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Virginia Code Commission

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VIRGINIA REGISTER INFORMATION PAGE

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

ADOPTION, AMENDMENT, AND REPEAL OF REGULATIONS

An agency wishing to adopt, amend, or repeal regulations must first publish in the *Virginia Register* a notice of intended regulatory action; a basis, purpose, substance and issues statement; an economic impact analysis prepared by the Department of Planning and Budget; the agency's response to the economic impact analysis; a summary; a notice giving the public an opportunity to comment on the proposal; and the text of the proposed regulation.

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

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

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

The Governor may review the final regulation during this time and, if he objects, forward his objection to the Registrar and the agency. In addition to or in lieu of filing a formal objection, the Governor may suspend the effective date of a portion or all of a regulation until the end of the next regular General Assembly session by issuing a directive signed by a majority of the members of the appropriate legislative body and the Governor. The Governor's objection or suspension of the regulation, or both, will be published in the *Virginia Register*. If the Governor finds that changes made to the proposed regulation have substantial impact, he may require the agency to provide an additional 30-day public comment period on the changes. Notice of the additional public comment period required by the Governor will be published in the *Virginia Register*.

The agency shall suspend the regulatory process for 30 days when it receives requests from 25 or more individuals to solicit additional public comment, unless the agency determines that the changes have minor or inconsequential impact.

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

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

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

FAST-TRACK RULEMAKING PROCESS

Section 2.2-4012.1 of the Code of Virginia provides an exemption from certain provisions of the Administrative Process Act for agency regulations deemed by the Governor to be noncontroversial. To use this process, Governor's concurrence is required and advance notice must be provided to certain legislative committees. Fast-track regulations will become effective on the date noted in the regulatory action if no objections to using the process are filed in accordance with § 2.2-4012.1.

EMERGENCY REGULATIONS

Pursuant to § 2.2-4011 of the Code of Virginia, an agency, upon consultation with the Attorney General, and at the discretion of the Governor, may adopt emergency regulations that are necessitated by an emergency situation. An agency may also adopt an emergency regulation when Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment. The emergency regulation becomes operative upon its adoption and filing with the Registrar of Regulations, unless a later date is specified. Emergency regulations are limited to no more than 18 months in duration; however, may be extended for six months under certain circumstances as provided for in § 2.2-4011 D. Emergency regulations are published as soon as possible in the *Register*. During the time the emergency status is in effect, the agency may proceed with the adoption of permanent regulations through the usual procedures. To begin promulgating the replacement regulation, the agency must (i) file the Notice of Intended Regulatory Action with the Registrar within 60 days of the effective date of the emergency regulation and (ii) file the proposed regulation with the Registrar within 180 days of the effective date of the emergency regulation. If the agency chooses not to adopt the regulations, the emergency status ends when the prescribed time limit expires.

STATEMENT

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

CITATION TO THE VIRGINIA REGISTER

The *Virginia Register* is cited by volume, issue, page number, and date. **29:5 VA.R. 1075-1192 November 5, 2012**, refers to Volume 29, Issue 5, pages 1075 through 1192 of the *Virginia Register* issued on November 5, 2012.

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 M. LeMunyon**, Vice Chair; **Gregory D. Habeeb**; **Ryan T. McDougle**; **Robert L. Calhoun**; **Leslie L. Lilley**; **E.M. Miller, Jr.**; **Thomas M. Moncure, Jr.**; **Christopher R. Nolen**; **Timothy Oksman**; **Charles S. Sharp**; **Noah P. Sullivan**; **Mark J. Vucci**.

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PUBLICATION SCHEDULE AND DEADLINES

This schedule is available on the *Register's* Internet home page (<http://register.dls.virginia.gov>).

November 2017 through November 2018

<u>Volume: Issue</u>	<u>Material Submitted By Noon*</u>	<u>Will Be Published On</u>
34:7	November 8, 2017	November 27, 2017
34:8	November 21, 2017 (Tuesday)	December 11, 2017
34:9	December 6, 2017	December 25, 2017
34:10	December 19, 2017 (Tuesday)	January 8, 2018
34:11	January 3, 2018	January 22, 2018
34:12	January 17, 2018	February 5, 2018
34:13	January 31, 2018	February 19, 2018
34:14	February 14, 2018	March 5, 2018
34:15	February 28, 2018	March 19, 2018
34:16	March 14, 2018	April 2, 2018
34:17	March 28, 2018	April 16, 2018
34:18	April 11, 2018	April 30, 2018
34:19	April 25, 2018	May 14, 2018
34:20	May 9, 2018	May 28, 2018
34:21	May 23, 2018	June 11, 2018
34:22	June 6, 2018	June 25, 2018
34:23	June 20, 2018	July 9, 2018
34:24	July 3, 2018 (Tuesday)	July 23, 2018
34:25	July 18, 2018	August 6, 2018
34:26	August 1, 2018	August 20, 2018
35:1	August 15, 2018	September 3, 2018
35:2	August 29, 2018	September 17, 2018
35:3	September 12, 2018	October 1, 2018
35:4	September 26, 2018	October 15, 2018
35:5	October 10, 2018	October 29, 2018
35:6	October 24, 2018	November 12, 2018
35:7	November 7, 2018	November 26, 2018

*Filing deadlines are Wednesdays unless otherwise specified.

PETITIONS FOR RULEMAKING

TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF OPTOMETRY

Initial Agency Notice

Title of Regulation: **18VAC105-20. Regulations Governing the Practice of Optometry.**

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

Name of Petitioner: Janet Swartz, National Glaucoma Society.

Nature of Petitioner's Request: To amend 18VAC105-20-70 to add the National Glaucoma Society to the list of approved providers of continuing education or to include a new category for nonprofit optometric organizations.

Agency Plan for Disposition of Request: In accordance with Virginia law, the petition has been filed with the Registrar of Regulations and will be published on November 27, 2017. Comment on the petition may be sent by email or regular mail or posted on the Virginia Regulatory Town Hall at www.townhall.virginia.gov; comment will be requested until December 20, 2017. Following receipt of all comments on the petition to amend regulations, the board will decide whether to make any changes to the regulatory language. This matter will be on the board's agenda for its next meeting following comment, scheduled for March 2, 2018.

Public Comment Deadline: December 20, 2017.

Agency Contact: Leslie L. Knachel, Executive Director, Department of Health Professions, 9960 Mayland Drive, Suite 300, Richmond, VA 23233, telephone (804) 367-4508, or email leslie.knachel@dhp.virginia.gov.

VA.R. Doc. No. R18-09; Filed October 31, 2017, 3:02 p.m.

NOTICES OF INTENDED REGULATORY ACTION

TITLE 6. CRIMINAL JUSTICE AND CORRECTIONS

CRIMINAL JUSTICE SERVICES BOARD

Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the Criminal Justice Services Board intends to consider amending **6VAC20-30, Rules Relating to Compulsory In-Service Training Standards for Law-Enforcement Officers, Jailors or Custodial Officers, Courtroom Security Officers, Process Service Officers and Officers of the Department of Corrections, Division of Operations, and 6VAC20-70, Rules Relating to Compulsory Minimum Training Standards for Noncustodial Employees of the Department of Corrections.** The purpose of the proposed action is to add a new in-service requirement for dispatchers who dispatch for law enforcement. The proposed regulatory action will include the in-service requirements for noncustodial employees of the Department of Corrections designated by the Director of the Department of Corrections to carry a firearm. The current in-service requirements, the process for obtaining partial in-service credit, and the use of multi-media in criminal justice training will be reviewed.

The agency does not intend to hold a public hearing on the proposed action after publication in the Virginia Register.

Statutory Authority: § 9.1-102 of the Code of Virginia.

Public Comment Deadline: December 27, 2017.

Agency Contact: Barbara Peterson-Wilson, Law Enforcement Program Coordinator, Department of Criminal Justice Services, 1100 Bank Street, Richmond, VA 23219, telephone (804) 225-4503, FAX (804) 786-0410, or email barbara.peterson-wilson@dcjs.virginia.gov.

VA.R. Doc. No. R18-5304; Filed October 26, 2017, 8:35 a.m.

TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF DENTISTRY

Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the Board of Dentistry intends to consider amending **18VAC60-25, Regulations Governing the Practice of Dental Hygienists.** The purpose of the proposed action is to amend 18VAC60-25-190, relating to requirements for continuing education for dental hygienists, to include the "competencies needed to provide care under

remote supervision," as specified in subsection F of § 54.1-2722 of the Code of Virginia. The proposed action requires a continuing education course of no less than two hours in duration offered by an approved sponsor and includes the specified course content.

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

Statutory Authority: §§ 54.1-2400, 54.1-2272, and 54.1-2729 of the Code of Virginia.

Public Comment Deadline: December 27, 2017.

Agency Contact: Sandra Reen, Executive Director, Board of Dentistry, 9960 Mayland Drive, Suite 300, Richmond, VA 23233, telephone (804) 367-4437, FAX (804) 527-4428, or email sandra.reen@dhp.virginia.gov.

VA.R. Doc. No. R18-5208; Filed November 13, 2017, 7:28 a.m.

TITLE 22. SOCIAL SERVICES

DEPARTMENT FOR AGING AND REHABILITATIVE SERVICES

Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the Department for Aging and Rehabilitative Services intends to consider amending **22VAC30-110, Assessment in Assisted Living Facilities.** The purpose of the proposed action is to review the regulation, which establishes standards regarding initial assessments, annual reassessments, post-assessment actions, and relocation procedures. The department will evaluate all current regulation content and clarify content that may be unclear or inconsistent with a goal of streamlining the public pay assessment process as much as possible while still ensuring that individuals undergo an appropriate review of their level of care. The department intends to include language permitting the use of video conferencing for assessments in specific circumstances, clarify language that addresses the portions of the uniform assessment instrument that are completed for public pay individuals, and add content regarding the timing of annual reassessments. Other revisions to the regulation content may also be proposed based on public comment or during the workgroup that will meet to discuss proposed changes.

The agency does not intend to hold a public hearing on the proposed action after publication in the Virginia Register.

Statutory Authority: § 51.5-131 of the Code of Virginia.

Public Comment Deadline: December 27, 2017.

Notices of Intended Regulatory Action

Announcement of Periodic Review and Small Business Impact Review: This regulation will undergo a periodic review pursuant to Executive Order 17 (2014) and a small business impact review pursuant to § 2.2-4007.1 of the Code of Virginia to determine whether this regulation should be terminated, 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.

Agency Contact: Paige McCleary, Adult Services Program Consultant, Department for Aging and Rehabilitative Services, 8004 Franklin Farms Drive, Richmond, VA 23229, telephone (804) 662-7605, or email paige.mccleary@dars.virginia.gov.

VA.R. Doc. No. R18-5335; Filed October 27, 2017, 3:45 p.m.

STATE BOARD OF SOCIAL SERVICES

Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the State Board of Social Services intends to consider amending **22VAC40-221, Additional Daily Supervision Rate Structure**. The purpose of the proposed action is to provide a comprehensive review of the regulations, which provides standards for local departments of social services to determine enhanced maintenance payments for foster and adoptive parents. In addition to the periodic review and a review of any impact on small businesses, a proposed amendment will include extending the amount of time that the uniform rate assessment tool is readministrated from three months to six months for the purpose of adoption assistance. Additional changes will be considered based on public comment received and further review.

The agency does not intend to hold a public hearing on the proposed action after publication in the Virginia Register.

Statutory Authority: § 63.2-217 of the Code of Virginia; 42 USC § 673.

Public Comment Deadline: December 27, 2017.

Announcement of Periodic Review and Small Business Impact Review: This regulation will undergo a periodic review pursuant to Executive Order 17 (2014) and a small business impact review pursuant to § 2.2-4007.1 of the Code of Virginia to determine whether this regulation should be terminated, 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.

Agency Contact: Traci B. Jones, Program Manager, Department of Social Services, 801 East Main Street, Richmond, VA 23219, telephone (804) 726-7499, or email traci.jones@dss.virginia.gov.

VA.R. Doc. No. R18-5241; Filed October 25, 2017, 12:57 p.m.

REGULATIONS

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

Symbol Key

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

TITLE 9. ENVIRONMENT

STATE AIR POLLUTION CONTROL BOARD

Final Regulation

Title of Regulation: **9VAC5-80. Permits for Stationary Sources (Rev. K16) (amending 9VAC5-80-320, 9VAC5-80-340, 9VAC5-80-2270, 9VAC5-80-2280, 9VAC5-80-2310, 9VAC5-80-2330, 9VAC5-80-2340; adding 9VAC5-80-342, 9VAC5-80-2282, 9VAC5-80-2342).**

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

Effective Date: January 1, 2018.

Agency Contact: Gary E. Graham, Department of Environmental Quality, 629 East Main Street, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4103, or email gary.graham@deq.virginia.gov.

Summary:

The amendments (i) sequentially increase the emissions fee rate over two years, (ii) change the method of calculating future Consumer Price Index emissions fee adjustments to an equivalent method that is consistent with the annual adjustments to Title V permit application fees and Title V permit maintenance fees, (iii) exclude greenhouse gas emissions from the calculation of emissions fees, (iv) increase permit application fees depending on the permit application type and clarify provisions for application amendments, (v) increase permit maintenance fees and establish a new minimum fee for synthetic minor sources, (vi) add definitions for the terms "greenhouse gases" and "regulated pollutant (for fee calculation)" and revise the definition of "actual emissions" so that emissions of greenhouse gases are excluded from the calculation of permit program emissions fees, and (vii) make various other changes as necessary to clarify and implement the changes.

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

9VAC5-80-320. Definitions.

A. For the purpose of applying this article in the context of the Regulations for the Control and Abatement of Air Pollution and related uses, the words or terms shall have the meanings given them in subsection C of this section.

B. As used in this article, all words and terms not defined in subsection C of this section shall have the meanings given them in 9VAC5-80-5 or 9VAC5-10 (General Definitions), unless otherwise required by context.

C. Terms defined.

"Actual emissions" means, for the purposes of this article, the actual rate of emissions in tons per year of any regulated ~~air~~ pollutant (for fee calculation) emitted from a source subject to this article over the preceding calendar year. Actual emissions may be calculated according to any method acceptable to the department provided such calculation takes into account the source's actual operating hours, production rates, in-place control equipment, and types of materials processed, stored, or combusted during the preceding calendar year. Any regulated pollutant which could be classed in more than one category shall be classed in only one category.

"Affected source" means a source that includes one or more affected units.

"Affected unit" means a unit that is subject to any federal acid rain emissions reduction requirement or acid rain emissions limitation under 40 CFR Parts 72, 73, 75, 77 or 78.

"Area source" means any stationary source that is not a major source. For purposes of this section, the phrase "area source" shall not include motor vehicles or nonroad vehicles.

"Greenhouse gases" means, for the purposes of this article, the aggregate group of the following gases: carbon dioxide, nitrous oxide, methane, hydrofluorocarbons, perfluorocarbons, and sulfur hexafluoride.

"Hazardous air pollutant" means any air pollutant listed in § 112(b) of the federal Clean Air Act, as amended by 40 CFR 63.60.

"Major source" means:

- a. For hazardous air pollutants other than radionuclides, any stationary source that emits or has the potential to emit, in the aggregate, 10 tons per year or more of any hazardous air pollutant or 25 tons per year or more of any combination of hazardous air pollutants. Notwithstanding the preceding sentence, emissions from any oil or gas exploration or production well (with its associated equipment) and emissions from any pipeline compressor or pump station shall not be aggregated with emissions from other similar units, whether or not such units are in a contiguous area or under common control, to determine whether such units or stations are major sources.

b. For air pollutants other than hazardous air pollutants, any stationary source that directly emits or has the potential to emit 100 tons per year or more of any air pollutant (including any major source of fugitive emissions of any such pollutant). The fugitive emissions of a stationary source shall not be considered in determining whether it is a major stationary source, unless the source belongs to one of the following categories of stationary source:

- (1) Coal cleaning plants (with thermal dryers);
- (2) Kraft pulp mills;
- (3) Portland cement plants;
- (4) Primary zinc smelters;
- (5) Iron and steel mills;
- (6) Primary aluminum ore reduction plants;
- (7) Primary copper smelters;
- (8) Municipal incinerators capable of charging more than 250 tons of refuse per day;
- (9) Hydrofluoric, sulfuric, or nitric acid plants;
- (10) Petroleum refineries;
- (11) Lime plants;
- (12) Phosphate rock processing plants;
- (13) Coke oven batteries;
- (14) Sulfur recovery plants;
- (15) Carbon black plants (furnace process);
- (16) Primary lead smelters;
- (17) Fuel conversion plant;
- (18) Sintering plants;
- (19) Secondary metal production plants;
- (20) Chemical process plants;
- (21) Fossil-fuel boilers (or combination thereof) totaling more than 250 million British thermal units per hour heat input;
- (22) Petroleum storage and transfer units with a total storage capacity exceeding 300,000 barrels;
- (23) Taconite ore processing plants;
- (24) Glass fiber processing plants;
- (25) Charcoal production plants;
- (26) Fossil-fuel-fired steam electric plants of more than 250 million British thermal units per hour heat input; or

(27) Any other stationary source category regulated under § 111 or 112 of the federal Clean Air Act for which the administrator has made an affirmative decision under § 302(j) of the federal Clean Air Act.

c. For ozone nonattainment areas, any stationary source with the potential to emit 100 tons per year or more of volatile organic compounds or nitrogen oxides in areas classified as "marginal" or "moderate," 50 tons per year or more in areas classified as "serious," 25 tons per year or more in areas classified as "severe," and 10 tons per year or more in areas classified as "extreme"; except that the references in this definition to 100, 50, 25, and 10 tons per year of nitrogen oxides shall not apply with respect to any source for which the administrator has made a finding that requirements under § 182(f) of the federal Clean Air Act (NO_x requirements for ozone nonattainment areas) do not apply.

d. For attainment areas in ozone transport regions, any stationary source with the potential to emit 50 tons per year or more of volatile organic compounds.

"Permit program costs" means all reasonable (direct and indirect) costs required to develop, administer, and enforce the permit program; and to develop and administer the Small Business Technical and Environmental Compliance Assistance Program established pursuant to the provisions of § 10.1-1323 of the Code of Virginia.

"Potential to emit" means the maximum capacity of a stationary source to emit any air pollutant under its physical and operational design. Any physical or operational limitation on the capacity of a source to emit an air pollutant, including air pollution control equipment and restrictions on hours of operation or on the type or amount of material combusted, stored, or processed, shall be treated as part of its design if the limitation is state and federally enforceable.

"Regulated air pollutant" means any of the following:

- a. Nitrogen oxides or any volatile organic compound.
- b. Any pollutant for which an ambient air quality standard has been promulgated except carbon monoxide.
- c. Any pollutant subject to any standard promulgated under § 111 of the federal Clean Air Act.
- d. Any pollutant subject to a standard promulgated under § 112 (hazardous air pollutants) or other requirements established under § 112 of the federal Clean Air Act, particularly §§ 112(b), 112(d), 112(g)(2), 112(j), and 112(r); except that any pollutant that is a regulated pollutant solely because it is subject to a standard or regulation under § 112(r) of the federal Clean Air Act shall be exempt from this article.

Regulations

"Regulated pollutant (for fee calculation)" means, for the purposes of this article, any regulated air pollutant except the following:

- a. Carbon monoxide;
- b. Any pollutant that is a regulated air pollutant solely because it is a Class I or II substance to a standard promulgated under or established by Title VI of the federal Clean Air Act;
- c. Any pollutant that is a regulated air pollutant solely because it is subject to a standard or regulation under § 112(r) of the federal Clean Air Act; or
- d. Greenhouse gases.

"Research and development facility" means all the following as applied to any stationary source:

- a. The primary purpose of the source is the conduct of either (i) research and development into new products or processes or into new uses for existing products or processes or (ii) basic research to provide for education or the general advancement of technology or knowledge;
- b. The source is operated under the close supervision of technically trained personnel; and
- c. The source is not engaged in the manufacture of products in any manner inconsistent with clause a (i) or (ii) of this definition.

