

18VAC110-20-322. Placement of chemicals in Schedule I.

A. Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following in Schedule I of the Drug Control Act:

1. Synthetic opioid. 1-(4-cinnamyl-2,6-dimethylpiperazin-1-yl)propan-1-one (other name: AP-238), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.
2. Compounds expected to have hallucinogenic properties.
 - a. 4-methallyloxy-3,5-dimethoxyphenethylamine (other name: Methallylescaline), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.
 - b. Alpha-pyrrolidino-2-phenylacetophenone (other name: alpha-D2PV), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of

such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. Cannabimimetic agents.

a. Ethyl 2-[1-pentyl-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: EDMB-PINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-phenethyl-1H-indazole-3-carboxamide (other name: ADB-PHETINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until August 16, 2023, unless enacted into law in the Drug Control Act.

B. Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following in Schedule I of the Drug Control Act:

1. Synthetic opioid. 2-(4-ethoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)-1H-benzimidazole (other names: N-pyrrolidino etonitazene, etonitazepyne), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.
2. Compounds expected to have hallucinogenic properties.
 - a. 1-(1,3-benzodioxol-5-yl)-2-(propylamino)-1-butanone (other names: 3,4-Methylenedioxy-alpha-propylaminobutiophenone; N-propyl butylone), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.
 - b. 2-(ethylamino)-1-phenylpentan-1-one (other names: N-ethylpentedrone, alpha-ethylaminopentiophenone), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.
 - c. 3,4-methylenedioxy-alpha-cyclohexylaminopropiophenone (other name: Cypuptylone), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.
 - d. 3,4-methylenedioxy-alpha-cyclohexylmethylamino propiophenone (other name: 3,4-Methylenedioxy-N,N-cyclohexylmethcathinone), its salts, isomers (optical, position, and geometric), and salts of isomers whenever

Regulations

the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

e. 3,4-methylenedioxy-alpha-isopropylaminobutophenone (other name: N-isopropyl butylone), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

f. 4-chloro-N-butylcathinone (other names: 4-chlorobutylcathinone, para-chloro-N-butylcathinone), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

g. 4-hydroxy-N-methyl-N-ethyltryptamine (other names: 4-hydroxy MET, Metocin), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. Central nervous system stimulant. 4-methylmethamphetamine (other names: N-alpha,4-trimethyl-benzeneethanamine, 4-MMA), including its salts, isomers, and salts of isomers.

4. Cannabimimetic agent. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indole-3-acetamide (other names: ADB-FUBIATA, AD-18, FUB-ACADB), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until March 14, 2024, unless enacted into law in the Drug Control Act.

C. Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following in Schedule I of the Drug Control Act:

1. Synthetic opioid. N,N-diethyl-2-[5-nitro-2-(4-propoxybenzyl)-1H-benzimidazol-1-yl]ethanamine (other name: Protonitazene), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

2. Compounds expected to have hallucinogenic properties. 1-(1,3-benzodioxol-5-yl)-2-(cyclohexylamino)butan-1-one (other names: Cybutylone, N-cyclohexyl Butylone), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. Compounds expected to have depressant properties. 8-bromo-6-(2-chlorophenyl)-1-methyl-4H-

[1,2,4]triazolo[4,3-a][1,4]benzodiazepine (other names: Clobromazolam, Phenazolam), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

4. Cannabimimetic agents.

a. 5-bromo-N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1H-indazole-3-carboxamide (other name: ADB-5Br-INACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-5-bromo-1-butylindazole-3-carboxamide (other name: ADB-5Br-BUTINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until July 31, 2024, unless enacted into law in the Drug Control Act.

VA.R. Doc. No. R23-7337; Filed November 30, 2022, 3:42 p.m.

Final Regulation

REGISTRAR'S NOTICE: The Board of Pharmacy is claiming an exemption from Article 2 of the Administrative Process Act in accordance with § 2.2-4006 A 13 of the Code of Virginia, which exempts amendments to regulations of the board to schedule a substance in Schedule I or II pursuant to subsection D of § 54.1-3443 of the Code of Virginia. The board will receive, consider, and respond to petitions by any interested person at any time with respect to reconsideration or revision.

Title of Regulation: 18VAC110-20. Regulations Governing the Practice of Pharmacy (amending 18VAC110-20-323).