An analytical laboratory that primarily supports a research and development facility is considered to be part of that facility.

"Stationary source" means any building, structure, facility or installation which emits or may emit any regulated air pollutant. A stationary source shall include all of the pollutant-emitting activities which belong to the same industrial grouping, are located on one or more contiguous or adjacent properties, and are under the control of the same persons (or persons under common control). Pollutant-emitting activities shall be considered as part of the same industrial grouping if they belong to the same "major group" (i.e., if they have the same two-digit code) as described in the Standard Industrial Classification Manual (see 9VAC5-20-21). Any research and development facility shall be considered a separate stationary source from the manufacturing or other facility with which it is co-located.

9VAC5-80-340. Annual permit program emissions fee calculation prior to [~~(insert effective date of the regulation)~~ January 1, 2018].

A. ~~The For annual permit program emissions fees due prior to [(insert effective date of the regulation) January 1, 2018],~~ the annual permit program emissions fee shall not exceed the base year amount of \$31.22 per ton of emissions, as provided in subsection B of Item 365 of the 2012 Appropriation Act

adjusted annually by the Consumer Price Index as provided in Title V of the federal Clean Air Act and associated regulations and policies.

1. The annual permit program emissions fee shall be increased (consistent with the need to cover reasonable costs) each year by the percentage, if any, by which the Consumer Price Index for the most recent calendar year ending before the beginning of such year exceeds the Consumer Price Index for the calendar year 1989. The Consumer Price Index for any calendar year is the average of the Consumer Price Index for all-urban consumers published by the U.S. Department of Labor, as of the close of the 12-month period ending on August 31 of each calendar year.
2. The revision of the Consumer Price Index which is most consistent with the Consumer Price Index for the calendar year 1989 shall be used.

B. ~~The For annual permit program emissions fees due prior to [(insert effective date of the regulation) January 1, 2018],~~ the annual permit program emissions fee described in subsection A of this section and the amount billed to the owner as provided in subsection A of 9VAC5-80-350 for a given year shall be calculated in accordance with the following formulae:

$$B = (A)(F)$$
$$F = X(1 + \Delta\text{CPI})$$
$$\Delta\text{CPI} = \frac{\text{CPI} - 122.15}{122.15}$$

where:

B = the amount billed to the owner during the year after the year in which the actual emissions occurred, expressed in dollars

A = actual emissions covered by permit fees, expressed in tons

F = the maximum adjusted fee per ton for the calendar year in which the actual emissions occurred, expressed in dollars per ton

X = 31.22, expressed in dollars per ton

ΔCPI = the difference between the CPI and 122.15 (the average of the Consumer Price Index for all-urban consumers for the 12-month period ending on August 31, 1989)

CPI = the average of the Consumer Price Index for all-urban consumers for the 12-month period ending on August 31 of the year in which the emissions actually occurred, expressed as a percentage

C. The actual emissions covered by the permit program emissions fees for the preceding year shall be calculated by

the owner and submitted to the department by April 15 of each year. The calculations and final amount of emissions are subject to verification and final determination by the department.

D. If the assessment of the annual permit program emissions fee calculated in accordance with subsections A, B, and C of this section results in a total amount of fee revenue in excess of the amount necessary to fund the permit program costs, a lesser annual permit program emissions fee may instead be calculated and assessed according to the formula specified in subsection E of this section. Any adjustments made to the annual permit program emissions fee shall be within the constraints of 40 CFR 70.9.

E. The lesser annual permit program emissions fee shall be calculated according to the following formula: the lesser annual permit program emissions fee is equal to the estimated permit program costs divided by the estimated actual emissions. The estimated permit program costs and estimated actual emissions shall be determined from the data specified in subdivisions 1 and 2 of this subsection, incorporating any anticipated adjustments to the data.

1. The current permit program costs shall be determined from the most recent available annual expenditure record of the amount spent by the department on permit program costs.
2. The current actual emissions shall be determined from the most recent available annual emissions inventory of the actual emissions for each regulated pollutant subject to fees from all sources subject to the annual permit program emissions fee.

9VAC5-80-342. Annual permit program emissions fee calculation on and after [~~(insert effective date of the regulation)~~ January 1, 2018].

A. On and after [~~(insert effective date of the regulation)~~ January 1, 2018], the amount of the annual permit program emissions fee shall be calculated as follows:

1. The amount of the annual permit program emissions fee (consistent with the need to cover reasonable costs) for each applicable source shall be the annual permit program emission fee rate (in dollars per ton of emissions) for the billing calendar year multiplied by the total actual emissions for the previous calendar year (in tons per year of emissions).
2. The annual permit program emissions fee rate shall be calculated as follows:
 - a. For permit program emission fees billed in calendar year 2018 (applied to 2017 emissions), the annual permit program emissions fee rate shall be \$73.01 per ton of emissions.

b. For permit program emission fees billed in calendar year 2019 (applied to 2018 emissions), the annual permit program emissions fee rate shall be \$83.96 per ton of emissions.

c. For permit program emissions fees billed after calendar year 2019, the annual permit program emissions fee rate shall be adjusted annually by the change in the Consumer Price Index (CPI) as specified in subdivision 3 of this subsection.

3. The annual adjustment of the permit program emissions fees shall be based upon the annual permit program emissions fee rate for the preceding calendar year and the change in the CPI value published by the U.S. Department of Labor for all-urban consumers over the 12-month period ending on August 31 of the calendar year preceding the calendar year in which the annual permit program emissions fee is assessed and billed.

a. The CPI for all-urban consumers that is published by the U.S. Department of Labor may be obtained online from the Bureau of Labor Statistics website at <http://data.bls.gov/cgi-bin/surveymost?cu>.

b. No CPI adjustment shall be made for annual permit program emissions fees assessed and billed in calendar years 2018 and 2019.

B. The actual emissions covered by the permit program emissions fees for the preceding year shall be calculated by the owner and submitted to the department by April 15 of each year. The calculations and final amount of emissions are subject to verification and final determination by the department.

C. If the assessment of the annual permit program emissions fee calculated in accordance with subsections A and B of this section results in a total amount of fee revenue in excess of the amount necessary to fund the permit program costs, a lesser annual permit program emissions fee may instead be calculated and assessed according to the formula specified in subsection D of this section. Any adjustments made to the annual permit program emissions fee shall be within the constraints of 40 CFR 70.9.

D. The lesser annual permit program emissions fee shall be calculated according to the following formula: the lesser annual permit program emissions fee is equal to the estimated permit program costs divided by the estimated actual emissions. The estimated permit program costs and estimated actual emissions shall be determined from the data specified in subdivisions 1 and 2 of this subsection, incorporating any anticipated adjustments to the data.

1. The current permit program costs shall be determined from the most recent available annual expenditure record of the amount spent by the department on permit program costs.

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2. The current actual emissions shall be determined from the most recent available annual emissions inventory of the actual emissions for each regulated pollutant subject to fees from all sources subject to the annual permit program emissions fee.

9VAC5-80-2270. General.

A. Any person submitting a permit application subject to this article shall pay a permit application fee in the amount determined in accordance with 9VAC5-80-2280 or 9VAC5-80-2282, as appropriate.

B. Permit application fees collected pursuant to this article for sources subject to Article 1 (9VAC5-80-50 et seq.) or Article 3 (9VAC5-80-360 et seq.) of this part or subject to Part II (9VAC5-85-20 et seq.) of 9VAC5-85 (Permits for Stationary Sources of Pollutants Subject to Regulation) shall not be used for any purpose other than as provided in Title V of the federal Clean Air Act and associated regulations and policies.

9VAC5-80-2280. Permit application fee calculation prior to [~~(insert effective date of the regulation or)~~ January 1, 2018 [~~, whichever is later~~].

Each permit application subject to this article that is received by the appropriate regional office prior to [~~(insert effective date of the regulation or)~~ January 1, 2018, [~~, whichever is later~~] shall be subject to a permit application fee. The amount of the application fee shall be calculated as follows:

1. The amount of the permit application fee shall be the largest applicable base permit application fee amount from Table 8-10A, adjusted annually by the change in the Consumer Price Index (CPI) as specified in subdivision 2 of this subsection.

TABLE 8-10A

BASE PERMIT APPLICATION FEES FOR STATIONARY SOURCES

Application for:	Base Permit Application Fee Amount
Sources subject to Title V permitting requirements:	
Major NSR permit	\$30,000
Major NSR permit amendment (except administrative)	\$7,000
State major permit	\$15,000
Minor NSR permit (that is not also a state major permit)	\$1,500

Minor NSR permit amendment (except administrative)	\$750
Title V permit	\$20,000
Title V permit renewal	\$10,000
Title V permit modification (except administrative)	\$3,500
State operating permit	\$7,000
State operating permit amendment (except administrative)	\$3,500
Title V General Permit	\$500
Sources subject to the requirements of a synthetic minor permit:	
Minor NSR permit	\$500
Minor NSR permit amendment (except administrative)	\$250
State operating permit	\$1,500
State operating permit amendment (except administrative)	\$800

2. The annual adjustment of the permit application fees shall be based upon the annually adjusted permit application fee amounts for the preceding calendar year and the change in the CPI value published by the U.S. Department of Labor for all-urban consumers over the 12-month period ending on August ~~30~~ 31 of the calendar year preceding the calendar year in which the application is first received by the appropriate regional office of the department.

a. The CPI for all-urban consumers published by the U.S. Department of Labor may be obtained online from the Bureau of Labor Statistics' Statistics website at <http://data.bls.gov/cgi-bin/surveymost?cu>.

b. There is no CPI adjustment for applications received prior to January 1, 2013.

3. The amount of the annually CPI-adjusted permit application fee shall be rounded down to the nearest whole dollar.

4. Applications that are received prior to [~~(insert effective date of the regulation or)~~ January 1, 2018, [~~, whichever is later~~] and that are amended on or after [~~(insert effective date of the regulation or)~~ January 1, 2018, [~~, whichever is later~~] are subject to the permit application fee calculated pursuant to the provisions 9VAC5-80-2282 B.

9VAC5-80-2282. Permit application fee calculation on and after [~~(insert effective date of the regulation or)~~ January 1, 2018 [~~(, whichever is later)~~].

A. Each permit application subject to this article that is received by the appropriate regional office on or after [~~(insert effective date of the regulation or)~~ January 1, 2018, [~~(whichever is later)~~] shall be subject to a permit application fee. The amount of the application fee shall be calculated as follows:

1. The amount of the permit application fee shall be the largest applicable base permit application fee amount from Table 8-10B, adjusted annually on January 1 of each calendar year after 2018 as specified in subdivisions 2 and 3 of this subsection.

TABLE 8-10B

BASE PERMIT APPLICATION FEES FOR STATIONARY SOURCES

Application for:	Base Permit Application Fee Amount
<u>Sources subject to Title V permitting requirements:</u>	
<u>Major NSR permit</u>	<u>\$63,000</u>
<u>Major NSR permit amendment (except administrative)</u>	<u>\$10,000</u>
<u>State major permit</u>	<u>\$25,000</u>
<u>Minor NSR permit (that is not also a state major permit)</u>	<u>\$5,000</u>
<u>Minor NSR permit amendment (except administrative)</u>	<u>\$2,500</u>
<u>Title V permit</u>	<u>\$35,000</u>
<u>Title V permit renewal</u>	<u>\$15,000</u>
<u>Title V permit modification (except administrative)</u>	<u>\$4,000</u>
<u>State operating permit</u>	<u>\$10,000</u>
<u>State operating permit amendment (except administrative)</u>	<u>\$4,000</u>
<u>Title V General Permit</u>	<u>\$531</u>
<u>Sources subject to the requirements of a synthetic minor permit:</u>	
<u>Minor NSR permit</u>	<u>\$3,000</u>
<u>Minor NSR permit amendment (except administrative)</u>	<u>\$1,000</u>

<u>State operating permit</u>	<u>\$5,000</u>
<u>State operating permit amendment (except administrative)</u>	<u>\$2,500</u>

2. Except as provided in subdivision 3 of this subsection, the annual adjustment of the permit application fees shall be based upon the permit application fee amounts for the preceding calendar year and the change in the CPI value published by the U.S. Department of Labor for all-urban consumers over the 12-month period ending on August 31 of the calendar year preceding the calendar year in which the application is received by the appropriate regional office of the department.

a. The CPI for all-urban consumers published by the U.S. Department of Labor may be obtained online from the Bureau of Labor Statistics website at <http://data.bls.gov/cgi-bin/surveymost?cu>.

b. There is no CPI adjustment of fees for applications received during calendar year 2019.

3. Instead of a CPI adjustment, each permit application fee amount for applications received in calendar year 2019 shall be increased to 10% more than the base permit application fee amount provided in Table 8-10B.

4. The amount of the permit application fee that is calculated as provided in subdivisions 1, 2, and 3 of this subsection shall be rounded down to the nearest whole dollar.

B. The provisions of this section also apply to permit applications received by the appropriate regional office prior to [~~(insert the effective date of the regulation)~~ January 1, 2018,] and amended on or after [~~(insert the effective date of the regulation)~~ January 1, 2018]. Those amended applications are subject to the permit application fee due as if the application was received on or after [~~(insert the effective date of the regulation)~~ January 1, 2018], less any prior permit application fee amount paid for that application.

Article 11

Annual Permit Maintenance Fees for Stationary Sources

9VAC5-80-2310. Applicability.

A. Except as provided in subsection C of this section, the provisions of this article apply to any stationary source that has begun normal operation and:

1. The stationary source is subject to the provisions of a permit issued pursuant to Article 1 (9VAC5-80-50 et seq.) or Article 3 (9VAC5-80-360 et seq.) of this part or pursuant to Part II (9VAC5-85-20 et seq.) of 9VAC5-85 (Permits for Stationary Sources of Pollutants Subject to Regulation);

2. The stationary source is subject to the permit requirements of Article 1 (9VAC5-80-50 et seq.) or

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Article 3 (9VAC5-80-360 et seq.) of this part or Part II (9VAC5-85-20 et seq.) of 9VAC5-85 (Permits for Stationary Sources of Pollutants Subject to Regulation), and is operating under an application shield under the provisions of 9VAC5-80-80 F or 9VAC5-80-430 F; or

3. The stationary source ~~would be~~ is subject to the permit requirements of Article 1 (9VAC5-80-50 et seq.) or Article 3 (9VAC5-80-360 et seq.) of this part or Part II ~~(9VAC5-85-40 (9VAC5-85-20 et seq.)~~ of 9VAC5-85 (Permits for Stationary Sources of Pollutants Subject to Regulation) in the absence of a permit issued under Article 5 (9VAC5-80-800 et seq.) or Article 6 (9VAC5-80-1100 et seq.) of this part or Part IV (9VAC5-85-60 et seq.) of 9VAC5-85 (Permits for Stationary Sources of Pollutants Subject to Regulation).

B. The provisions of this article apply throughout the Commonwealth of Virginia.

C. The provisions of this article shall not apply to ~~the following:~~ 1. Any any stationary source that began normal operation during the calendar year for which the annual permit maintenance fee is assessed.

~~2. Any synthetic minor source that is not a synthetic minor 80% source and is not otherwise subject to the permit requirements of Article 1 (9VAC5-80-50 et seq.) or Article 3 (9VAC5-80-360 et seq.) of this part or Part II (9VAC5-85-20 et seq.) of 9VAC5-85 (Permits for Stationary Sources of Pollutants Subject to Regulation).~~

D. The department shall make any final determinations required by this article, including [~~but not limited to~~]:

1. The applicability of this article;
2. The amount of permit maintenance fees owed; and
3. The applicability of terms to a particular stationary source or permit.

9VAC5-80-2330. General.

A. The owner of any stationary source subject to this article shall pay an annual permit maintenance fee in the amount determined in accordance with 9VAC5-80-2340 or 9VAC5-80-2342, as appropriate.

B. Annual permit maintenance fees collected pursuant to this article for sources subject to Article 1 (9VAC5-80-50 et seq.) or Article 3 (9VAC5-80-360 et seq.) of this part or subject to Part II (9VAC5-85-20 et seq.) of 9VAC5-85 (Permits for Stationary Sources of Pollutants Subject to Regulation) shall not be used for any purpose other than as provided in Title V of the federal Clean Air Act and associated regulations and policies.

9VAC5-80-2340. Annual permit maintenance fee calculation prior to [~~(insert effective date of the regulation) January 1, 2018~~].

A. ~~Each~~ Prior to [(insert effective date of the regulation) January 1, 2018], each stationary source subject to this article shall be assessed an annual permit maintenance fee.

B. The amount of the permit maintenance fee shall be calculated as follows:

1. The amount of the annual permit maintenance fee shall be the largest applicable base permit maintenance fee amount from Table 8-11A, adjusted annually by the change in the Consumer Price Index (CPI) as specified in subdivision 2 of this subsection.

TABLE 8-11A

BASE PERMIT MAINTENANCE FEES FOR STATIONARY SOURCES

Stationary Source Type	Base Permit Maintenance Fee Amount
Title V Complex Major Source	\$10,000
Title V Major Source	\$3,500
Title V Source By Rule	\$1,500
Synthetic Minor 80% Source	\$1,000

2. The annual adjustment of the permit maintenance fees shall be based upon the annual permit maintenance fee amount for the preceding calendar year and the change in the CPI value published by the U.S. Department of Labor for all-urban consumers over the 12-month period ending on August ~~30~~ 31 of the calendar year preceding the calendar year in which the permit maintenance fee is assessed.

a. The CPI for all-urban consumers published by the U.S. Department of Labor may be obtained online from the Bureau of Labor Statistics' Statistics website at <http://data.bls.gov/cgi-bin/surveymost?cu>.

b. No CPI adjustment shall be made for annual permit maintenance fees assessed in calendar year 2012.

3. The amount of the annual permit maintenance fee shall be rounded down to the nearest whole dollar.

C. The provisions of this section shall not apply to any synthetic minor source that is not a synthetic minor 80% source and is not otherwise subject to the permit requirements of Article 1 (9VAC5-80-50 et seq.) or Article 3 (9VAC5-80-360 et seq.) of this part or Part II (9VAC5-85-20 et seq.) of 9VAC5-85 (Permits for Stationary Sources of Pollutants Subject to Regulation).

9VAC5-80-2342. Annual permit maintenance fee calculation on and after [insert effective date of the regulation] January 1, 2018]

A. On and after [insert effective date of the regulation] January 1, 2018,] each stationary source subject to this article shall be assessed a permit maintenance fee on an annual basis.

B. The amount of the annual permit maintenance fee shall be calculated as follows:

1. The amount of the annual permit maintenance fee shall be the largest applicable base permit maintenance fee amount from Table 8-11B, adjusted annually as specified in subdivisions 2 and 3 of this subsection.

TABLE 8-11B

BASE PERMIT MAINTENANCE FEES FOR STATIONARY SOURCES

Stationary Source Type	Base Permit Maintenance Fee Amount
Title V Complex Major Source	\$21,263
Title V Major Source	\$7,442
Title V Source By Rule	\$2,392
Synthetic Minor 80% Source (SM-80 Source)	\$1,594
Synthetic Minor Source (other than SM-80 Source)	\$500

2. Except as provided in subdivision 3 of this subsection, the annual adjustment of the permit maintenance fees shall be based upon the annual permit maintenance fee amount for the preceding calendar year and the change in the CPI value published by the U.S. Department of Labor for all-urban consumers over the 12-month period ending on August 31 of the calendar year preceding the calendar year in which the permit maintenance fee is assessed and billed.

a. The CPI for all-urban consumers published by the U.S. Department of Labor may be obtained online from the Bureau of Labor Statistics website at <http://data.bls.gov/cgi-bin/surveymost?cu>.

b. No annual CPI adjustment shall be made to permit maintenance fees for source types in years for which the adjusted permit maintenance fees for those source types are specified in subdivision 3 of this subsection.