Statutory Authority: §§ 54.1-2400 and 54.1-3443 of the Code of Virginia.

Effective Date: February 1, 2023.

Agency Contact: Caroline Juran, RPh, Executive Director, Board of Pharmacy, 9960 Mayland Drive, Suite 300, Richmond, VA 23233-1463, telephone (804) 367-4456, FAX (804) 527-4472, or email caroline.juran@dhp.virginia.gov.

Summary:

The amendments (i) add 24 compounds to Schedules I through V and (ii) delete one compound from Schedule II of the Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia) pursuant to § 54.1-3443 of Code of Virginia to conform Virginia scheduled drugs with federal scheduling actions. These amendments represent changes made by the federal government January 2021 through July 6, 2022.

18VAC110-20-323. Scheduling for conformity with federal law or rule.

Pursuant to subsection E of § 54.1-3443 of the Code of Virginia and in order to conform the Drug Control Act to recent scheduling changes enacted in federal law or rule, the board:

1. Adds MT-45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine) to Schedule I;
2. Adds Dronabinol ((-)-delta-9-trans tetrahydrocannabinol) in an oral solution in a drug product approved for marketing by the U.S. Food and Drug Administration to Schedule II;
3. Deletes naldemedine from Schedule II;
4. Deletes naloxegol and 6 β -naltrexol from Schedule II; ~~and~~
5. Replaces 4-anilino-N-phenethyl-4-piperidine (CASRN 21409-26-7) in Schedule II with 4-anilino-N-phenethylpiperidine (ANPP);
6. Adds 4-methyl-5-(4-methylphenyl)-4,5-dihydro-1,3-oxazol-2-amine (4,4'-Dimethylaminorex, 4,4'-DMAR) to Schedule I;
7. Adds 1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)pyrrolo [2,3-b]pyridine-3-carboxamide (5F-CUMYL-P7AICA) to Schedule I;
8. Adds ethyl N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]carbamate (fentanyl carbamate) to Schedule I;
9. Adds N-(2-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]prop-2-enamide (ortho-fluoroacryl fentanyl) to Schedule I;
10. Adds N-(2-fluorophenyl)-2-methyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (ortho-fluoroisobutyl fentanyl) to Schedule I;
11. Adds N-(4-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide (para-fluoro furanyl fentanyl) to Schedule I;
12. Adds N-(2-fluorophenyl)-N-[1-[2-(2-fluorophenyl)ethyl]piperidin-4-yl]propanamide (2'-fluoro ortho-fluorofentanyl; 2'-fluoro 2-fluorofentanyl) to Schedule I;
13. Adds N-[1-[2-(4-methylphenyl)ethyl]piperidin-4-yl]-N-phenylacetamide (4'-methyl acetyl fentanyl) to Schedule I;
14. Adds N,3-diphenyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (β '-phenyl fentanyl; beta'-phenyl fentanyl; 3-phenylpropanoyl fentanyl) to Schedule I;
15. Adds N-phenyl-N-[1-(2-phenylpropyl)piperidin-4-yl]propanamide (β -methyl fentanyl) to Schedule I;
16. Adds N-(2-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]butanamide (ortho-fluorobutyl fentanyl; 2-fluorobutyl fentanyl) to Schedule I;

17. Adds N-(2-methylphenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide (ortho-methyl acetylfentanyl; 2-methyl acetylfentanyl) to Schedule I;

18. Adds 2-methoxy-N-(2-methylphenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide (ortho-methyl methoxyacetylfentanyl; 2-methyl methoxyacetyl fentanyl) to Schedule I;

19. Adds N-(4-methylphenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (para-methylfentanyl; 4-methylfentanyl) to Schedule I;

20. Adds N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]thiophene-2-carboxamide (thiophene fentanyl) to Schedule I;

21. Adds N-(4-chlorophenyl)-2-methyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (para-chloroisobutyl fentanyl) to Schedule I;

22. Adds 24. 2-[2-[(4-butoxyphenyl)methyl]-5-nitrobenzimidazol-1-yl]-N,N-diethylethanamine (Butonitazene) to Schedule I;

23. Adds N,N-diethyl-2-[2-[(4-fluorophenyl)methyl]-5-nitrobenzimidazol-1-yl] ethanamine (Flunitazene) to Schedule I;

24. Adds Olliceridine to Schedule II;

25. Deletes Samidorphan from Schedule II;

26. Adds Remimazolam to Schedule IV;

27. Adds Serdexmethylphenidate to Schedule IV;

28. Adds Lemborexant to Schedule IV;

29. Adds Daridorexant to Schedule IV; and

30. Adds Ganaxolone to Schedule V.

VA.R. Doc. No. R23-7344; Filed November 30, 2022, 3:38 p.m.

GOVERNOR

EXECUTIVE ORDER NUMBER 24 (2022)

Banning the Use of Certain Applications and Websites on State Government Technology

Importance of Initiative

Safeguarding data and ensuring cybersecurity are increasingly important aspects of state government, as evidenced by the sensitive information held on state government servers, such as health records or tax information. Information technology infrastructure has become an integral part of the routine operations of state government and a critical component of serving the citizens of the Commonwealth.

Applications and websites such as TikTok and WeChat provide foreign governments, such as the Chinese Communist Party, with the potential to gain access to the information stored on mobile devices, including location services and browsing history.

As a result of the growing concern over foreign cybersecurity threats, the Department of Defense has already issued a directive to all service members to remove applications from their government-issued or owned devices. Further, the Federal Bureau of Investigation has expressed concerns about applications that could be used by the Chinese government to control software or data collection on devices that would compromise sensitive or personal information.

Directive

Accordingly, pursuant to the authority vested in me in Article V of the Constitution of Virginia and as the Chief Executive of the Commonwealth, and pursuant to § 2.2-103 of the Code of Virginia, I hereby direct and order that no employee of any agency of the Commonwealth of Virginia shall download or use TikTok or WeChat applications or any other applications developed by ByteDance Limited or Tencent Holdings Limited or visit the TikTok or WeChat website on any government-issued devices, including state-issued cell phones, laptops, or other devices capable of connecting to the internet except for public safety purposes.

Further, no person or entity contracting with the Commonwealth, including but not limited to all agencies, boards, commissions, institutions of higher education, or authorities, or agents thereof, may download or use TikTok or WeChat applications or any other application developed by ByteDance Limited or Tencent Holdings Limited, or visit the TikTok or WeChat websites on state-owned or leased equipment.

Any employee of the Commonwealth, or person or entity contracting with the Commonwealth, who has already downloaded TikTok or WeChat applications or any other applications developed by ByteDance Limited or Tencent Holdings Limited to any government-issued devices as listed

above are hereby directed to remove, delete, and uninstall these applications by December 31, 2022.

Additional Directive

No person shall access TikTok or WeChat or any other application developed by ByteDance Limited or Tencent Holdings Limited through Commonwealth owned, operated, or maintained wireless network.

This applies to all Executive Offices, Secretariat Offices and Executive Branch Agencies under Virginia Information Technologies Agency. Other units or entities of state government shall comply with this directive in the manner which best suits their information technology capability and network security needs.

Accordingly, the Virginia Information Technologies Agency is directed to restrict access to these websites and applications in accordance with this Executive Order.

An authorized information technology officer or chief administrative officer for all Executive Branch Agencies shall send written confirmation and report of compliance with this directive to the Secretary of Administration by January 15, 2023.

Effective Date of the Executive Order

This Executive Order shall be effective upon its signing and shall remain in force and effect unless amended or rescinded by further executive order or directive. Given under my hand and under the Seal of the Commonwealth of Virginia, this 16th day of December, 2022.

/s/ Glenn Youngkin, 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.

VIRGINIA CANNABIS CONTROL AUTHORITY

Title of Document: [Guidance on Home Cultivation.](#)

Public Comment Deadline: February 1, 2023.

Effective Date: February 2, 2023.

Agency Contact: Shawn Casey, Senior Policy Manager, Virginia Cannabis Control Authority, 333 East Franklin Street, Richmond, VA 23219, telephone (804) 548-5916, or email shawn.casey@cca.virginia.gov.

BOARD OF DENTISTRY

Title of Document: [Clinical Competency Requirements for Applicants for Licensure, Reactivation, or Reinstatement.](#)

Public Comment Deadline: February 1, 2023.

Effective Date: February 2, 2023.