3. Other adjustments to annual permit maintenance fees shall be made as follows:

a. Adjusted permit maintenance fees that are assessed and billed in calendar year 2019 shall be as specified in Table 8-11C.

TABLE 8-11C

ADJUSTED PERMIT MAINTENANCE FEES BILLED IN CALENDAR YEAR 2019

Stationary Source Type	Permit Maintenance Fee Amount
Title V Complex Major Source	\$23,389
Title V Major Source	\$8,186
Title V Source By Rule	\$2,790
Synthetic Minor 80% Source	\$1,860
Synthetic Minor Source (other than SM-80 Source)	\$550

b. Adjusted annual permit maintenance fees for Title V Sources by Rule and SM-80 Sources that are assessed and billed in calendar year 2020 shall be as specified in Table 8-11D. Annual permit maintenance fees for other stationary source types that are assessed and billed in calendar year 2020 shall be adjusted as specified in subdivision 2 of this subsection.

TABLE 8-11D

ADJUSTED PERMIT MAINTENANCE FEES BILLED IN CALENDAR YEAR 2020

Stationary Source Type	Permit Maintenance Fee Amount
Title V Source By Rule	\$3,189
Synthetic Minor 80% Source	\$2,126

4. The amount of the annual permit maintenance fee shall be rounded down to the nearest whole dollar.

VA.R. Doc. No. R17-4981; Filed November 8, 2017, 9:56 a.m.

DEPARTMENT OF ENVIRONMENTAL QUALITY

Final Regulation

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

Title of Regulation: 9VAC15-30. Regulations for the Certification of Recycling Machinery and Equipment for Local Tax Exemption Purposes (amending 9VAC15-30-140, 9VAC15-30-170).

Statutory Authority: § 58.1-3661 of the Code of Virginia.

Regulations

Effective Date: December 27, 2017.

Small Business Impact Review Report of Findings: This final regulatory action serves as the report of the findings of the regulatory review pursuant to § 2.2-4007.1 of the Code of Virginia.

Agency Contact: Leslie D. Beckwith, Department of Environmental Quality, 629 East Main Street, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4123, FAX (804) 698-4234, or email leslie.beckwith@deq.virginia.gov.

Summary:

The amendments update citations to the Administrative Process Act.

9VAC15-30-140. Appeal procedure.

All appeals taken from actions of the director relative to the provisions of this chapter shall be governed by the Administrative Process Act (~~Chapter 1.1-1 (§ 9-6-14:1 et seq.) of Title 9 (§ 2.2-4000 et seq.)~~) of the Code of Virginia.

9VAC15-30-170. Administrative procedures for variances.

A. General petitioning requirements. The petition shall be submitted to the director by certified mail and shall include:

1. The petitioner's name and address;
2. A statement of petitioner's interest in the proposed action;
3. A description of desired action and a citation of the regulation from which a variance is requested;
4. A description of need and justification for the proposed action;
5. The duration of the variance, if applicable;
6. The potential impact of the variance on public health or the environment;
7. Other information believed by the applicant to be pertinent; and
8. The following statement signed by the petitioner or authorized representative:

"I certify that I have personally examined and am familiar with the information submitted in this petition and all attached documents, and that, based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the submitted information is true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment."

B. Petition processing.

1. After receiving a petition that includes the information required in subsection A of this section, the director will

determine whether the information received is sufficient to render the decision. If the information is deemed insufficient, the director will specify additional information needed and request that it be furnished.

2. The petitioner may submit the additional information requested, or may attempt to show that no reasonable basis exists for additional information. If the director agrees that no reasonable basis exists for the request for additional information, he will act in accordance with subdivision 3 of this subsection. If the director continues to believe that a reasonable basis exists to require the submission of such information, he will proceed with the denial action in accordance with the Administrative Process Act.

3. Decisions to grant or deny a petition are subject to the provisions of Article 3 of the Virginia Administrative Process Act (~~§ 9-6-14:1~~ 2.2-4000 et seq. of the Code of Virginia).

C. Petition resolution. If the director grants a variance request, the notice to the petitioner shall provide that the variance may be terminated upon a finding by the director that the petitioner has failed to comply with any requirements of the variance.

VA.R. Doc. No. R18-5134; Filed October 26, 2017, 12:18 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 where no agency discretion is involved. The State Board of Health will receive, consider, and respond to petitions by any interested person at any time with respect to reconsideration or revision.

Title of Regulation: **12VAC5-90. Regulations for Disease Reporting and Control (amending 12VAC5-90-80).**

Statutory Authority: § 32.1-35 of the Code of Virginia.

Effective Date: December 27, 2017.

Agency Contact: Diane Woolard, PhD, Director, Disease Surveillance, Department of Health, 109 Governor Street, Richmond, VA 23219, telephone (804) 864-8124, or email diane.woolard@vdh.virginia.gov.

Summary:

Chapter 280 of the 2017 Acts of Assembly requires the State Board of Health to adopt regulations to include

neonatal abstinence syndrome on the list of diseases that are required to be reported in accordance with § 32.1-35 of the Code of Virginia. The amendments implement this mandate.

Part III
Reporting of Disease

12VAC5-90-80. Lists of diseases that shall be reported.

A. Reportable disease list. The board declares suspected or confirmed cases of the following named diseases, toxic effects, and conditions to be reportable by the persons enumerated in 12VAC5-90-90. Conditions identified by an asterisk (*) require immediate communication to the local health department by the most rapid means available upon suspicion or confirmation, as defined in subsection C of this section. Other conditions should be reported within three days of suspected or confirmed diagnosis, unless otherwise specified in this section.

Acquired immunodeficiency syndrome (AIDS)
Amebiasis
*Anthrax
Arboviral infections (e.g., CHIK, dengue, EEE, LAC, SLE, WNV, Zika)
Babesiosis
*Botulism
*Brucellosis
Campylobacteriosis
Chancroid
Chickenpox (Varicella)
Chlamydia trachomatis infection
*Cholera
*Coronavirus infection, severe
Creutzfeldt-Jakob disease if ~~<55~~ younger than 55 years of age
Cryptosporidiosis
Cyclosporiasis
*Diphtheria
*Disease caused by an agent that may have been used as a weapon
Ehrlichiosis/Anaplasmosis
Escherichia coli infection, Shiga toxin-producing
Giardiasis
Gonorrhea

Granuloma inguinale
*Haemophilus influenzae infection, invasive
Hantavirus pulmonary syndrome
Hemolytic uremic syndrome (HUS)
*Hepatitis A
Hepatitis B (acute and chronic)
Hepatitis C (acute and chronic)
Hepatitis, other acute viral
Human immunodeficiency virus (HIV) infection
Influenza
*Influenza-associated deaths in children ~~<18~~ younger than 18 years of age
Lead, reportable levels
Legionellosis
Leprosy (Hansen's disease)
Leptospirosis
Listeriosis
Lyme disease
Lymphogranuloma venereum
Malaria
*Measles (Rubeola)
*Meningococcal disease
Mumps
Neonatal abstinence syndrome (NAS)
Ophthalmia neonatorum
*Outbreaks, all (including ~~but not limited to~~ foodborne, healthcare-associated, occupational, toxic substance-related, and waterborne)
*Pertussis
*Plague
*Poliovirus infection, including poliomyelitis
*Psittacosis
*Q fever
*Rabies, human and animal
Rabies treatment, post-exposure
*Rubella, including congenital rubella syndrome
Salmonellosis
Shigellosis

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*Smallpox (Variola)

Spotted fever rickettsiosis

Staphylococcus aureus infection, vancomycin-intermediate or vancomycin-resistant

Streptococcal disease, Group A, invasive or toxic shock

Streptococcus pneumoniae infection, invasive, in children \leq younger than five years of age

Syphilis (report *primary and *secondary syphilis by rapid means)

Tetanus

Toxic substance-related illness

Trichinosis (Trichinellosis)

*Tuberculosis, active disease

Tuberculosis infection in children \leq younger than four years of age

*Tularemia

*Typhoid/Paratyphoid fever

*Unusual occurrence of disease of public health concern

*Vaccinia, disease or adverse event

*Vibrio infection

*Viral hemorrhagic fever

*Yellow fever

Yersiniosis

B. Conditions reportable by directors of laboratories. Conditions identified by an asterisk (*) require immediate communication to the local health department by the most rapid means available upon suspicion or confirmation, as defined in subsection C of this section. Other conditions should be reported within three days of suspected or confirmed diagnosis.

Amebiasis - by microscopic examination, culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

*Anthrax - by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

Arboviral infection e.g., for example, CHIK, dengue, EEE, LAC (also known as California encephalitis), SLE, WNV, Zika - by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

Babesiosis - by culture, antigen detection, nucleic acid detection, microscopic examination, or serologic results consistent with recent infection

*Botulism - by culture, nucleic acid detection, or identification of neurotoxin in a clinical specimen

*Brucellosis - by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

Campylobacteriosis - by culture or culture-independent diagnostic test (CIDT) (i.e., antigen detection or nucleic acid detection). For CIDT, also submit all available culture results (positive or negative) associated with a positive result.

Chancroid - by culture, antigen detection, or nucleic acid detection

Chickenpox (Varicella) - by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

Chlamydia trachomatis infection - by culture, antigen detection, nucleic acid detection or, for lymphogranuloma venereum, serologic results consistent with recent infection

*Cholera - by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

*Coronavirus infection, severe - by culture, nucleic acid detection, or serologic results consistent with recent infection

Creutzfeldt-Jakob disease if \leq 55 younger than 55 years of age by histopathology in patients under the age of 55 years

Cryptosporidiosis - by microscopic examination, antigen detection, or nucleic acid detection

Cyclosporiasis - by microscopic examination or nucleic acid detection

*Diphtheria - by culture or histopathology

Ehrlichiosis/Anaplasmosis - by culture, nucleic acid detection, microscopic examination, or serologic results consistent with recent infection

Escherichia coli infection, Shiga toxin-producing - by culture, Shiga toxin detection (e.g., nucleic acid detection, EIA), or serologic results consistent with recent infection

Giardiasis - by microscopic examination, antigen detection, or nucleic acid detection

Gonorrhea - by microscopic examination of a urethral smear (males only) or endocervical smear (females only), culture, antigen detection, or nucleic acid detection. Include available antimicrobial susceptibility findings in report.

*Haemophilus influenzae infection, invasive - by culture, antigen detection, or nucleic acid detection from a normally sterile site

Hantavirus pulmonary syndrome - by antigen detection (immunohistochemistry), nucleic acid detection, or serologic results consistent with recent infection

*Hepatitis A - by detection of IgM antibodies

Hepatitis B (acute and chronic) - by detection of HBsAg, HBeAg, or IgM antibodies or nucleic acid detection. For any reportable hepatitis finding, submit all available results from the hepatitis panel.

Hepatitis C (acute and chronic) - by hepatitis C virus antibody (anti-HCV) positive, HCV antigen positive, or HCV RNA positive by nucleic acid test. For all hepatitis C patients, also report available results of serum alanine aminotransferase (ALT) and all available results from the hepatitis panel.

Hepatitis, other acute viral – any finding indicative of acute infection with hepatitis D, E, or other cause of viral hepatitis. For any reportable hepatitis finding, submit all available results from the hepatitis panel.

Human immunodeficiency virus (HIV) infection - by culture, antigen detection, nucleic acid detection, or detection of antibody. For HIV-infected patients, report all results of CD4 and HIV viral load tests, including undetectable viral loads. For HIV-infected patients, report all HIV genetic nucleotide sequence data associated with HIV drug resistance tests by electronic submission. For children less younger than three years of age, report all tests regardless of the test findings (e.g., negative or positive).

Influenza - by culture, antigen detection by direct fluorescent antibody (DFA), or nucleic acid detection

Lead, reportable levels - by any detectable blood lead level in children ages 0-15 years or levels greater than or equal to 5 five µg/dL in persons older than 15 years of age

Legionellosis - by culture, antigen detection (including urinary antigen), nucleic acid detection, or serologic results consistent with recent infection

Leptospirosis - by culture, microscopic examination by dark field microscopy, nucleic acid detection, or serologic results consistent with recent infection

Listeriosis - by culture from a normally sterile site. If associated with miscarriage or stillbirth, by culture from placental or fetal tissue

Lyme disease - by culture, antigen detection, or detection of antibody confirmed with a supplemental test

Malaria - by microscopic examination, antigen detection, or nucleic acid detection

*Measles (Rubeola) - by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

*Meningococcal disease - by culture, nucleic acid detection, or antigen detection from a normally sterile site

Mumps - by culture, nucleic acid detection, or serologic results consistent with recent infection

*Mycobacterial diseases - (See 12VAC5-90-225 B) Report any of the following:

1. Acid fast bacilli by microscopic examination;
2. Mycobacterial identification - preliminary and final identification by culture or nucleic acid detection;
3. Drug susceptibility test results for *M. tuberculosis*.

*Pertussis - by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

*Plague - by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

*Poliovirus infection - by culture

*Psittacosis - by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

*Q fever - by culture, antigen detection, nucleic acid detection, immunohistochemical methods, or serologic results consistent with recent infection

*Rabies, human and animal - by culture, antigen detection by direct fluorescent antibody test, nucleic acid detection, or, for humans only, serologic results consistent with recent infection

*Rubella - by culture, nucleic acid detection, or serologic results consistent with recent infection

Salmonellosis - by culture, antigen detection, or nucleic acid detection

Shigellosis - by culture, antigen detection, or nucleic acid detection

*Smallpox (Variola) - by culture or nucleic acid detection

Spotted fever rickettsiosis - by culture, antigen detection (including immunohistochemical staining), nucleic acid detection, or serologic results consistent with recent infection

Staphylococcus aureus infection, resistant, ~~as defined below~~ specifically:

Vancomycin-intermediate or vancomycin-resistant Staphylococcus aureus infection - by antimicrobial susceptibility testing of a Staphylococcus aureus isolate, with a vancomycin susceptibility result of intermediate or resistant, cultured from a clinical specimen. Include available antimicrobial susceptibility findings in report.

Regulations

Streptococcal disease, Group A, invasive or toxic shock - for invasive disease, by culture from a normally sterile site; for streptococcal toxic shock, by culture from any body site

Streptococcus pneumoniae infection, invasive, in children ~~≤~~ younger than five years of age - by culture from a normally sterile site in a child under the age of five years

*Syphilis - by darkfield microscopy, antigen detection, nucleic acid detection, or serology by either treponemal or nontreponemal methods

Toxic substance-related illness - by blood or urine laboratory findings above the normal range, including but not limited to heavy metals, pesticides, and industrial-type solvents and gases. When applicable and available, report speciation of metals when blood or urine levels are elevated in order to differentiate the chemical species (elemental, organic, or inorganic).

Trichinosis (Trichinellosis) - by microscopic examination of a muscle biopsy or serologic results consistent with recent infection

*Tularemia - by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

*Typhoid/Paratyphoid fever - by culture, antigen detection, or nucleic acid detection

*Vaccinia, disease or adverse event - by culture or nucleic acid detection

*Vibrio infection - isolation of any species of the family Vibrionaceae (other than toxigenic Vibrio cholera O1 or O139, which are reportable as cholera) from a clinical specimen by culture, antigen detection, or nucleic acid detection

*Viral hemorrhagic fever - by culture, antigen detection (including immunohistochemical staining), nucleic acid detection, or serologic results consistent with recent infection

*Yellow fever - by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

Yersiniosis - by culture, nucleic acid detection, or serologic results consistent with recent infection

C. Reportable diseases requiring rapid communication. Certain of the diseases in the list of reportable diseases, because of their extremely contagious nature or their potential for greater harm, or both, require immediate identification and control. Reporting of persons confirmed or suspected of having these diseases, listed ~~below~~ in this subsection, shall be made immediately by the most rapid means available, preferably by telephone to the local health department. (These

same diseases are also identified by an asterisk (*) in subsections A and B, where applicable, of this section.)

Anthrax

Botulism

Brucellosis

Cholera

Coronavirus infection, severe

Diphtheria

Disease caused by an agent that may have been used as a weapon

Haemophilus influenzae infection, invasive

Hepatitis A

Influenza-associated deaths in children ~~<18~~ younger than 18 years of age

Influenza A, novel virus

Measles (Rubeola)

Meningococcal disease

Outbreaks, all

Pertussis

Plague

Poliovirus infection, including poliomyelitis

Psittacosis

Q fever

Rabies, human and animal

Rubella, including congenital rubella syndrome

Smallpox (Variola)

Syphilis, primary and secondary

Tuberculosis, active disease

Tularemia

Typhoid/Paratyphoid fever

Unusual occurrence of disease of public health concern

Vaccinia, disease or adverse event

Vibrio infection

Viral hemorrhagic fever

Yellow fever

D. Toxic substance-related illnesses. All toxic substance-related illnesses, including pesticide and heavy metal poisoning or illness resulting from exposure to an

occupational dust or fiber or radioactive substance, shall be reported.

If such illness is verified or suspected and presents an emergency or a serious threat to public health or safety, the report of such illness shall be made immediately by the most rapid means available, preferably by telephone.

E. Outbreaks. The occurrence of outbreaks or clusters of any illness ~~which that~~ may represent a group expression of an illness ~~which that~~ may be of public health concern shall be reported to the local health department immediately by the most rapid means available, preferably by telephone.

F. Unusual or ill-defined diseases or emerging or reemerging pathogens. Unusual or emerging conditions of public health concern shall be reported to the local health department immediately by the most rapid means available, preferably by telephone. In addition, the commissioner or his designee may establish surveillance systems for diseases or conditions that are not on the list of reportable diseases. Such surveillance may be established to identify cases (delineate the magnitude of the situation), to identify the mode of transmission and risk factors for the disease, and to identify and implement appropriate action to protect public health. Any person reporting information at the request of the department for special surveillance or other epidemiological studies shall be immune from liability as provided by § 32.1-38 of the Code of Virginia.

G. Neonatal abstinence syndrome. Neonatal abstinence syndrome shall be reported by physicians and directors of medical care facilities when a newborn has been diagnosed with neonatal abstinence syndrome, a condition characterized by clinical signs of withdrawal from exposure to prescribed or illicit drugs. Reports shall be submitted within one month of diagnosis by entering the information into the online Confidential Morbidity Report portal available on the Department of Health's website at <http://vdh.virginia.gov/morbidity-report>.

VA.R. Doc. No. R18-5250; Filed October 26, 2017, 8:57 p.m.

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TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF DENTISTRY

Emergency Regulation

Title of Regulation: 18VAC60-25. Regulations Governing the Practice of Dental Hygiene (amending 18VAC60-25-190).

Statutory Authority: §§ 54.1-2400, 54.1-2272, and 54.1-2729 of the Code of Virginia.

Effective Dates: November 13, 2017, through May 12, 2019.

Agency Contact: Sandra Reen, Executive Director, Board of Dentistry, 9960 Mayland Drive, Suite 300, Richmond, VA 23233, telephone (804) 367-4437, FAX (804) 527-4428, or email sandra.reen@dhp.virginia.gov.

Preamble:

Section 2.2-4011 of the Code of Virginia states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of § 2.2-4006 A 4 of the Code of Virginia. Chapter 410 of the 2017 Acts of Assembly, which amended § 54.1-2722 of the Code of Virginia, clarifies continuing education requirements for dental hygienists practicing under remote supervision and requires the Board of Dentistry to adopt regulations implementing the provision of the act.

The emergency regulation requires a dental hygienist practicing under supervision to complete a continuing education course of at least two hours that is offered by an accredited dental education program or a sponsor listed in subsection C of 18VAC60-25-190 that includes certain course content as outlined in new subsection H of 18VAC60-25-190.

18VAC60-25-190. Requirements for continuing education.