Agency Contact: Erin Barrett, Senior Policy Analyst, Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Suite 300, Henrico, VA 23233, telephone (804) 367-4688, or email erin.barrett@dhp.virginia.gov.

DEPARTMENT OF HOUSING AND COMMUNITY DEVELOPMENT

Title of Document: [Utility Leverage Program – Unserved Certification Guidelines.](#)

Public Comment Deadline: February 1, 2023.

Effective Date: February 2, 2023.

Agency Contact: Kyle Flanders, Senior Policy Analyst, Department of Housing and Community Development, Main Street Centre, 600 East Main Street, Suite 300, Richmond, VA 23219, telephone (804) 786-6761, or email kyle.flanders@dhcd.virginia.gov.

BOARD OF MEDICINE

BOARD OF NURSING

Title of Document: [Practice Agreement Requirements for Licensed Nurse Practitioners \(Advanced Practice Registered Nurses\).](#)

Public Comment Deadline: February 1, 2023.

Effective Date: February 2, 2023.

Agency Contact: Erin Barrett, Senior Policy Analyst, Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Suite 300, Henrico, VA 23233, telephone (804) 367-4688, or email erin.barrett@dhp.virginia.gov.

BOARD OF PHARMACY

Titles of Documents: [Competency Examination Required for Licensure as a Pharmacist National Association of Boards of Pharmacy Licensure Examination Passing Score.](#)

[Dispensing with an Authorized Generic.](#)

[Guidance for Free Clinic Pharmacy Permit Applicants.](#)

[Guidelines for Provision of Counseling and Information by Pharmacists regarding Proper Disposal of Unused Dispensed Drugs.](#)

[Proof of Identity for when Dispensing Schedule II Drugs.](#)

[Mobile Units for Dispensing for the Indigent or Underserved Population.](#)

Public Comment Deadline: February 1, 2023.

Effective Date: February 2, 2023.

Agency Contact: Erin Barrett, Senior Policy Analyst, Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Suite 300, Henrico, VA 23233, telephone (804) 367-4688, or email erin.barrett@dhp.virginia.gov.

Guidance Documents

BOARD OF SOCIAL WORK

Title of Document: [Guidance on Technology-Assisted Therapy and the Use of Social Media.](#)

Public Comment Deadline: February 1, 2023.

Effective Date: February 2, 2023.

Agency Contact: Erin Barrett, Senior Policy Analyst, Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Suite 300, Henrico, VA 23233, telephone (804) 367-4688, or email erin.barrett@dhp.virginia.gov.

COMMONWEALTH TRANSPORTATION BOARD

Titles of Documents: [Interagency Scenic Roads Map Advisory Committee Policy and Selection Criteria.](#)

[Virginia Official State Transportation Map Policy and Procedures.](#)

Public Comment Deadline: February 1, 2023.

Effective Date: February 2, 2023.

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

STATE WATER CONTROL BOARD

Title of Document: [Accelerated Nonpoint Source Nutrient Credit Release for Stream Restoration Projects.](#)

Public Comment Deadline: February 1, 2023.

Effective Date: February 2, 2023.

Agency Contact: Tyler Monteith, Department of Environmental Quality, 1111 East Main Street, Suite 1400, P.O. Box 1105, Richmond, VA 23219, telephone (804) 489-1809, or email tyler.monteith@deq.virginia.gov.

* * *

Title of Document: [Amendment No. 4. Water Compliance Auditing Manual Revisions – Section I.H \(Assessment of Unauthorized Discharges, Overflows, and Bypasses of Sanitary Wastewater\) and Appendix 1 \(Point Assessment Criteria\).](#)

Public Comment Deadline: February 1, 2023.

Effective Date: February 2, 2023.

Agency Contact: Matthew Stafford, Department of Environmental Quality, 1111 East Main Street, Suite 1400, P.O. Box 1105, Richmond, VA 23219, telephone (804) 298-4956, or email matthew.stafford@deq.virginia.gov.

GENERAL NOTICES

DEPARTMENT OF ENVIRONMENTAL QUALITY

Proposed Consent Special Order for Dixon Automotive and Haley Builders - King William County

The Department of Environmental Quality (DEQ) proposes to issue a consent special order to Dixon Automotive and Haley Builders for alleged violations of the State Water Control Law at the property located at 956 Richmond Tappahannock Highway, Suite 4, King William County, Virginia. A description of the proposed action is available at the DEQ office listed or online at <https://www.deq.virginia.gov/permits-regulations/public-notices/enforcement-orders>. The staff contact will accept email or postal mail from January 2, 2023, through February 1, 2023.