A. In order to renew an active license, a dental hygienist shall complete a minimum of 15 hours of approved continuing education. Continuing education hours in excess of the number required for renewal may be transferred or credited to the next renewal year for a total of not more than 15 hours.

1. A dental hygienist shall be required to maintain evidence of successful completion of a current hands-on course in basic cardiopulmonary resuscitation for health care providers.

2. A dental hygienist who monitors patients under general anesthesia, deep sedation, or conscious/moderate sedation shall complete four hours every two years of approved continuing education directly related to monitoring of such anesthesia or sedation as part of the hours required for licensure renewal.

3. Up to two hours of the 15 hours required for annual renewal may be satisfied through delivery of dental hygiene services, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those services. One hour of continuing education may be credited for three hours of providing such volunteer services, as documented by the health department or free clinic.

Regulations

B. An approved continuing education program shall be relevant to the treatment and care of patients and shall be:

1. Clinical courses in dental or dental hygiene practice; or
2. Nonclinical subjects that relate to the skills necessary to provide dental hygiene services and are supportive of clinical services (i.e., patient management, legal and ethical responsibilities, risk management, and recordkeeping). Courses not acceptable for the purpose of this subsection include, but are not limited to, estate planning, financial planning, investments, and personal health.

C. Continuing education credit may be earned for verifiable attendance at or participation in any course, to include audio and video presentations, that meets the requirements in subdivision B 1 of this section and is given by one of the following sponsors:

1. The American Dental Association and the National Dental Association and their constituent and component/branch associations;
2. The American Dental Hygienists' Association and the National Dental Hygienists Association and their constituent and component/branch associations;
3. The American Dental Assisting Association and its constituent and component/branch associations;
4. The American Dental Association specialty organizations and their constituent and component/branch associations;
5. A provider accredited by the Accreditation Council for Continuing Medical Education for Category 1 credits;
6. The Academy of General Dentistry and its constituent and component/branch associations;
7. Community colleges with an accredited dental hygiene program if offered under the auspices of the dental hygienist program;
8. A college or university that is accredited by an accrediting agency approved by the U.S. Department of Education or a hospital or health care institution accredited by the Joint Commission on Accreditation of Healthcare Organizations;
9. The American Heart Association, the American Red Cross, the American Safety and Health Institute, and the American Cancer Society;
10. A medical school accredited by the American Medical Association's Liaison Committee for Medical Education or a dental school or dental specialty residency program accredited by the Commission on Dental Accreditation of the American Dental Association;

11. State or federal government agencies (i.e., military dental division, Veteran's Administration, etc.);

12. The Commonwealth Dental Hygienists' Society;

13. The MCV Orthodontic Education and Research Foundation;

14. The Dental Assisting National Board and its affiliate, the Dental Auxiliary Learning and Education Foundation;

15. The American Academy of Dental Hygiene, its constituent and component/branch associations; or

16. A regional testing agency (i.e., Central Regional Dental Testing Service, Northeast Regional Board of Dental Examiners, Southern Regional Testing Agency, Council of Interstate Testing Agencies, or Western Regional Examining Board) when serving as an examiner.

D. Verification of compliance.

1. All licensees are required to verify compliance with continuing education requirements at the time of annual license renewal.

2. Following the renewal period, the board may conduct an audit of licensees to verify compliance.

3. Licensees selected for audit shall provide original documents certifying that they have fulfilled their continuing education requirements by the deadline date as specified by the board.

4. Licensees are required to maintain original documents verifying the date and the subject of the program or activity, the sponsor, and the amount of time earned. Documentation shall be maintained for a period of four years following renewal.

5. Failure to comply with continuing education requirements may subject the licensee to disciplinary action by the board.

E. Exemptions.

1. A licensee is exempt from completing continuing education requirements and considered in compliance on the first renewal date following the licensee's initial licensure.

2. The board may grant an exemption for all or part of the continuing education requirements due to circumstances beyond the control of the licensee, such as temporary disability, mandatory military service, or officially declared disasters. A written request with supporting documents must be submitted at least 30 days prior to the deadline for renewal.

F. The board may grant an extension for up to one year for completion of continuing education upon written request with an explanation to the board prior to the renewal date.

G. Continuing education hours required by board order shall not be used to satisfy the continuing education requirement for license renewal or reinstatement.

H. In order to practice under remote supervision in accordance with subsection F of § 54.1-2722 of the Code of Virginia, a dental hygienist shall complete a continuing education course of no less than two hours in duration that is offered by an accredited dental education program or a sponsor listed in subsection C of this section and that includes the following course content:

1. Intent and definitions of remote supervision;
2. Review of dental hygiene scope of practice and delegation of services;
3. Administration of controlled substances;
4. Patient records, documentation, and risk management;
5. Remote supervision laws for dental hygienists and dentists;
6. Written practice protocols; and
7. Settings allowed for remote supervision.

VA.R. Doc. No. R18-5208; Filed November 13, 2017, 7:28 a.m.

BOARD OF MEDICINE

Final Regulation

REGISTRAR'S NOTICE: The Board of Medicine is claiming an exemption from Article 2 of the Administrative Process Act in accordance with § 2.2-4006 A 6 of the Code of Virginia, which excludes regulations of the regulatory boards served by the Department of Health Professions pursuant to Title 54.1 of the Code of Virginia that are limited to reducing fees charged to regulants and applicants. The Board of Medicine will receive, consider, and respond to petitions by any interested person at any time with respect to reconsideration or revision.

Titles of Regulations: **18VAC85-20. Regulations Governing the Practice of Medicine, Osteopathic Medicine, Podiatry, and Chiropractic (amending 18VAC85-20-22).**

18VAC85-40. Regulations Governing the Practice of Respiratory Therapists (amending 18VAC85-40-35).

18VAC85-50. Regulations Governing the Practice of Physician Assistants (amending 18VAC85-50-35).

18VAC85-80. Regulations Governing the Licensure of Occupational Therapists (amending 18VAC85-80-26).

18VAC85-101. Regulations Governing the Practice of Radiologic Technology (amending 18VAC85-101-25).

18VAC85-110. Regulations Governing the Practice of Licensed Acupuncturists (amending 18VAC85-110-35).

18VAC85-120. Regulations Governing the Licensure of Athletic Trainers (amending 18VAC85-120-35).

18VAC85-130. Regulations Governing the Practice of Licensed Midwives (amending 18VAC85-130-30).

18VAC85-140. Regulations Governing the Practice of Polysomnographic Technologists (amending 18VAC85-140-40).

18VAC85-150. Regulations Governing the Practice of Behavior Analysis (amending 18VAC85-150-40).

18VAC85-160. Regulations Governing the Registration of Surgical Assistants and Surgical Technologists (amending 18VAC85-160-40).

18VAC85-170. Regulations Governing the Practice of Genetic Counselors (amending 18VAC85-170-40).

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

Effective Date: December 17, 2017.

Agency Contact: William L. Harp, M.D., Executive Director, Board of Medicine, 9960 Mayland Drive, Suite 300, Richmond, VA 23233-1463, telephone (804) 367-4621, FAX (804) 527-4429, or email william.harp@dhp.virginia.gov.

Summary:

The amendments apply a one-time fee reduction applicable for all professions regulated by the Board of Medicine for the next renewal cycle in 2018 or 2019.

18VAC85-20-22. Required fees.

A. Unless otherwise provided, fees established by the board shall not be refundable.

B. All examination fees shall be determined by and made payable as designated by the board.

C. The application fee for licensure in medicine, osteopathic medicine, and podiatry shall be \$302, and the fee for licensure in chiropractic shall be \$277.

D. The fee for a temporary authorization to practice medicine pursuant to clauses (i) and (ii) of § 54.1-2927 B (i) and (ii) of the Code of Virginia shall be \$25.

E. The application fee for a limited professorial or fellow license issued pursuant to 18VAC85-20-210 shall be \$55. The annual renewal fee shall be \$35. For renewal of a limited professorial or fellow license in 2016, the fee shall be \$30. An additional fee for late renewal of licensure shall be \$15.

F. The application fee for a limited license to interns and residents pursuant to 18VAC85-20-220 shall be \$55. The annual renewal fee shall be \$35. For renewal of a limited license to interns and residents in 2016, the fee shall be \$30. An additional fee for late renewal of licensure shall be \$15.

Regulations

G. The fee for a duplicate wall certificate shall be \$15; the fee for a duplicate license shall be \$5.00.

H. The fee for biennial renewal shall be \$337 for licensure in medicine, osteopathic medicine, and podiatry and \$312 for licensure in chiropractic, due in each even-numbered year in the licensee's birth month. An additional fee for processing a late renewal application within one renewal cycle shall be \$115 for licensure in medicine, osteopathic medicine, and podiatry and \$105 for licensure in chiropractic. For renewal of licensure in ~~2016~~ 2018, the fee shall be \$270 for licensure in medicine, osteopathic medicine, and podiatry and \$250 for licensure in chiropractic.

I. The fee for requesting reinstatement of licensure or certification pursuant to § 54.1-2408.2 of the Code of Virginia or for requesting reinstatement after any petition to reinstate the certificate or license of any person has been denied shall be \$2,000.

J. The fee for reinstatement of a license issued by the Board of Medicine pursuant to § 54.1-2904 of the Code of Virginia that has expired for a period of two years or more shall be \$497 for licensure in medicine, osteopathic medicine, and podiatry (\$382 for reinstatement application in addition to the late fee of \$115) and \$472 for licensure in chiropractic (\$367 for reinstatement application in addition to the late fee of \$105). The fee shall be submitted with an application for licensure reinstatement.

K. The fee for a letter of verification of licensure shall be \$10, and the fee for certification of grades to another jurisdiction by the board shall be \$25. ~~Fees shall be due and payable upon submitting a request for verification or certification to the board.~~

L. The fee for biennial renewal of an inactive license shall be \$168, due in the licensee's birth month. An additional fee for late renewal of licensure shall be \$55 for each renewal cycle. ~~For renewal of an inactive license in 2016, the fee shall be \$135.~~

M. The fee for an application or for the biennial renewal of a restricted volunteer license shall be \$75, due in the licensee's birth month. An additional fee for late renewal of licensure shall be \$25 for each renewal cycle. For renewal of a restricted volunteer license in 2016, the fee shall be \$65.

N. The fee for a returned check shall be \$35.

18VAC85-40-35. Fees.

The following fees are required:

1. The application fee, payable at the time the application is filed, shall be \$130.
2. The biennial fee for renewal of active licensure shall be \$135 and for renewal of inactive licensure shall be \$70, payable in each odd-numbered year in the license holder's birth month. For ~~2017~~ 2019, the fee for renewal of an

active license shall be \$108, and the fee for renewal of an inactive license shall be \$54.

3. The additional fee for late renewal of licensure within one renewal cycle shall be \$50.

4. The fee for reinstatement of a license issued by the Board of Medicine pursuant to § 54.1-2904 of the Code of Virginia, which has lapsed for a period of two years or more, shall be \$180 and must be submitted with an application for licensure reinstatement.

5. The fee for reinstatement of a license pursuant to § 54.1-2408.2 of the Code of Virginia shall be \$2,000.

6. The fee for a duplicate license shall be \$5.00, and the fee for a duplicate wall certificate shall be \$15.

7. The fee for a returned check shall be \$35.

8. The fee for a letter of good ~~standing/verification~~ standing or verification to another jurisdiction shall be \$10; the fee for certification of grades to another jurisdiction shall be \$25.

9. The fee for an application or for the biennial renewal of a restricted volunteer license shall be \$35, due in the licensee's birth month. An additional fee for late renewal of licensure shall be \$15 for each renewal cycle.

18VAC85-50-35. Fees.

Unless otherwise provided, the following fees shall not be refundable:

1. The initial application fee for a license, payable at the time application is filed, shall be \$130.

2. The biennial fee for renewal of an active license shall be \$135 and for renewal of an inactive license shall be \$70, payable in each odd-numbered year in the birth month of the licensee. For ~~2017~~ 2019, the fee for renewal of an active license shall be \$108, and the fee for renewal of an inactive license shall be \$54.

3. The additional fee for late renewal of licensure within one renewal cycle shall be \$50.

4. A restricted volunteer license shall expire 12 months from the date of issuance and may be renewed without charge by receipt of a renewal application that verifies that the physician assistant continues to comply with provisions of § 54.1-2951.3 of the Code of Virginia.

5. The fee for review and approval of a new protocol submitted following initial licensure shall be \$15.

6. The fee for reinstatement of a license pursuant to § 54.1-2408.2 of the Code of Virginia shall be \$2,000.

7. The fee for a duplicate license shall be \$5.00, and the fee for a duplicate wall certificate shall be \$15.

8. The fee for a returned check shall be \$35.

9. The fee for a letter of good ~~standing/verification~~ standing or verification to another jurisdiction shall be \$10.

10. The fee for an application or for the biennial renewal of a restricted volunteer license shall be \$35, due in the licensee's birth month. An additional fee for late renewal of licensure shall be \$15 for each renewal cycle.

18VAC85-80-26. Fees.

A. The following fees have been established by the board:

1. The initial fee for the occupational therapist license shall be \$130; for the occupational therapy assistant, it shall be \$70.

2. The fee for reinstatement of the occupational therapist license that has been lapsed for two years or more shall be \$180; for the occupational therapy assistant, it shall be \$90.

3. The fee for active license renewal for an occupational therapist shall be \$135; for an occupational therapy assistant, it shall be \$70. The fees for inactive license renewal shall be \$70 for an occupational therapist and \$35 for an occupational therapy assistant. Renewals shall be due in the birth month of the licensee in each even-numbered year. For ~~2016~~ 2018, the fee for renewal of an active license as an occupational therapist shall be \$108; for an occupational therapy assistant, it shall be \$54. For renewal of an inactive license in ~~2016~~ 2018, the fees shall be \$54 for an occupational therapist and \$28 for an occupational therapy assistant.

4. The additional fee for processing a late renewal application within one renewal cycle shall be \$50 for an occupational therapist and \$30 for an occupational therapy assistant.

5. The fee for a letter of good standing or verification to another ~~state~~ jurisdiction for a license shall be \$10.

6. The fee for reinstatement of licensure pursuant to § 54.1-2408.2 of the Code of Virginia shall be \$2,000.

7. The fee for a returned check shall be \$35.

8. The fee for a duplicate license shall be \$5.00, and the fee for a duplicate wall certificate shall be \$15.

9. The fee for an application or for the biennial renewal of a restricted volunteer license shall be \$35, due in the licensee's birth month. An additional fee for late renewal of licensure shall be \$15 for each renewal cycle.

B. Unless otherwise provided, fees established by the board shall not be refundable.

18VAC85-101-25. Fees.

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Initial licensure fees.

1. The application fee for radiologic technologist or radiologist assistant licensure shall be \$130.

2. The application fee for the radiologic technologist-limited licensure shall be \$90.

3. All examination fees shall be determined by and made payable as designated by the board.

C. Licensure renewal and reinstatement for a radiologic technologist or a radiologist assistant.

1. The fee for active license renewal for a radiologic technologist shall be \$135, and the fee for inactive license renewal shall be \$70. For ~~2017~~ 2019, the fees for renewal shall be \$108 for an active license as a radiologic technologist and \$54 for an inactive license. If a radiologist assistant holds a current license as a radiologic technologist, the renewal fee shall be \$50. If a radiologist assistant does not hold a current license as a radiologic technologist, the renewal fee shall be \$150. For renewal of a radiologist assistant license in ~~2017~~ 2019, the fee shall be \$40 for a radiologist assistant with a current license as a radiologic technologist and \$120 for a radiologist assistant without a current license as a radiologic technologist.

2. An additional fee of \$50 to cover administrative costs for processing a late renewal application within one renewal cycle shall be imposed by the board.

3. The fee for reinstatement of a radiologic technologist or a radiologist assistant license that has lapsed for a period of two years or more shall be \$180 and shall be submitted with an application for licensure reinstatement.

4. The fee for reinstatement of a license pursuant to § 54.1-2408.2 of the Code of Virginia shall be \$2,000.

D. Licensure renewal and reinstatement for a radiologic technologist-limited.

1. The fee for active license renewal shall be \$70, and the fee for inactive license renewal shall be \$35. For ~~2017~~ 2019, the fees for renewal shall be \$54 for an active license as a radiologic technologist and \$28 for an inactive license.

2. An additional fee of \$25 to cover administrative costs for processing a late renewal application within one renewal cycle shall be imposed by the board.

3. The fee for reinstatement of a license that has lapsed for a period of two years or more shall be \$120 and shall be submitted with an application for licensure reinstatement.

4. The fee for reinstatement of a license pursuant to § 54.1-2408.2 of the Code of Virginia shall be \$2,000.

Regulations

E. Other fees.

1. The application fee for a traineeship as a radiologic technologist or a radiologic technologist-limited shall be \$25.
2. The fee for a letter of good standing or verification to another state for licensure shall be \$10; the fee for certification of scores to another jurisdiction shall be \$25.
3. The fee for a returned check shall be \$35.
4. The fee for a duplicate license shall be \$5.00, and the fee for a duplicate wall certificate shall be \$15.

18VAC85-110-35. Fees.

Unless otherwise provided, the following fees shall not be refundable:

1. The application fee for a license to practice as an acupuncturist shall be \$130.
2. The fee for biennial active license renewal shall be \$135; the fee for biennial inactive license renewal shall be \$70. For ~~2017~~ 2019, the fee for renewal of an active license shall be \$108, and the fee for renewal of an inactive license shall be \$54.
3. The additional fee for processing a late renewal within one renewal cycle shall be \$50.
4. The fee for reinstatement of a license which has expired for two or more years shall be \$180.
5. The fee for a letter of good ~~standing/verification~~ standing or verification of a license to another jurisdiction shall be \$10.
6. The fee for reinstatement of a license pursuant to § 54.1-2408.2 of the Code of Virginia shall be \$2,000.
7. The fee for a duplicate wall certificate shall be \$15.
8. The fee for a duplicate renewal license shall be \$5.00.
9. The fee for a returned check shall be \$35.
10. The fee for an application or for the biennial renewal of a restricted volunteer license shall be \$35, due in the licensee's birth month. An additional fee for late renewal of licensure shall be \$15 for each renewal cycle.

18VAC85-120-35. Fees.

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. The following fees have been adopted by the board:

1. The application fee shall be \$130.
2. The fee for renewal of licensure shall be \$135 and shall be due in the licensee's birth month, in each odd-numbered year.

3. A fee of \$50 for processing a late renewal within one renewal cycle shall be paid in addition to the renewal fee.
4. The fee for reinstatement of a license that has expired for two or more years shall be \$180 and shall be submitted with an application for reinstatement.
5. The fee for reinstatement of a license pursuant to § 54.1-2408.2 of the Code of Virginia shall be \$2,000.
6. The fee for a duplicate renewal license shall be \$5.00, and the fee for a duplicate wall certificate shall be \$15.
7. The fee for a returned check shall be \$35.
8. The fee for a letter of verification to another jurisdiction shall be \$10.
9. The fee for an inactive license shall be \$70, and the fee for a late renewal shall be \$25.
10. For ~~2017~~ 2019, the fee for renewal of an active license shall be \$108, and the fee for renewal of an inactive license shall be \$54.

18VAC85-130-30. Fees.

Unless otherwise provided, the following fees shall not be refundable:

1. The application fee for a license to practice as a midwife shall be \$277.
2. The fee for biennial active license renewal shall be \$312; the additional fee for late renewal of an active license within one renewal cycle shall be \$105.
3. The fee for biennial inactive license renewal shall be \$168; the additional fee for late renewal of an inactive license within one renewal cycle shall be \$55.
4. The fee for reinstatement of a license that has expired for a period of two years or more shall be \$367 in addition to the late fee. The fee shall be submitted with an application for licensure reinstatement.
5. The fee for a letter of good ~~standing/verification~~ standing or verification of a license to another jurisdiction shall be \$10.
6. The fee for an application for reinstatement if a license has been revoked or if an application for reinstatement has been previously denied shall be \$2,000.
7. The fee for a duplicate wall certificate shall be \$15.
8. The fee for a duplicate renewal license shall be \$5.00.
9. The fee for a returned check shall be \$35.
10. For ~~2017~~ 2019, the fee for renewal of an active license shall be \$250, and the fee for renewal of an inactive license shall be \$125.