Contact Information: Cara Witte, Enforcement Specialist, Department of Environmental Quality, Piedmont Regional Office, 4949-A Cox Road, Glen Allen, VA 23060, telephone (804) 712-4192, or email cara.witte@deq.virginia.gov.

Proposed Consent Special Order for Shoosmith Bros Inc. - Chesterfield County

The Department of Environmental Quality (DEQ) proposes to issue a consent special order to Shoosmith Bros Inc. for alleged violation of the Virginia Waste Management Act and State Water Control Law at the facility located at 11800 Lewis Road, Chester, Virginia. A description of the proposed action is available at the DEQ office listed or online at www.deq.virginia.gov. The staff contact will accept comments by email or postal mail from January 2, 2023, through February 2, 2023.

Contact Information: Jeff Reynolds, Enforcement Manager, Department of Environmental Quality, 4949-A Cox Road, Glen Allen, VA 23060, telephone (804) 720-4754, or email jefferson.reynolds@deq.virginia.gov.

Proposed Enforcement Action for Speedy's Auto Service - City Of Richmond

The Department of Environmental Quality (DEQ) proposes to issue an enforcement action to Speedy's Auto Services for alleged violation of the State Water Control Law at 5300 Midlothian Turnpike, Richmond, Virginia. A description of the proposed action is available at the DEQ office listed or online at <https://www.deq.virginia.gov/permits-regulations/public-notices/enforcement-orders>. The staff contact will accept comments by email or postal mail from January 2, 2023, through February 1, 2023.

Contact Information: Cara Witte, Enforcement Specialist, Department of Environmental Quality, Piedmont Regional Office, 4949-A Cox Road, Glen Allen, VA 23060, telephone (804) 712-4192, or email cara.witte@deq.virginia.gov.

DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

Draft Baby Care Provider Manual Chapter V

The draft Baby Care Provider Manual Chapter V is now available on the Department of Medical Assistance Services website at <https://www.dmas.virginia.gov/for-providers/general-information/medicaid-provider-manual-drafts/>.

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, or email emily.mcclellan@dmas.virginia.gov.

Draft Early Intervention Services Provider Manual Chapter V

The draft Early Intervention Services Provider Manual Chapter V is now available on the Department of Medical Assistance Services website at <https://www.dmas.virginia.gov/for-providers/general-information/medicaid-provider-manual-drafts/> for public comment until January 5, 2023.

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, or email emily.mcclellan@dmas.virginia.gov.

Draft Eligibility Manual Transmittal

A draft Medicaid Eligibility Manual Transmittal, DMAS-26, is available for review and comment on the Department of Medical Assistance Services website at <https://www.dmas.virginia.gov/for-providers/general-information/medicaid-provider-manual-drafts/>.

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, or email emily.mcclellan@dmas.virginia.gov.

Draft Mental Health Services Provider Manual Appendix G

The draft Mental Health Services Provider Manual Appendix G is now available on the Department of Medical Assistance Services website at <https://www.dmas.virginia.gov/for-providers/general-information/medicaid-provider-manual-drafts/> for public comment until January 11, 2023.

Contact Information: Meredith Lee, Policy, Regulations, and Manuals Supervisor, Department of Medical Assistance Services, 600 East Broad Street, Suite 1300, Richmond, VA 23219, telephone (804) 371-0552, FAX (804) 786-1680, or email meredith.lee@dmas.virginia.gov.

General Notices

Draft Plan First Provider Manual Chapter V

The draft Plan First Provider Manual Chapter V is now available on the Department of Medical Assistance Services website at <https://www.dmas.virginia.gov/for-providers/general-information/medicaid-provider-manual-drafts/> for public comment until January 5, 2023.

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, or email emily.mcclellan@dmas.virginia.gov.

Draft Plan First Provider Manual Chapter VI

The draft Plan First Provider Manual Chapter VI is now available on the Department of Medical Assistance Services website at <https://www.dmas.virginia.gov/for-providers/general-information/medicaid-provider-manual-drafts/>.

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, or email emily.mcclellan@dmas.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.