18VAC85-140-40. Fees.

The following fees are required:

1. The application fee, payable at the time the application is filed, shall be \$130.
2. The biennial fee for renewal of active licensure shall be \$135 and for renewal of inactive licensure shall be \$70, payable in each odd-numbered year in the license holder's birth month. For ~~2017~~ 2019, the renewal fee for an active license shall be \$108, and the renewal fee for an inactive license shall be \$54.
3. The additional fee for late renewal of licensure within one renewal cycle shall be \$50.
4. The fee for reinstatement of a license that has lapsed for a period of two years or more shall be \$180 and must be submitted with an application for licensure reinstatement.
5. The fee for reinstatement of a license pursuant to § 54.1-2408.2 of the Code of Virginia shall be \$2,000.
6. The fee for a duplicate license shall be \$5.00, and the fee for a duplicate wall certificate shall be \$15.
7. The fee for a returned check shall be \$35.
8. The fee for a letter of good standing or verification to another jurisdiction shall be \$10.

18VAC85-150-40. Fees.

A. The following fees have been established by the board:

1. The initial fee for the behavior analyst license shall be \$130; for the assistant behavior analyst license, it shall be \$70.
2. The fee for reinstatement of the behavior analyst license that has been lapsed for two years or more shall be \$180; for the assistant behavior analyst license, it shall be \$90.
3. The fee for active license renewal for a behavior analyst shall be \$135; for an assistant behavior analyst, it shall be \$70. The fees for inactive license renewal shall be \$70 for a behavior analyst and \$35 for an assistant behavior analyst. Renewals shall be due in the birth month of the licensee in each odd-numbered year. For ~~2017~~ 2019, the renewal of an active license as a behavior analyst shall be \$108, and the renewal fee for an inactive license shall be \$54; the renewal fee for an active license as an assistant behavior analyst shall be \$54, and the renewal fee for an inactive license shall be \$28.
4. The additional fee for processing a late renewal application within one renewal cycle shall be \$50 for a behavior analyst and \$30 for an assistant behavior analyst.
5. The fee for a letter of good standing or verification to another ~~state~~ jurisdiction for a license shall be \$10.

6. The fee for reinstatement of licensure pursuant to § 54.1-2408.2 of the Code of Virginia shall be \$2,000.

7. The fee for a returned check shall be \$35.

8. The fee for a duplicate license shall be \$5.00, and the fee for a duplicate wall certificate shall be \$15.

B. Unless otherwise provided, fees established by the board shall not be refundable.

18VAC85-160-40. Fees.

A. The following fees have been established by the board:

1. The fee for registration as a surgical assistant or surgical technologist shall be \$75.

2. The fee for renewal of registration shall be \$70. Renewals shall be due in the birth month of the registrant in each even-numbered year. For ~~2016~~ 2018, the renewal fee shall be \$54.

3. The additional fee for processing a late renewal application within one renewal cycle shall be \$25.

4. The fee for a returned check shall be \$35.

B. Unless otherwise provided, fees established by the board are not refundable.

18VAC85-170-40. Fees.

The following fees are required:

1. The application fee for licensure, payable at the time the application is filed, shall be \$130.

2. The application fee for a temporary license, payable at the time the application is filed, shall be \$50.

3. The biennial fee for renewal of active licensure shall be \$135 and for renewal of inactive licensure shall be \$70, payable in each odd-numbered year in the license holder's birth month. For 2019, the renewal fee for an active license shall be \$108, and the renewal fee for an inactive license shall be \$54.

4. The additional fee for late renewal of licensure within one renewal cycle shall be \$50.

5. The fee for reinstatement of a license that has lapsed for a period of two years or more shall be \$180 and shall be submitted with an application for licensure reinstatement.

6. The fee for reinstatement of a license pursuant to § 54.1-2408.2 of the Code of Virginia shall be \$2,000.

7. The fee for a duplicate license shall be ~~\$5~~ \$5.00, and the fee for a duplicate wall certificate shall be \$15.

8. The fee for a returned check shall be \$35.

9. The fee for a letter of good standing or letter of verification to another jurisdiction shall be \$10.

VA.R. Doc. No. R18-5319; Filed October 31, 2017, 8:58 a.m.

Regulations

Proposed Regulation

Title of Regulation: 18VAC85-21. Regulations Governing Prescribing of Opioids and Buprenorphine (adding 18VAC85-21-10 through 18VAC85-21-170).

Statutory Authority: §§ 54.1-2400 and 54.1-2928.2 of the Code of Virginia.

Public Hearing Information:

December 1, 2017 - 8:35 a.m. - Perimeter Center, 9960 Mayland Drive, Suite 201, Richmond, VA 23233

Public Comment Deadline: January 26, 2018.

Agency Contact: William L. Harp, M.D., Executive Director, Board of Medicine, 9960 Mayland Drive, Suite 300, Richmond, VA 23233, telephone (804) 367-4558, FAX (804) 527-4429, or email william.harp@dhp.virginia.gov.

Basis: Section 54.1-2400 of the Code of Virginia provides the Board of Medicine the authority to promulgate regulations to administer the regulatory system. In addition, the board is mandated to adopt regulations pursuant to § 54.1-2928.2 of the Code of Virginia, which was enacted in the 2017 Session of the General Assembly.

Purpose: The purpose of the regulatory action is the establishment of requirements for prescribing of controlled substances containing opioids or buprenorphine to address the overdose and addiction crisis in the Commonwealth. Reducing the quantity of opioids in the Commonwealth's homes and communities has already been shown to have a cost benefit and will ultimately have a direct public health, safety, and welfare benefit in a reduction in opioid misuse and opioid overdose deaths. The goal is to provide prescribers with definitive rules to follow so that they may feel more assured of their ability to treat pain in an appropriate manner to avoid under-prescribing or over-prescribing and thereby protect the public health.

Substance: The regulations establish the practitioners to whom the rules apply and the exceptions or non-applicability. Regulations for the management of acute pain include requirements for the evaluation of the patient, limitations on quantity and dosage, and medical recordkeeping. Regulations for management of chronic pain include requirements for evaluation and treatment, including a treatment plan, informed consent and agreement, consultation with other providers, and medical recordkeeping. Regulations for prescribing of buprenorphine include requirements for patient assessment and treatment planning, limitations on prescribing the buprenorphine mono-product (without naloxone), dosages, co-prescribing of other drugs, consultation, and medical records for opioid addiction treatment.

Issues: The primary advantage to the public is a reduction in the amount of opioid medication that is available in Virginia communities. A limitation on the quantity of opioids that may be prescribed should result in fewer people becoming

addicted to pain medication, which sometimes leads them to turn to heroin and other illicit drugs. Persons who are receiving opioids for chronic pain should be more closely monitored to ensure that the prescribing is appropriate and necessary. A limitation on prescribing the buprenorphine mono-product should result in a reduction in the number of tablets that are sold on the street. The primary disadvantage to the public may be that more explicit rules for prescribing may result in some physicians choosing not to manage chronic pain patients in their practice.

The primary advantage to the Commonwealth is the potential reduction in the number of persons addicted to opioids and deaths from overdoses. There are no disadvantages.

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. Pursuant to Chapters 291¹ and 682² of the 2017 Acts of Assembly, the Board of Medicine (Board) proposes a permanent regulation for the prescription of opioids in the management of acute and chronic pain. This proposed regulation also sets rules for the use of buprenorphine in treating pain and, separately, as part of addiction treatment.

Prior to this, the Board promulgated an emergency regulation that became effective on March 15, 2017, followed by an amended emergency regulation that became effective on August 24, 2017. The emergency regulation is currently set to expire on September 14, 2018.

Result of Analysis. There is insufficient data to accurately compare the magnitude of the benefits versus the costs.

Estimated Economic Impact. The Board reports that this regulation is being proposed to "address the opioid abuse crisis in Virginia." Prior to the legislation enacted by the 2017 General Assembly, no regulations existed for opioid treatment of acute or chronic pain. In March 2017, Chapters 291 and 682 of the Acts of the Assembly became law. Acute and chronic pain are defined in the proposed regulation as follows:

- Acute pain, is "pain that occurs within the normal course of a disease or condition or as the result of surgery for which controlled substances may be prescribed for no more than three months."
- Chronic pain, is "nonmalignant pain that goes beyond the normal course of a disease or condition for which controlled substances may be prescribed for a period of greater than three months."

Each Chapter requires the Board of Medicine to promulgate regulations for prescription of opioids. For the treatment of acute pain, these Chapters require that the Board's regulation include:

(i) requirements for an appropriate patient history and evaluation, (ii) limitations on dosages or day supply of drugs prescribed, (iii) requirements for appropriate documentation in the patient's health record, and (iv) a requirement that the prescriber request and review information contained in the Prescription Monitoring Program in accordance with § 54.1-2522.1.

For the treatment of chronic pain, the Chapters require the regulations to include the requirements listed above for acute pain treatment, as well as requirements for:

(i) development of a treatment plan for the patient, (ii) an agreement for treatment signed by the provider and the patient that includes permission to obtain urine drug screens [UDS], and (iii) periodic review of the treatment provided at specific intervals to determine the continued appropriateness of such treatment.

Chapters 291 and 682 also require that the Board's regulations include rules for:

the use of buprenorphine in the treatment of addiction, including a requirement for referral to or consultation with a provider of substance abuse counseling in conjunction with treatment of opioid dependency with products containing buprenorphine.

This proposed regulation will apply to all doctors and physician assistants. However, it will not apply to: (1) the treatment of acute and chronic pain related to cancer or to such pain treatment for patients in hospice care or palliative care, (2) the treatment of acute and chronic pain during a hospital admission, or in nursing homes or assisted living facilities that use a sole source pharmacy or (3) a patient enrolled in a clinical trial authorized by state or federal law.

Requirements in the Proposed Regulation

Requirements for Acute Pain Treatment. For the treatment of acute pain, the Board proposes to require that the doctor or physician assistant: (1) take a patient history, (2) perform a physical examination appropriate for the complaint, and (3) assess the patient's history and risk of substance misuse. The Board also proposes to limit opioid prescriptions for all non-surgical acute care to a seven-day supply unless extenuating circumstances are clearly documented. For opioids prescribed as a part of a surgical procedure, the Board proposes to limit such prescriptions to a 14 day supply within the perioperative period³ unless extenuating circumstances are documented. The Board also proposes to set record-keeping requirements for acute pain to include a description of the pain, a presumptive diagnosis, a treatment plan, and information on medication prescribed or administered.

Requirements for both Acute and Chronic Pain Treatment. In treating acute or chronic pain, the Board proposes four requirements. First, practitioners will be required to consider nonpharmacologic⁴ and non-opioid treatments⁵ prior to

treatment with opioids." Second, practitioners will be required to query the state's Prescription Monitoring Program (PMP). For acute pain treatment, this will occur before prescribing an opioid; for chronic pain, this will occur prior to beginning treatment and at least every three months thereafter. Third, the Board proposes to require that, "practitioners shall carefully consider and document in the medical record the reasons to exceed 50 MME/day"⁶ if they prescribe opioids in excess of that daily dosage, and to require that, "prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist." Fourth, practitioners will be required to prescribe naloxone⁷ "when risk factors of prior overdose, substance misuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present." Practitioners also will be required to limit co-prescribing of drugs that may increase the risk of accidental overdose when taken with opioids.

Requirements Solely for the Treatment of Chronic Pain. For treatment of chronic pain, the Board proposes to specify medical record-keeping requirements. The Board also proposes to require signed patient agreements and urine or serum drug testing "at the initiation of chronic pain management and at least every three months for the first year of treatment and at least every six months thereafter." Practitioners also will be required to regularly evaluate patients for opioid use disorder and to initiate treatment for opioid use disorder or to refer the patient for evaluation and treatment if opioid use disorder is diagnosed.

Requirements for Treatment with Buprenorphine. The Board proposes four requirements for the prescribing of buprenorphine. First, the Board proposes to specify that buprenorphine is not to be used to treat acute pain in an outpatient setting except when a prescriber obtains a Substance Abuse and Mental Health Services Administration waiver and is treating pain in a patient whose primary diagnosis is the disease of addiction. Second, the Board proposes to ban the use of buprenorphine mono-product⁸ in pill form for treating chronic pain. Third, the Board proposes to ban the use of the mono-product to treat addiction except: (1) for pregnant women, (2) when converting a patient from methadone or the mono-product to buprenorphine containing naloxone (limit of seven days), (3) in formulations other than tablet form for indications approved by the FDA, and (4) for up to three percent of any prescribers' addiction patients who have a demonstrated intolerance to naloxone. Fourth, the proposed regulation would also limit dosages of buprenorphine and the co-prescribing of certain other drugs with buprenorphine, as well as require PMP queries for addiction patients.

Benefits and Costs of the Proposed Regulation. The requirements in the proposed regulation appear to confer a mix of benefits and costs, including those resulting from the mandatory use of drug testing, restrictions on the use of

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buprenorphine, preferences for non-opioid treatments, and use of the PMP. Except for the estimated costs directly resulting from mandatory drug testing, there is insufficient quantitative data to accurately determine, and thus compare, the magnitude of direct benefits versus direct costs. In part this is because the scope and range of potential impacts (cost and benefit) cannot be readily identified. To the extent that the proposed regulation reduces the rate of prescription substance misuse, including drug addiction, savings or cost avoidance could be achieved from reduction in expenditures on the treatment of, and consequences from, substance misuse.⁹ However, to the extent that the regulations create a disincentive to obtaining, or limit access to, opioid therapy, any savings or cost avoidance may be offset by direct and indirect costs resulting from untreated pain¹⁰ or a shift to illicit drugs.¹¹

Direct Benefits and Costs of Drug Testing. Drug testing, typically through a urine drug screen (UDS) appears to confer direct benefits on all patients, although it is likely that a subset will receive higher benefits. As noted in the literature,

Pain management is a critical element of patient care. Over the last 2 decades the emphasis on managing pain has led to a substantial increase in the prescription of opioids. While opioids can significantly improve the quality of life for the patients, there are many concerns.... Therefore, monitoring adherence for patients on (or considered candidates for) opioid treatment is a critical element of pain management.... Of the various tools, UDS is perhaps the most effective in detecting non-adherence, and is viewed as the de facto monitoring tool.¹²

There are two main types of UDS: immunoassay testing ("dipstick") and chromatography (i.e., gas chromatography/mass spectrometry [GC/MS] or high-performance liquid chromatography). Both types of UDS can assist practitioners in creating initial treatment plans and also indicate when adjustments are required throughout the course of treatment. In addition, testing can be used to monitor drug elimination rates and ensure that a steady state of the prescribed drug has been achieved. Furthermore, non-prescribed drugs can be identified and appropriate actions taken, including referral for substance use disorder. Monitoring urine toxicology also can help practitioners comply with federal Drug Enforcement Agency requirements, which require practitioners to minimize abuse and diversion.¹³ However, quantitative data on the value of these benefits does not appear to be readily available. Moreover, full realization of the benefits of UDS may require both types of test: an initial immunoassay test in a practitioner's office followed by a confirmatory GC/MS test in a laboratory.

In order to quantify the costs of drug testing, the number of patients who will likely be affected by urine testing requirements must be estimated. The Board did not provide estimates of the number of patients affected, so estimates

from relevant literature on the prevalence of chronic pain were considered. Estimates of the percentage of the population affected by acute pain do not appear to be readily available.

Using information taken from the 2012 National Health Interview Survey (NHIS), National Institutes of Health staff estimated that 11.2 percent of the adult population experiences chronic pain—that is, they had pain every day for the preceding three months.¹⁴ In Virginia, using 2016 Census Bureau data on population by age, this equates to 732,669 adults. On the high end, the Institutes of Medicine (IOM) report that common chronic pain conditions are prevalent among 37 percent of adults, "amounting to approximately 116 million adults in 2010—a conservative estimate as neither acute pain nor children are included."¹⁵ This equates to approximately 2.4 million adult Virginians.

Although these two estimates may indicate the extent of chronic pain among adults, they may not indicate the extent to which persons with chronic pain seek opioid therapy. A low-end estimate is supported by at least one study (Boudreau, et al, 2009),¹⁶ that indicates that 3 to 4 percent of the adult population were prescribed longer-term opioid therapy.¹⁷ (Note: to the extent that opioid prescription rates have increased since this study was conducted, this estimate would be too low.)

These three estimates will be used to estimate the potential number of adults in Virginia who could be affected by the proposed regulation (Table 1). Using these population estimates, and the Board's estimate that the average cost of an initial "dipstick" UDS is \$50, direct costs of the new requirements for the initial UDS would likely be between \$12 million and \$141 million for the initial screen, assuming all persons with chronic pain seek opioid therapy. Subsequently, the annual cost for four quarters of drug tests would be between \$57 million and \$605 million, assuming all persons with chronic pain seek and continue to receive opioid therapy for a full year. To the extent these assumptions are not borne out, the cost would decrease. After the first year, these costs would decrease as patients shift from quarterly to biannual testing.

Potential Ranges of Persons with Chronic Pain	Estimated Number of Adult Virginians with Chronic Pain	Cost of Initial Test *	Additional Cost of All First Year Quarterly Tests *
Boudreau et al (3.5%)	228,959	\$12 million	\$57 million

NHIS estimate (11.2%)	732,669	\$37 million	\$183 million
IOM estimate (37%)	2,420,423	\$121 million	\$605 million
* Assumes 100 percent of all persons with chronic pain within each of the three estimates are treated with opioids.			

These estimated costs may potentially increase to the extent that testing is repeated because practitioners account for the possibility of unexpected drug screen results, such as false positive and false negative results in the immunoassay or "dipstick" test typically used in a practitioner's office.¹⁸ A false positive result occurs when the test result is "positive" but the indicated substance is not actually present. A false negative occurs when the test fails to indicate the presence of substances that are actually present. These and other unexpected results that could prompt re-testing could occur for a variety of reasons, including failure to take the prescribed medication, testing error, metabolic differences, and drug interactions. Brahm et al. notes that false positive opiate results have been reported for certain antibiotics (quinolones and ofloxacin).¹⁹ Although re-testing is recommended, it may have unintended consequences:

the use of medications with the potential for false-positive UDS results may present a significant liability for individuals required to undergo random or periodic UDSs as a component of a recovery or court-ordered monitoring program or as a condition of employment. In addition, false-positive UDS results may affect the clinician-patient relationship by raising issues of trust.²⁰

As noted in the literature, "the interpretation of opioid testing results is far less straightforward than many health care providers who utilize this testing appreciate."²¹ There are two main types of urine drug screening: immunoassay testing and chromatography (i.e., gas chromatography/mass spectrometry [GC/MS] or high-performance liquid chromatography). Immunoassay tests use antibodies to detect the presence of drugs. These tests can be processed rapidly, are inexpensive, and are the preferred initial test for screening.²² When urine tests have unexpected results, the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain recommends²³ that a, "confirmatory test using a method selective enough to differentiate specific opioids and metabolites (e.g., gas or liquid chromatography/mass spectrometry) might be warranted."²⁴ Although these tests can cost several hundred dollars or more, they are the forensic criterion standard means of confirming initial screening tests because they have a low incidence of false positive results and are very sensitive and specific.²⁵ Board staff referred to the CDC Guideline, and also stated that the treatment agreement signed by the patient

would indicate the actions to be taken if unexpected results cannot be explained.

Indirect Benefits and Costs of Drug Testing. The use of drug screens appears to have a mix of benefits and costs. As noted by the CDC Guideline, practitioners should use unexpected results to improve patient safety. This could include several strategies that, if properly designed and applied, would appear to confer this benefit. Examples of responses to an unexpected drug screen result include a change in pain management strategy, tapering or discontinuing opioids, more frequent re-evaluation, offering naloxone, or referring for treatment for substance use disorder. The CDC notes that practitioners:

should not dismiss patients from care based on a urine drug test result because this could constitute patient abandonment and could have adverse consequences for patient safety, potentially including the patient obtaining opioids from alternative sources and the clinician missing opportunities to facilitate treatment for substance use disorder.

Board staff appear to agree with this guidance, adding that a patient could also be released from care if they do not comply with the treatment plan.²⁶ The Board has also stated that patients should not be abandoned. As noted in a letter from the Board to practitioners:

As you consider these regulations, make sure that the needs of patients currently receiving opioids for chronic pain are taken into account. It is critically important that no patients in Virginia find themselves looking for narcotics outside of the medical system – i.e., on the street.²⁷

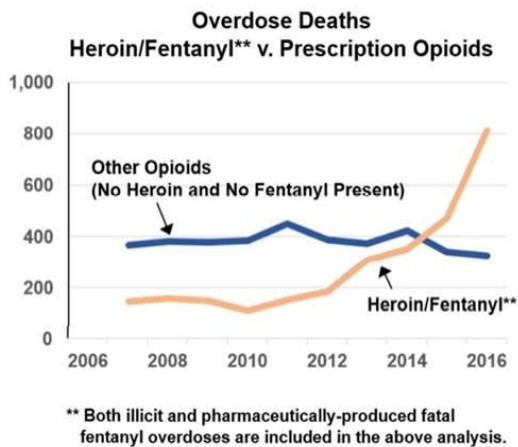
However, as documented in some of the available literature, the use of drug screens may create a disincentive for certain patients to continue seeking treatment and thus may stop pursuing opioid therapy.²⁸ Moreover, Board staff also acknowledge that the drug testing and other requirements in the proposed regulation will create disincentives for primary care physicians to treat pain using opioid therapy. And given that the Board has stated that the regulation is, in part, designed to "provide the board with a tool to discipline physicians whose practices do not meet the standard of care,"²⁹ the regulation may cause some primary care physicians to no longer treat chronic pain patients with opioids.

In addition, examples of some recent literature notes that, "individuals who lost access [to prescription opioids] have turned to cheaper, more accessible, and more potent black market opioid alternatives—including heroin—in unprecedented numbers."³⁰ Thus an additional unintended consequence of the regulations may be a shift in demand from legal prescriptions to illegal street drugs, including heroin and fentanyl (in combination or separately). As noted in a recent

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issue of the International Journal of Drug Policy, "prescribing restrictions forced a minority of dependent users to more potent and available street heroin."³¹ The federal Drug Enforcement Administration notes that "fentanyl can serve as substitute for heroin in opioid dependent individuals."³²

As noted by the Board, "the purpose of the regulations" is in part "to assist physicians in treating opioid dependent patients."³³ However, to the extent that some patients, particularly those with substance use disorder, no longer obtain treatment, they may seek illicit substances. It is not clear if this is occurring in Virginia, but data released by the Office of the Chief Medical Examiner (OCME) indicate that "there has not been a significant increase or decrease in fatal prescription opioid overdoses" from 2007 to 2016, but "fatal fentanyl overdoses increased by 176.4% from 2015 to 2016."³⁴ (This trend is illustrated in the figure below.) Although it does not appear that the OCME can determine whether the fentanyl was illicit or pharmaceutically-produced, staff at the Department of Forensic Science (DFS) report that over the last 12 years submissions of prescription fentanyl have averaged between 25 and 27 samples per year. In contrast, data reported by DFS indicate that the number of submissions of illicit fentanyl increased by 1,656 percent from 2013 to 2016.³⁵



Indirect Benefits and Costs of Restrictions on Use of Buprenorphine. The Board's proposed restrictions on the use of buprenorphine are aimed at decreasing the abuse of the mono-product of this drug ("Subutex") because it has become a popular drug of abuse. To the extent the proposed regulation decreases abuse, then a benefit will be conferred. However, any decrease in the abuse of this drug attributable to these proposed restrictions would need to be weighed against the costs that may accrue for chronic pain patients and individuals in addiction treatment.

Board staff reports that the cost of Suboxone (which contains buprenorphine plus naloxone) is higher than the cost of Subutex. To the extent, therefore, that certain patients are no longer able to obtain prescriptions for Subutex, then they will

likely incur increased costs. As noted by Board staff, demand for opiates is highest in the places where health insurance coverage is lowest. Therefore, these cost increases may disproportionately fall upon patients who pay for prescriptions (and drug screens) out of pocket. Additionally, it is reported that some portion of the general population has an allergy or sensitivity to naloxone and would not be able to take Suboxone.

In response to concerns raised about restrictions on prescription of the mono-product that did not account for individuals who had an allergy or sensitivity, as well as the ability to pay, the Board voted to allow treatment with the mono-product for up to three percent of any prescribers' addiction patients who have a demonstrated intolerance to naloxone. This allowance was made for individuals in addiction treatment but not for chronic pain patients (who presumably would have the same incidence of Naloxone allergies). The Board believes that this three percent allowance will be sufficient to cover the portion of addiction patients who have a true allergy/insensitivity. These individuals are not likely, however, to be evenly spread among all doctors. This means that some doctors may have more than three percent of their patients for whom the mono-product would be the preferred treatment and some may have less. Because of this, some patients and practitioners may see disruptions in treatment.

Indirect Benefits and Costs of Preferences for Alternative Treatments. The proposed regulation's requirements that alternative treatments (both nonpharmacologic and non-opioid) be given consideration prior to prescription of opioids for both acute pain and chronic pain is being proposed to reduce the number of such prescriptions. Board staff state that nonpharmacologic treatments may include physical therapy, chiropractic, and acupuncture.

In addition, non-opioid treatments can include treatment with acetaminophen and nonsteroidal anti-inflammatory drugs (NSAIDs) as well as selected antidepressants and anticonvulsants. Although these drugs do not have the addiction risks of opioids, they may pose other health risks for certain patients. As noted by the CDC Guideline, although NSAIDs are recommended as first-line treatment for osteoarthritis or low back pain they do have risks, including gastrointestinal bleeding or perforation as well as renal and cardiovascular risks. Increasing use of non-opioid treatments like NSAIDs will therefore need to balance the benefits of non-opioid therapy with these and other risks.

Indirect Benefits and Costs of Prescription Monitoring Program (PMP) Queries. Virginia statute presently requires PMP checks for any prescriptions anticipated to be used for more than seven consecutive days. The proposed regulation adds to the statutory requirements, and proposes to require that PMP queries be run for all individuals who are prescribed opioids. Board staff reports that some hospitals already

require PMP queries for prescriptions issued in the emergency rooms (ER). Other hospitals that do not currently have this policy will likely accrue staff time costs. To the extent that use of the PMP lowers the volume of drugs diverted from licit to illicit uses, the new requirement will provide the benefit of reductions in the costs of illicit drug use in the state.

Indirect Benefits and Costs of Record-Keeping Requirements. The Board's proposed record-keeping requirements for acute pain are likely already common medical practice; thus licensees are unlikely to incur any costs from that portion of the proposed regulation that covers the treatment of acute pain. Likewise, most of the proposed requirements for taking a patient history and assessing a patient's complaint are likely common practice now and should not cause any additional costs. The proposed requirement that doctors in an acute care setting perform a risk assessment for substance misuse³⁶ on all patients who may be prescribed opioids may not presently be a part of standard patient care. To the extent that doctors treating acute pain do not currently assess risk of substance misuse, costs would be incurred for their time to perform such assessments.

Businesses and Entities Affected. These proposed regulatory changes will affect all doctors of medicine, osteopathic medicine, and podiatry as well as physician assistants. These proposed regulations also will affect all patients (both acute care and chronic care) who have been treated with opioids since the emergency regulation went into effect, and all patients who may be treated with opioids in the future. Additionally, individuals in treatment for addiction who are prescribed buprenorphine will be affected. Health insurance providers also will be affected. Board staff reports that the Board currently licenses 38,646 doctors of medicine, 3,117 doctors of osteopathic medicine, 616 doctors of podiatry, and 3,647 physician assistants. The Board has no estimates of the number of chronic pain patients that might be affected by this proposed regulation. Based on estimates of the number of the American adults who suffer from common chronic pain conditions, it is likely that this proposed regulation will affect at least hundreds of thousands of chronic care patients in Virginia and may affect as many as several million.

Localities Particularly Affected. No locality likely will be affected by these proposed regulatory changes.

Projected Impact on Employment. There is no apparent impact on employment. To the extent that the regulation reduces rates of addiction, productivity would increase.

Effects on the Use and Value of Private Property. There is no apparent impact on the use and value of private property.

Real Estate Development Costs. These proposed regulatory changes are unlikely to affect real estate development costs in the Commonwealth.

Small Businesses:

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

Costs and Other Effects. Based on Virginia Employment Commission data, there are 4,757 offices of physicians with fewer than 500 employees in the Commonwealth, thus likely qualifying as small businesses. These firms likely will incur increased costs associated with bookkeeping, staff wages, increased documentation requirements, and new drug testing requirements for chronic pain patients in the proposed regulation. Alternatively, adherence to the practices required by the regulation may have an unknown impact on liability insurance and associated costs that may result in savings.

Alternative Method that Minimizes Adverse Impact. There is no apparent alternative method that would minimize impact and achieve the purpose of the regulation.

Adverse Impacts:

Businesses. Doctors who practice independently may incur changes to current business practices related to increased bookkeeping, staff impacts associated with increased documentation requirements, and implementation of new drug testing requirements for chronic pain patients in the proposed regulation.

Localities. Localities in the Commonwealth are unlikely to see any adverse impacts from these proposed regulatory changes.

Other Entities. Chronic pain patients, or their insurance providers, may incur large annual costs on account of drug testing requirements and on account of restrictions on the prescription of buprenorphine mono-product that are in the proposed regulation. The Commonwealth of Virginia may incur increased costs on account of these proposed regulatory changes, including employee health benefits. The Department of Corrections may incur increased costs for drug testing and limitations on prescribing of Buprenorphine for prisoners housed in prisons statewide, and the Department of Medical Assistance Services may incur increased costs for Medicaid patients who are in treatment for chronic pain or who are undergoing addiction treatment with Buprenorphine.

References:

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¹<http://leg1.state.va.us/cgi-bin/legp504.exe?171+ful+CHAP0291>.

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³Perioperative is defined by the Oxford English Dictionary as "a process or treatment occurring or performed at or around the time of an operation."

⁴These treatments can include such things as physical therapy, chiropractic care, and acupuncture.

⁵The Centers for Disease Control and Prevention's Guideline for Prescribing Opioids for Chronic Pain indicates that nonpharmacologic and non-opioid treatments include cognitive behavioral therapy, exercise therapy, interventional treatments, multimodal pain treatment, acetaminophen, nonsteroidal anti-inflammatory drugs, antidepressants, and anticonvulsants.

⁶MME is an abbreviation for morphine milligram equivalent, which provides a standard value for equating the potency of different opioids.

⁷Naloxone, sold under the brand name Narcan among others, is a medication used to block the effects of opioids, especially in overdose.

⁸Buprenorphine comes in two forms: the mono-product form of buprenorphine only contains buprenorphine and is sold under the name Subutex. The other form of buprenorphine also contains naloxone, and is sold under the brand name Suboxone. The mono-product is more subject to abuse, but a certain unknown portion of the population has an allergy/sensitivity to naloxone and therefore would not tolerate Suboxone.

⁹Florence, Curtis S, Chao Zhou, Feijun Luo, Likang Xu. The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013. *Medical Care*, 2016; 54 (10): 901.

¹⁰Institute of Medicine (US) Committee on Advancing Pain Research, Care, and Education. *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research*. Washington (DC): National Academies Press (US); 2011. https://www.ncbi.nlm.nih.gov/books/NBK91497/pdf/Bookshelf_NBK91497.pdf.

¹¹Beletsky, Leo, and Corey Davis; Today's fentanyl crisis: Prohibition's Iron Law, revisited, *International Journal of Drug Policy* 46 (2017) 156–159.

¹²Krishnamurthy et al., Impact of Urine Drug Screening on No Shows and Dropouts among Chronic Pain Patients: A Propensity-Matched Cohort Study. *Pain Physician*. 2016 Feb; 19(2):89-100.

¹³Vadivelu, et. al; The Implications of Urine Drug Testing in Pain Management, *Current Drug Safety* 2010, 5 (267-270).

¹⁴Nahin, Richard; Estimates of Pain Prevalence and Severity in Adults: United States, 2012." *The Journal of Pain: official Journal of the American Pain Society* 16.8 (2015): 769–780. Studies using National Health and Nutrition Examination Survey consistently estimated chronic pain (pain ≥3 months) prevalence at 13 to 15%. (Nahin 2012).

¹⁵Institutes of Medicine 2011 (p. 62).

¹⁶Boudreau, et al., Trends in De-facto Long-term Opioid Therapy for Chronic Non-Cancer Pain, *Pharmacoepidemiol Drug Saf*. 2009 December; 18(12): 1166–1175. Note: the authors state that "Our results may not be generalizable to care delivered and/or financed in other types of health care systems and other regions of the US."

¹⁷Defined as episodes lasting longer than 90 days that had 120+ total days supply of dispensed medication or 10+ opioid prescriptions dispensed within a given year were classified as long-term opioid episodes. Boudreau et al., cited in Volkow and McLellan, Opioid Abuse in Chronic Pain — Misconceptions and Mitigation Strategies, *N Engl J Med* 2016; 374:1253-63.

¹⁸A review of the diagnostic accuracy of urine drug testing found that, in a worst case scenario, 32.9% of patients' specimens to the lab because of abnormal results. (Christo, et al., *Urine Drug Testing In Chronic Pain, Pain Physician* 2011; 14:123-143). Pollack, et al. (2001) reported a false positive rate of 7% for simple urine tests. Vadivelu, et al. reports that 11-21% of initial immunoassay tests are disproven by a followup GC/MS.

¹⁹Brahm, et al.; Commonly prescribed medications and potential false-positive urine drug screens; *Am J Health-Syst Pharm—Vol 67 Aug 15, 2010, 1344-1350*.

²⁰Brahm, et al.

²¹Milone, Michael; Laboratory Testing for Prescription Opioids, *J Med Toxicol*. 2012 Dec; 8(4): 408–416.

²²Standridge et al., Urine Drug Screening: A Valuable Office Procedure, *Am Fam Physician*. 2010 Mar 1; 81(5):635-640.

²³CDC Guideline also only recommends initial drug testing before treatment and that clinicians "consider" drug testing annually thereafter. The CDC reports that this is a type B recommendation based on level 4 evidence. That is, they recommend that clinicians should retain the choice to make individual decisions on this issue because it is based on the lowest quality evidence.

²⁴Unexpected results would include tests that are positive for non-prescribed or illicit drugs, and tests that are negative for expected prescription drugs.

²⁵Addiction Doctor Mary McMasters estimates that GC/MS testing costs between \$200 and \$300. See also Vadivelu, et al.

²⁶In order to not abandon patients, doctors would likely provide referrals to other pain doctors and would give patients a "reasonable" amount of time to

find another doctor. The doctors to whom such patients would be referred are under no obligation to treat them however.

²⁷<https://www.dhp.virginia.gov/medicine/newsletters/OpioidPrescribingBuprenorphine03142017.pdf>.

²⁸Krishnamurthy et al. found that administration of urine drug screens at a first doctor visit was associated with an increased rate of no-shows (23.75%) when compared to patients who did not undergo urine drug screens at a first doctor visit (10.24%). Krishnamurthy et al., "Impact of Urine Drug Screening on No Shows and Dropouts among Chronic Pain Patients: A Propensity-Matched Cohort Study." *Pain Physician*. 2016 Feb; 19(2):89-100.

²⁹http://townhall.virginia.gov/L/GetFile.cfm?File=C:\TownHall\docroot\meeting\26\25243\Minutes_DHP_25243_v2.pdf.

³⁰Beletsky, Leo, and Corey Davis; Today's fentanyl crisis: Prohibition's Iron Law, revisited, *International Journal of Drug Policy* 46 (2017) 156–159.

³¹Rhodes, Tim; Fentanyl in the US heroin supply: A rapidly changing risk environment, *International Journal of Drug Policy* 46 (2017) 107–111.

³²https://departments.arlingtonva.us/wp-content/uploads/sites/6/2017/06/heroin_fentanyl_brochure.pdf.

³³http://townhall.virginia.gov/L/GetFile.cfm?File=C:\TownHall\docroot\meeting\26\25243\Minutes_DHP_25243_v2.pdf.

³⁴http://www.vdh.virginia.gov/content/uploads/sites/18/2016/04/Fatal-Drug-Overdoses-Quarterly-Report-Q1-2017_Updated.pdf.

³⁵http://www.dfs.virginia.gov/wp-content/uploads/2017/07/CY16DfsDataReport_Final.pdf Slide 27.

³⁶The term "substance misuse" is not defined in the proposed regulation.

Agency's Response to Economic Impact Analysis:

The Board of Medicine and the Department of Health Professions do not concur with the result of the economic impact analysis (EIA) that "there is insufficient data to accurately compare the magnitude of the benefits versus the costs." The focus of the analysis was on the cost of one requirement of regulation, urine drug screens. We believe the analysis failed to fully analyze the personal and societal costs of opioid addiction. It is the position of the agency that reducing the quantity of opioids in our homes and communities has already been shown to have a cost-benefit and will ultimately have a direct benefit in a reduction in opioid misuse and opioid overdose deaths.

1. The agency believes the analysis does not include sufficient data about the current crisis in opioid overdose deaths.

In 2015, there were 811 opioid deaths and in 2016, there were 1,133 – a 40% increase. In a preliminary report from the Department of Criminal Justice Services (DCJS), the number for 2017 is expected to be 1,181. The result of the 2017 National Drug Threat Assessment notes that controlled prescription drugs have been linked to the largest number of overdose deaths of any illicit drug class since 2001. For each of these deaths, there are immeasurable costs. For the purpose of an economic analysis, medical malpractice carriers and civil litigants can attribute costs in dollars and cents for each year of life lost.

Yearly direct and indirect costs related to prescription opioids have been estimated (based on studies published since 2010) to be \$53.4 billion for nonmedical use of prescription opioids; \$55.7 billion for abuse, dependence (i.e., opioid use disorder), and misuse of prescription opioids; and \$20.4 billion for direct and indirect costs related to opioid-related overdose alone. While we acknowledge that these are national figures, the EIA has used national data to extrapolate the costs of urine drug screens for Virginians. Copious amounts of data exist in national and state reports on the opioid crisis for which these regulations offer a partial solution.

2. The agency believes the analysis does not make the connection between the opioid crisis of fentanyl and heroin to the prescribing of opioid pain medication.

One of the primary purposes of these regulations is to reduce the number of persons who enter the pipeline of addiction through a legitimately prescribed opioid. The National Institute on Drug Abuse reports that a study of young, urban injection drug users interviewed in 2008 and 2009 found that 86% had used opioid pain relievers nonmedically prior to using heroin, and their initiation into nonmedical use was characterized by three main sources of opioids: family, friends, or personal prescriptions. Examining national-level general population heroin data (including those in and not in treatment), nearly 80% of heroin users reported using prescription opioids prior to heroin.

The report from DCJS noted that "data from Department of Forensic Sciences (DFS) and Office of the Chief Medical Examiner (OCME) demonstrate that there are still a large number of individuals using prescription opioids non-medically. These individuals are at risk of overdose death through the prescription drugs they are currently using, but they are also at a higher risk of using heroin in the future. Although only a small percentage of individuals who abuse prescription opioids move on to heroin, a high percentage of heroin users report that their first opioid was a prescription drug

(<https://www.drugabuse.gov/publications/researchreports/relationship-between-prescription-drug-abuse-heroin-use/>). Additionally, non-medical users of prescription opioids may seek to acquire those drugs illegally, putting themselves at risk of purchasing and using counterfeit pills made with fentanyl and fentanyl analogs."

Data from OCME indicates that between 2013 and 2016, the number of prescription opioid fatalities involving fentanyl and/or heroin increased 69%. In 2016, 37% of prescription opioid fatalities also involved fentanyl and/or heroin. Although illicit fentanyl cases increased 207% between 2015 and 2016, there were almost four times as many heroin cases and four times as many prescription opioid cases that year.

Data from the Virginia Prescription Monitoring Program shows that since the adoption of emergency regulation there has been a drop in morphine milligram equivalents (MME).

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MME per day is the amount of morphine an opioid dose is equal to, often used to gauge the abuse and overdose potential of the amount of opioid being prescribed at a particular time. The Centers for Disease Control and Prevention indicate that individuals taking greater than 90 MME/day are at a higher risk of overdose and death. The total number of patients prescribed high dosages declined from 169,145 individuals in the fourth quarter of 2016 to 137,618 individuals in the third quarter of 2017, or an 18.6% decline in individuals receiving greater than 100 MME/day. The data is an indicator of the effectiveness of the emergency regulation being replaced with the proposed regulations for which the EIA was prepared.

Numerous reports in the press have made the connection between the overdose death of a person who was prescribed on opioid following an accident or medical procedure. The intent of this regulation is to require prescribers to prescribe fewer quantities for shorter periods of time and to consider nonpharmacological alternatives or non-opioid medications that have the effect of addressing a patient's pain without the potential for addiction and long-term, costly consequences.

3. The agency believes the analysis has not included sufficient data on cost savings relating to a reduction on opioid prescribing.

For example, this agency provided information from the Department of Medical Assistance Services, which experienced a 44% decrease in opioid days-supply and 27% decrease in opioid prescription spending when that agency implemented the CDC guidelines on which these regulations were based, for an annual reduction in drug spending on opioids of approximately \$466,000. It is that agency's belief that costs related to an increase in urine drug screens (which have been routinely required by pain management physicians prior to adoption of these regulations) would be more than offset by the decrease in spending on opioid prescriptions, so it would be budget neutral or result in a net cost savings.

Data from the Prescription Monitoring Program (PMP) show that from the fourth quarter of 2016 to the third quarter of 2017 pain reliever doses declined from 129,797,789 to 77,729,833, which represents a 40.15% decline. It is apparent that the emergency regulations are having a positive effect on the costs of prescription opioids – a cost benefit to consumers and insurers that could be reflected in the EIA.

4. There is an incorrect statement in the analysis about one regulatory requirement.

On pages 3 and 12 of the EIA, the analysis notes that the regulation requires prescribers to query the PMP for all individuals before prescribing an opioid. In fact, the regulation states that "the prescriber shall perform a history and physical examination appropriate to the complaint, query the Prescription Monitoring Program as set forth in § 54.1-2522.1 of the Code of Virginia..." Section 54.1-2522.1 requires a prescriber to query "at the time of initiating a new

course of treatment to a human patient that includes the prescribing of opioids anticipated at the onset of treatment to last more than seven consecutive days." While the agency may believe a prescriber should query before prescribing on opioid for any period of time, that is not what the law and regulation require. It is required only if a prescription is being written "to last more than seven consecutive days."

Summary:

The proposed regulatory action adopts requirements for the prescribing of opioids and products containing buprenorphine as required by Chapters 291 and 682 of the 2017 Acts of Assembly. The regulations establish the practitioners to whom the regulations apply and the exceptions to or nonapplicability of the regulations. Regulations for the management of acute pain include requirements for the evaluation of the patient, limitations on quantity and dosage, and medical recordkeeping. Regulations for the management of chronic pain include requirements for evaluation and treatment, including a treatment plan; informed consent and agreement; consultation with other providers; and medical recordkeeping. Regulations for the prescribing of buprenorphine include requirements for patient assessment and treatment planning, limitations on prescribing the buprenorphine mono-product (without naloxone), dosages, co-prescribing of other drugs, consultation, and medical records for opioid addiction treatment. The regulation replaces emergency regulations currently in effect.

CHAPTER 21

REGULATIONS GOVERNING PRESCRIBING OF OPIOIDS AND BUPRENORPHINE

Part I

General Provisions

18VAC85-21-10. Applicability.

A. This chapter shall apply to doctors of medicine, osteopathic medicine, and podiatry and to physician assistants.

B. This chapter shall not apply to:

1. The treatment of acute or chronic pain related to (i) cancer, (ii) a patient in hospice care, or (iii) a patient in palliative care;

2. The treatment of acute or chronic pain during an inpatient hospital admission or in a nursing home or an assisted living facility that uses a sole source pharmacy; or

3. A patient enrolled in a clinical trial as authorized by state or federal law.

18VAC85-21-20. Definitions.

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

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

"Board" means the Virginia Board of Medicine.

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

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

"FDA" means the U.S. Food and Drug Administration.

"MME" means morphine milligram equivalent.

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

"SAMHSA" means the federal Substance Abuse and Mental Health Services Administration.

Part II
Management of Acute Pain

18VAC85-21-30. Evaluation of the acute pain patient.

A. Nonpharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids. If an opioid is considered necessary for the treatment of acute pain, the practitioner shall give a short-acting opioid in the lowest effective dose for the fewest possible days.

B. Prior to initiating treatment with a controlled substance containing an opioid for a complaint of acute pain, the prescriber shall perform a history and physical examination appropriate to the complaint, query the Prescription Monitoring Program as set forth in § 54.1-2522.1 of the Code of Virginia, and conduct an assessment of the patient's history and risk of substance misuse.

18VAC85-21-40. Treatment of acute pain with opioids.

A. Initiation of opioid treatment for patients with acute pain shall be with short-acting opioids.

1. A prescriber providing treatment for acute pain shall not prescribe a controlled substance containing an opioid in a quantity that exceeds a seven-day supply as determined by the manufacturer's directions for use, unless extenuating circumstances are clearly documented in the medical record. This shall also apply to prescriptions of a controlled

substance containing an opioid upon discharge from an emergency department.

2. An opioid prescribed as part of treatment for a surgical procedure shall be for no more than 14 consecutive days in accordance with manufacturer's direction and within the immediate perioperative period, unless extenuating circumstances are clearly documented in the medical record.

B. Initiation of opioid treatment for all patients shall include the following:

1. The practitioner shall carefully consider and document in the medical record the reasons to exceed 50 MME/day.

2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist.

3. Naloxone shall be prescribed for any patient when risk factors of prior overdose, substance misuse, doses in excess of 120 MME/day, or concomitant benzodiazepine are present.

C. Due to a higher risk of fatal overdose when opioids are prescribed with benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses if these medications are prescribed.

D. Buprenorphine is not indicated for acute pain in the outpatient setting, except when a prescriber who has obtained a SAMHSA waiver is treating pain in a patient whose primary diagnosis is the disease of addiction.

18VAC85-21-50. Medical records for acute pain.

The medical record shall include a description of the pain, a presumptive diagnosis for the origin of the pain, an examination appropriate to the complaint, a treatment plan, and the medication prescribed or administered to include the date, type, dosage, and quantity prescribed or administered.

Part III
Management of Chronic Pain

18VAC85-21-60. Evaluation of the chronic pain patient.

A. Prior to initiating management of chronic pain with a controlled substance containing an opioid, a medical history and physical examination, to include a mental status examination, shall be performed and documented in the medical record, including:

1. The nature and intensity of the pain;
2. Current and past treatments for pain;
3. Underlying or coexisting diseases or conditions;

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4. The effect of the pain on physical and psychological function, quality of life, and activities of daily living;

5. Psychiatric, addiction, and substance misuse history of the patient and any family history of addiction or substance misuse;

6. A urine drug screen or serum medication level;

7. A query of the Prescription Monitoring Program as set forth in § 54.1-2522.1 of the Code of Virginia;

8. An assessment of the patient's history and risk of substance misuse; and

9. A request for prior applicable records.

B. Prior to initiating opioid treatment for chronic pain, the practitioner shall discuss with the patient the known risks and benefits of opioid therapy and the responsibilities of the patient during treatment to include securely storing the drug and properly disposing of any unwanted or unused drugs. The practitioner shall also discuss with the patient an exit strategy for the discontinuation of opioids in the event they are not effective.

18VAC85-21-70. Treatment of chronic pain with opioids.

A. Nonpharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids.

B. In initiating and treating with an opioid, the practitioner shall:

1. Carefully consider and document in the medical record the reasons to exceed 50 MME/day;

2. Prior to exceeding 120 MME/day, the practitioner shall document in the medical record the reasonable justification for such doses or refer to or consult with a pain management specialist;

3. Prescribe naloxone for any patient when risk factors of prior overdose, substance misuse, doses in excess of 120 MME/day, or concomitant benzodiazepine are present; and

4. Document the rationale to continue opioid therapy every three months.

C. Buprenorphine mono-product in tablet form shall not be prescribed for chronic pain.

D. Due to a higher risk of fatal overdose when opioids, including buprenorphine, are given with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses of these medications if prescribed.

E. The practitioner (i) shall regularly evaluate the patient for opioid use disorder and (ii) shall initiate specific treatment for

opioid use disorder, consult with an appropriate health care provider, or refer the patient for evaluation and treatment if indicated.

18VAC85-21-80. Treatment plan for chronic pain.

A. The medical record shall include a treatment plan that states measures to be used to determine progress in treatment, including pain relief and improved physical and psychosocial function, quality of life, and daily activities.

B. The treatment plan shall include further diagnostic evaluations and other treatment modalities or rehabilitation that may be necessary depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment.

C. The prescriber shall document in the medical record the presence or absence of any indicators for medication misuse or diversion and shall take appropriate action.

18VAC85-21-90. Informed consent and agreement for treatment for chronic pain.

A. The practitioner shall document in the medical record informed consent, to include risks, benefits, and alternative approaches, prior to the initiation of opioids for chronic pain.

B. There shall be a written treatment agreement signed by the patient in the medical record that addresses the parameters of treatment, including those behaviors that will result in referral to a higher level of care, cessation of treatment, or dismissal from care.

C. The treatment agreement shall include notice that the practitioner will query and receive reports from the Prescription Monitoring Program and permission for the practitioner to:

1. Obtain urine drug screens or serum medication levels when requested; and

2. Consult with other prescribers or dispensing pharmacists for the patient.

D. Expected outcomes shall be documented in the medical record including improvement in pain relief and function or simply in pain relief. Limitations and side effects of chronic opioid therapy shall be documented in the medical record.

18VAC85-21-100. Opioid therapy for chronic pain.

A. The practitioner shall review the course of pain treatment and any new information about the etiology of the pain and the patient's state of health at least every three months.

B. Continuation of treatment with opioids shall be supported by documentation of continued benefit from such prescribing. If the patient's progress is unsatisfactory, the practitioner shall assess the appropriateness of continued use of the current treatment plan and consider the use of other therapeutic modalities.

C. The practitioner shall check the Prescription Monitoring Program at least every three months after the initiation of treatment.

D. The practitioner shall order and review a urine drug screen or serum medication levels at the initiation of chronic pain management and at least every three months for the first year of treatment and at least every six months thereafter.

E. The practitioner (i) shall regularly evaluate the patient for opioid use disorder and (ii) shall initiate specific treatment for opioid use disorder, consult with an appropriate health care provider, or refer the patient for evaluation for treatment if indicated.

18VAC85-21-110. Additional consultations.

A. When necessary to achieve treatment goals, the prescriber shall refer the patient for additional evaluation and treatment.

B. When a prescriber makes the diagnosis of opioid use disorder, treatment for opioid use disorder shall be initiated or the patient shall be referred for evaluation and treatment.

18VAC85-21-120. Medical records for chronic pain.

The prescriber shall keep current, accurate, and complete records in an accessible manner readily available for review to include:

1. The medical history and physical examination;
2. Past medical history;
3. Applicable records from prior treatment providers or any documentation of attempts to obtain those records;
4. Diagnostic, therapeutic, and laboratory results;
5. Evaluations and consultations;
6. Treatment goals;
7. Discussion of risks and benefits;
8. Informed consent and agreement for treatment;
9. Treatments;
10. Medications (including date, type, dosage, and quantity prescribed and refills);
11. Patient instructions; and
12. Periodic reviews.

Part IV

Prescribing of Buprenorphine for Addiction Treatment

18VAC85-21-130. General provisions pertaining to prescribing of buprenorphine for addiction treatment.

A. Practitioners engaged in office-based opioid addiction treatment with buprenorphine shall have obtained a

SAMHSA waiver and the appropriate U.S. Drug Enforcement Administration registration.

B. Practitioners shall abide by all federal and state laws and regulations governing the prescribing of buprenorphine for the treatment of opioid use disorder.

C. Physician assistants and nurse practitioners who have obtained a SAMHSA waiver shall only prescribe buprenorphine for opioid addiction pursuant to a practice agreement with a waived doctor of medicine or doctor of osteopathic medicine.

D. Practitioners engaged in medication-assisted treatment shall either provide counseling in their practice or refer the patient to a mental health service provider, as defined in § 54.1-2400.1 of the Code of Virginia, who has the education and experience to provide substance misuse counseling. The practitioner shall document provision of counseling or referral in the medical record.

18VAC85-21-140. Patient assessment and treatment planning for addiction treatment.

A. A practitioner shall perform and document an assessment that includes a comprehensive medical and psychiatric history, substance misuse history, family history and psychosocial supports, appropriate physical examination, urine drug screen, pregnancy test for women of childbearing age and ability, a check of the Prescription Monitoring Program, and, when clinically indicated, infectious disease testing for human immunodeficiency virus, hepatitis B, hepatitis C, and tuberculosis.

B. The treatment plan shall include the practitioner's rationale for selecting medication-assisted treatment, patient education, written informed consent, how counseling will be accomplished, and a signed treatment agreement that outlines the responsibilities of the patient and the prescriber.

18VAC85-21-150. Treatment with buprenorphine for addiction.

A. Buprenorphine without naloxone (buprenorphine mono-product) shall not be prescribed except:

1. When a patient is pregnant;
2. When converting a patient from methadone or buprenorphine mono-product to buprenorphine containing naloxone for a period not to exceed seven days;
3. In formulations other than tablet form for indications approved by the FDA; or
4. For patients who have a demonstrated intolerance to naloxone; such prescriptions for the mono-product shall not exceed 3.0% of the total prescriptions for buprenorphine written by the prescriber, and the exception shall be clearly documented in the patient's medical record.

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B. Buprenorphine mono-product tablets may be administered directly to patients in federally licensed opioid treatment programs. With the exception of those conditions listed in subsection A of this section, only the buprenorphine product containing naloxone shall be prescribed or dispensed for use off site from the program.

C. The evidence for the decision to use buprenorphine mono-product shall be fully documented in the medical record.

D. Due to a higher risk of fatal overdose when buprenorphine is prescribed with other opioids, benzodiazepines, sedative hypnotics, carisoprodol, and tramadol, the prescriber shall only co-prescribe these substances when there are extenuating circumstances and shall document in the medical record a tapering plan to achieve the lowest possible effective doses if these medications are prescribed.

E. Prior to starting medication-assisted treatment, the practitioner shall perform a check of the Prescription Monitoring Program.

F. During the induction phase, except for medically indicated circumstances as documented in the medical record, patients should be started on no more than eight milligrams of buprenorphine per day. The patient shall be seen by the prescriber at least once a week.

G. During the stabilization phase, the prescriber shall increase the daily dosage of buprenorphine in safe and effective increments to achieve the lowest dose that avoids intoxication, withdrawal, or significant drug craving.

H. Practitioners shall take steps to reduce the chances of buprenorphine diversion by using the lowest effective dose, appropriate frequency of office visits, pill counts, and checks of the Prescription Monitoring Program. The practitioner shall also require urine drug screens or serum medication levels at least every three months for the first year of treatment and at least every six months thereafter.

I. Documentation of the rationale for prescribed doses exceeding 16 milligrams of buprenorphine per day shall be placed in the medical record. Dosages exceeding 24 milligrams of buprenorphine per day shall not be prescribed.

J. The practitioner shall incorporate relapse prevention strategies into counseling or assure that they are addressed by a mental health service provider, as defined in § 54.1-2400.1 of the Code of Virginia, who has the education and experience to provide substance misuse counseling.

18VAC85-21-160. Special populations in addiction treatment.

A. Pregnant women may be treated with the buprenorphine mono-product, usually 16 milligrams per day or less.

B. Patients younger than the age of 16 years shall not be prescribed buprenorphine for addiction treatment unless such treatment is approved by the FDA.

C. The progress of patients with chronic pain shall be assessed by reduction of pain and functional objectives that can be identified, quantified, and independently verified.

D. Practitioners shall (i) evaluate patients with medical comorbidities by history, physical exam, appropriate laboratory studies and (ii) be aware of interactions of buprenorphine with other prescribed medications.

E. Practitioners shall not undertake buprenorphine treatment with a patient who has psychiatric comorbidities and is not stable. A patient who is determined by the prescriber to be psychiatrically unstable shall be referred for psychiatric evaluation and treatment prior to initiating medication-assisted treatment.

18VAC85-21-170. Medical records for opioid addiction treatment.

A. Records shall be timely, accurate, legible, complete, and readily accessible for review.

B. The treatment agreement and informed consent shall be maintained in the medical record.

C. Confidentiality requirements of 42 CFR Part 2 shall be followed.

D. Compliance with 18VAC85-20-27, which prohibits willful or negligent breach of confidentiality or unauthorized disclosure of confidential Prescription Monitoring Program information, shall be maintained.

VA.R. Doc. No. R17-5033; Filed November 4, 2017, 11:37 a.m.

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

Final Regulation

REGISTRAR'S NOTICE: The Board for Waterworks and Wastewater Works Operators and Onsite Sewage System Professionals is claiming an exemption from Article 2 of the Administrative Process Act in accordance with § 2.2-4006 A 6 of the Code of Virginia, which excludes regulations of the regulatory boards served by the Department of Professional and Occupational Regulation pursuant to Title 54.1 of the Code of Virginia that are limited to reducing fees charged to regulants and applicants. The Board for Waterworks and Wastewater Works Operators and Onsite Sewage System Professionals will receive, consider, and respond to petitions by any interested person at any time with respect to reconsideration or revision.

Title of Regulation: 18VAC160-30. Waterworks and Wastewater Works Operators Licensing Regulations (amending 18VAC160-30-40).

Statutory Authority: §§ 54.1-113 and 54.1-201 of the Code of Virginia.

Effective Date: January 1, 2018.

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

Summary:

The amendments reduce the renewal and reinstatement fees for (i) wastewater works operator licenses that expire on February 28, 2018 and (ii) waterworks operator licenses that expire on February 28, 2019, to comply with § 54.1-113 of the Code of Virginia.

18VAC160-30-40. Fee schedule.

Fee Type	Fee Amount	When Due
Initial application (for each profession, class, and category of license)	\$100	With application
Renewal (for each profession, class, and category of license)	\$80	With renewal application
Reinstatement (for each profession, class, and category of license)	\$105 (renewal fee + \$25 reinstatement fee)	With reinstatement application

For wastewater works operator licenses expiring on February 28, 2018, and waterworks operator licenses expiring on February 28, 2019, the renewal fee shall be \$50. For reinstatement applications received after February 28, 2018, and on or before February 29, 2020, the total reinstatement fee shall be \$75.

VA.R. Doc. No. R18-5311; Filed November 2, 2017, 11:36 a.m.

Final Regulation

REGISTRAR'S NOTICE: The Board for Waterworks and Wastewater Works Operators and Onsite Sewage System Professionals is claiming an exemption from Article 2 of the Administrative Process Act in accordance with § 2.2-4006 A 6 of the Code of Virginia, which excludes regulations of the regulatory boards served by the Department of Professional and Occupational Regulation pursuant to Title 54.1 of the

Code of Virginia that are limited to reducing fees charged to regulants and applicants. The Board for Waterworks and Wastewater Works Operators and Onsite Sewage System Professionals will receive, consider, and respond to petitions by any interested person at any time with respect to reconsideration or revision.

Title of Regulation: 18VAC160-40. Onsite Sewage System Professionals Licensing Regulations (amending 18VAC160-40-40).

Statutory Authority: §§ 54.1-201 and 54.1-2301 of the Code of Virginia.

Effective Date: January 1, 2018.

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

Summary:

The amendments reduce (i) renewal fees for onsite sewage system professional licenses that expire on or after January 31, 2018, and before January 31, 2020 and (ii) reinstatement fees for reinstatement applications received after January 31, 2018, and on or before January 31, 2020, to comply with § 54.1-113 of the Code of Virginia.

18VAC160-40-40. Fee schedule.

Fee Type	Fee Amount	When Due
Initial application (for each profession, class, and category of license)	\$100	With application
Renewal (for each profession, class, and category of license)	\$80	With renewal application
Reinstatement (for each profession, class, and category of license)	\$105 (renewal fee + \$25 reinstatement fee)	With reinstatement application

For licenses expiring on or after January 31, 2018, and before January 31, 2020, the renewal fee shall be \$50. For reinstatement applications received after January 31, 2018, and on or before January 31, 2020, the total reinstatement fee shall be \$75.

VA.R. Doc. No. R18-5312; Filed November 2, 2017, 11:37 a.m.

GOVERNOR

EXECUTIVE ORDER NUMBER SEVENTY-THREE (2017)

ESTABLISHMENT OF AN ADVISORY COUNCIL ON ENVIRONMENTAL JUSTICE

Part I – Importance of the Initiative

The Constitution of Virginia states that it is the Commonwealth's policy to "protect its atmosphere, lands, and waters from pollution, impairment, or destruction, for the benefit, enjoyment, and general welfare of the people of the Commonwealth." The protection of our natural resources applies equally to all individuals. However, some environmental impacts may be compounded or concentrated as the result of demographic factors. This issue, known as environmental justice, is defined by the U.S. Environmental Protection Agency as the fair treatment and meaningful involvement of all people regardless of race, color, faith, national origin, or income, with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.

It is important that no segment of the population, especially individuals most impacted and vulnerable, should bear disproportionately high or adverse effects from pollution. To ensure that all people and perspectives have a voice, the Commonwealth needs a sustained conduit for recommendations on environmental justice. While some state agencies incorporate environmental justice into their review process, there is currently no consistency in how these issues are evaluated within the Executive Branch.

Part II – Establishment of the Advisory Council on Environmental Justice

The Commonwealth requires a consistent, action-oriented approach to incorporating environmental justice into decision-making. Accordingly, I hereby formally convene the Governor's Advisory Council on Environmental Justice ("Council") to provide independent advice and recommendations to the Executive Branch.

Part III – Composition of the Council

The Governor will appoint members to carry out the assigned functions of the Council, and the members shall serve at the Governor's pleasure. In addition, staff support may be provided by the following individuals or their designee:

- Secretary of Natural Resources;
- Secretary of Agriculture and Forestry;
- Secretary of Commerce and Trade;
- Secretary of Education;
- Secretary of Health and Human Resources;
- Secretary of Public Safety and Homeland Security; and

Secretary of Transportation;

Part IV – Duties of the Council

The Council shall provide advice and recommendations to the Executive Branch on the following:

1. Integrating environmental justice considerations throughout the Commonwealth's programs, regulations, policies, and procedures;
2. Improving the environment and public health in communities disproportionately burdened by environmental pollution and risks;
3. Ensuring transparent, authentic, and equitable engagement in decision-making, building capacity in disproportionately burdened communities, and promoting collaborative problem-solving for issues involving environmental justice;
4. Strengthening partnerships on environmental justice among governmental agencies, including Federal, State, Tribal, and local governments;
5. Enhancing research and assessment approaches related to environmental justice;
6. Receiving comments, concerns, and recommendations from individuals throughout the Commonwealth; and
7. Developing resources and strategies to provide and disseminate information to the public.

The Council will draft an annual report containing specific recommendations in furtherance of these issues, including recommendations on proposed legislation, regulations, policies, and commencement of research initiatives.

Effective Date of the Executive Order

This Executive Order shall be effective upon its signing and shall remain in full force and effect unless amended or rescinded by further executive order.

Given under my hand and under the Seal of the Commonwealth of Virginia this 31st Day of October, 2017.

/s/ Terence R. McAuliffe
Governor

GENERAL NOTICES/ERRATA

STATE CORPORATION COMMISSION

Bureau of Insurance

November 3, 2017

Administrative Letter 2017-04

TO: All Title Insurance Companies Licensed under Title 38.2 of the Code of Virginia

RE: Closing Protection Letters

The Bureau of Insurance ("Bureau") is aware that several title insurance companies are imposing a monetary charge for the issuance of a closing protection letter ("CPL"). Inconsistencies have arisen as to whether the charge should be identified as an administrative fee or premium. The Bureau finds that a charge levied by a title insurance company for the issuance of a CPL is premium because there is a loss-based cost associated with the issuance of a CPL, and the exposure created by a CPL is not a "fixed expense" (a known, set dollar amount of expense incurred during the calendar year) or a "variable expense" (a known percentage of premiums written, but variable in the amount based on written premium) connected with issuing title insurance in Virginia.

Accordingly, the Bureau hereby instructs title insurance companies that impose a charge for the issuance of a CPL to treat that charge as premium. The CPL charges should be reported as direct premiums written, not other income. As a reminder, the CPL must cover the same exposures covered by the title insurance policy, and cannot extend coverage beyond matters affecting the condition of the title to property or status of any lien on property.¹

Questions concerning this administrative letter may be addressed to Edward J. Buyalos, Jr., Chief Financial Auditor, Financial Regulation Division, Virginia Bureau of Insurance, State Corporation Commission, P.O. Box 1157, Richmond, VA 23218, telephone (804) 371-9605, or email ed.buyalos@scc.virginia.gov.

/s/ Jacqueline K. Cunningham
Commissioner of Insurance

¹ Administrative Letter 1995-8.

DEPARTMENT OF ENVIRONMENTAL QUALITY

Culpeper North Solar LLC Notice of Intent for Small Renewable Energy (Solar) Project Permit by Rule - Culpeper County, Virginia

Culpeper North Solar LLC has provided the Department of Environmental Quality with a notice of intent to submit the necessary documentation for a permit by rule for a small renewable energy project (solar) in Culpeper County, Virginia, pursuant to 9VAC15-60. The project will be located on 296 acres across multiple parcels on land west of

Stevensburg Road, east of Glen Ella Road, north of Greens Corner Road, and south of Bel Pre Road. The solar project conceptually consists of approximately 85,000 335-watt panels plus eight 2.7-megawatt inverters, which will provide a maximum 20 megawatts of nameplate capacity.

Contact Information: Mary E. Major, Department of Environmental Quality, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4423, FAX (804) 698-4510, or email mary.major@deq.virginia.gov.

Ladybug Solar LLC Notice of Intent for Small Renewable Energy (Solar) Project Permit by Rule - Mecklenburg County

Ladybug Solar LLC has provided the Department of Environmental Quality with a notice of intent to submit the necessary documentation for a permit by rule for a small renewable energy (solar) project. The project is 65 megawatts and will be located east of Highway 1 and southwest of Belfield Road, near Bracy in Mecklenburg County and will cover approximately 478 acres. The project will consist of ground-mounted arrays and will utilize photovoltaic solar modules and single-axis tracking technology.

Contact Information: Mary E. Major, Department of Environmental Quality, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4423, FAX (804) 698-4510, or email mary.major@deq.virginia.gov.

Reservoir Solar LLC Withdrawal of Notice of Intent for Small Renewable Energy (Solar) Project Permit by Rule - Louisa County

Reservoir Solar LLC has notified the Department of Environmental Quality of the withdrawal of the July 21, 2017, notice of intent to submit the necessary documentation for a permit by rule for a small renewable energy project (solar) in Louisa County. The original notice of intent was published in the Virginia Register on August 21, 2017, Volume 33, Issue 26. The project was to be located on 1400 acres across multiple parcels on land west of Mineral Avenue and Kennon Road north of Jefferson Highway, south of Davis Highway, and east of School Bus Road and would have provided a maximum 99.9 megawatts of nameplate capacity.

Contact Information: Mary E. Major, Department of Environmental Quality, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4423, FAX (804) 698-4510, or email mary.major@deq.virginia.gov.

SB Solar LLC Notice of Intent for Small Renewable Energy (Solar) Project Permit by Rule - Halifax County

SB Solar LLC has provided the Department of Environmental Quality a notice of intent to submit the necessary documentation for a permit by rule for a small renewable energy (solar) project. The project is 10 megawatts and is to

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be located west of Huell Matthews Highway and south of East Hycy Road, near Nathalie in Halifax County and will cover approximately 185 acres. The project will consist of ground-mounted arrays and will utilize photovoltaic solar modules and single-axis tracking technology.

Contact Information: Mary E. Major, Department of Environmental Quality, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4423, FAX (804) 698-4510, or email mary.major@deq.virginia.gov.

Turner Solar LLC Notice of Intent for Small Renewable Energy (Solar) Project Permit by Rule - Henrico County

Turner Solar LLC has provided the Department of Environmental Quality a notice of intent to submit the necessary documentation for a permit by rule for a small renewable energy project (solar) in Henrico County, Virginia, pursuant to 9VAC15-60. The project will be located on 463 acres on one parcel of land west of Strath Road, east of Varina Road, north of Kingsland Road, and south of Battery Gregg Drive. The solar project conceptually consists of approximately 85,000 335-watt panels plus eight 2.7-megawatt inverters, which will provide a maximum 20 megawatts of nameplate capacity.

Contact Information: Mary E. Major, Department of Environmental Quality, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4423, FAX (804) 698-4510, or email mary.major@deq.virginia.gov.

Virginia Solar LLC Withdrawal of Notice of Intent for Small Renewable Energy (Solar) Project Permit by Rule - Culpeper County

Virginia Solar LLC has notified the Department of Environmental Quality that the notice of intent to submit the necessary documentation for a permit by rule for a small renewable energy project (solar) in Culpeper County is withdrawn. The original notice of intent was published in the Virginia Register on March 6, 2017, Volume 33, Issue 14. The project, called Brandy Station, was to be located on 180 acres across multiple parcels, on land north of Greens Corner Road, west of Stevensburg Road, and east of Glen Ella Road and would have provided a maximum of 20 megawatts of nameplate capacity.

Contact Information: Mary E. Major, Department of Environmental Quality, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4423, FAX (804) 698-4510, or email mary.major@deq.virginia.gov.

Water Strider Solar LLC Notice of Intent for Small Renewable Energy (Solar) Project Permit by Rule - Halifax County

Water Strider Solar LLC has provided the Department of Environmental Quality a notice of intent to submit the necessary documentation for a permit by rule for a small

renewable energy (solar) project. The project is 80 megawatts and is to be located north of Stage Coach Road near Nathalie in Halifax County and will cover approximately 1,134 acres. The project will consist of ground-mounted arrays and will utilize photovoltaic solar modules and single-axis tracking technology.

Contact Information: Mary E. Major, Department of Environmental Quality, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4423, FAX (804) 698-4510, or email mary.major@deq.virginia.gov.

VIRGINIA LOTTERY

Director's Orders

The following Director's Orders of the Virginia Lottery were filed with the Virginia Registrar of Regulations on November 1, 2017, and November 8, 2017. The orders may be viewed at the Virginia Lottery, 600 East Main Street, Richmond, Virginia, or at the office of the Registrar of Regulations, 900 East Main Street, 11th Floor, Richmond, Virginia.

Director's Order Number One Hundred Thirty-One (17)

Virginia's Computer-Generated Lottery Game "Mega Millions" Final Rules for Game Operation (this Director's Order becomes effective with the October 31, 2017, drawing, fully replaces any and all prior Virginia Lottery "Mega Millions" game rules, and shall remain in full force and effect unless amended or rescinded by further Director's Order)

Director's Order Number One Hundred Sixty-Five (17)

Virginia Lottery's Computer-Generated Game "Cash 5" Final Rules for Game Operation (This Director's Order becomes effective on October 13, 2017, fully replaces any and all prior Virginia Lottery "Cash 5" game rules, and shall remain in full force and effect unless amended or rescinded by further Director's Order)

Director's Order Number One Hundred Sixty-Six (17)

Certain Virginia Lottery Scratch Games; End of Games.

In accordance with the authority granted by §§ 2.2-4002 B 15 and 58.1-4006 A of the Code of Virginia, I hereby give notice that the following Virginia Lottery instant games will officially end at midnight on November 3, 2017:

Game 1782	7X The Money
Game 1766	Tripling Crossword
Game 1762	5X The Money
Game 1736	10X The Money
Game 1710	Million \$\$ Match (TOP)
Game 1707	\$15 Million Payout
Game 1690	Double Payout

Game 1672	Find the 8's
Game 1653	Frogger
Game 1646	Lucky 5s
Game 1575	Green
Game 1559	Double Dollar Fortune
Game 1473	Win It All
Game 1464	\$3,000,000 Jackpot

The last day for lottery retailers to return for credit unsold tickets from any of these games will be December 19, 2017. The last day to redeem winning tickets for any of these games will be May 2, 2018, 180 days from the declared official end of the game. Claims for winning tickets from any of these games will not be accepted after that date. Claims that are mailed and received in an envelope bearing a postmark of the United States Postal Service or another sovereign nation of May 2, 2018, or earlier, will be deemed to have been received on time. This notice amplifies and conforms to the duly adopted State Lottery Board regulations for the conduct of lottery games.

This order is available for inspection and copying during normal business hours at the Virginia Lottery headquarters, 600 East Main Street, Richmond, Virginia, and at any Virginia Lottery regional office. A copy may be requested by mail by writing to Director's Office, Virginia Lottery, 600 East Main Street, Richmond, Virginia 23219.

This Director's Order becomes effective on October 13, 2017, and shall remain in full force and effect unless amended or rescinded by further Director's Order.

Director's Order Number One Hundred Sixty-Nine (17)

Virginia Lottery's "FY18 eXTRA Chances Scratch Promotion" Final Rules for Operation (effective November 1, 2017)

Director's Order Number One Hundred Seventy (17)

Certain Virginia Promotion; Rescission of Promotion - 2 Ways 2 Win Scratch Incentive Promotion (68 2017) (effective November 1, 2017)

Director's Order Number One Hundred Seventy-One (17)

Virginia Lottery's "2 Ways to Win Scratch Retailer Incentive Promotion" (effective November 1, 2017)

Director's Order Number One Hundred Seventy-Eight (17)

Virginia Lottery's Scratch Game 1813 "X The Money Bingo" Final Rules for Game Operation (effective November 6, 2017)

Director's Order Number One Hundred Seventy-Nine (17)

Virginia Lottery's Scratch Game 1862 "7" Final Rules for Game Operation (effective November 6, 2017)

Director's Order Number One Hundred Eighty (17)

Virginia Lottery's Scratch Game 1834 "Weekly Half Grand" Final Rules for Game Operation (effective November 6, 2017)

Director's Order Number One Hundred Eighty-One (17)

Virginia Lottery's Scratch Game 1835 "Weekly Grand" Final Rules for Game Operation (effective November 6, 2017)

Director's Order Number One Hundred Eighty-Two (17)

Virginia Lottery's Computer-Generated Game "Virginia's New Year's Millionaire Raffle" Final Rules for Game Operation (effective November 7, 2017)

Director's Order Number One Hundred Eighty-Three (17)

Certain Virginia Print 'n Play Game - Virginia Lottery's "Print 'n Play Bonus Bingo" (151 2017) (effective October 27, 2017)

Director's Order Number One Hundred Eighty-Four (17)

Virginia Lottery's Computer-Generated Game "Print 'n Play Bullseye Bingo" Final Rules for Game Operation (effective October 28, 2017)

Director's Order Number One Hundred Eighty-Nine (17)

Virginia Computer-Generated Lottery Game "Mega Millions" Final Rules for Game Operation (this Director's Order becomes effective nunc pro tunc to the October 31, 2017, drawing, fully replaces any and all prior Virginia Lottery "Mega Millions" game rules, and shall remain in full force and effect unless amended or rescinded by further Director's Order)

VIRGINIA WORKERS' COMPENSATION COMMISSION

Public Comment on Proposed Medical Fee Schedule Regulations

The Virginia Workers' Compensation Commission is accepting public comment on the proposed regulations implementing the Medical Fee Schedules and Ground Rules adopted by the Commission on June 13, 2017, which establish the maximum fees for fee scheduled medical services rendered to injured workers pursuant to the Virginia Workers' Compensation Act (Title 65.2 of the Code of Virginia). The proposed regulations may be accessed at <http://www.workcomp.virginia.gov/content/medical-fee-schedule-regulations>.

Persons wishing to provide written comment are encouraged to do so electronically at

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<http://www.workcomp.virginia.gov/content/Medical-Fee-Schedules-Special-Notice>. Written comments may also be submitted via email to drema.thompson@workcom.virginia.gov or by mail to Drema Thompson, Medical Fee Services Manager, Virginia Workers' Compensation Commission, 1000 DMV Drive, Richmond, VA 23220. Written comments will be accepted through November 27, 2017.

Contact Information: Drema Thompson, Medical Fee Services Manager, 1000 DMV Drive, Richmond, VA 23220, telephone (804) 774-4165, FAX (804) 823-6932, or email drema.thompson@workcomp.virginia.gov.

STATE WATER CONTROL BOARD

Proposed Consent Order for Fork Union Military Academy

An enforcement action has been proposed for the Fork Union Military Academy for violations at the Fork Union Military Academy STP in Fluvanna County, Virginia. The State Water Control Board proposes to issue a consent order to the Fork Union Military Academy to address noncompliance with State Water Control Law. A description of the proposed action is available at the Department of Environmental Quality office named below or online at www.deq.virginia.gov. Tamara Ambler will accept comments by email at tamara.ambler@deq.virginia.gov, FAX at (540) 574-7878, or postal mail at Department of Environmental Quality, Valley Regional Office, P.O. Box 3000, Harrisonburg, VA 22801, from November 27, 2017, to December 28, 2017.

Proposed Consent Special Order for Kiptopeke Villas, LLC

An enforcement action has been proposed for Kiptopeke Villas, LLC for violations at the site located at 3540 Kiptopeke Drive in Northampton County, Virginia. The State Water Control Board proposes to issue a special order by consent to Kiptopeke Villas, LLC to address noncompliance with the State Water Control Law and regulations. A description of the proposed action is available at the Department of Environmental Quality office named below or online at www.deq.virginia.gov. Kristen Sadtler will accept comments by email at kristen.sadtler@deq.virginia.gov, FAX at (804) 698-4277, or postal mail at Department of Environmental Quality, Central Office, P.O. Box 1105, Richmond, VA 23218, from December 11, 2017, to January 10, 2017.

Proposed Enforcement Action for the Department of the Navy, Commander, Navy Region Mid-Atlantic

An enforcement action has been proposed for Department of the Navy, Commander, Navy Region Mid-Atlantic for

violations of the State Water Control Law in York County, Virginia. A description of the proposed action is available at the Department of Environmental Quality office named below or online at www.deq.virginia.gov. Russell Deppe will accept comments by email at russell.deppe@deq.virginia.gov, FAX at (757) 518-2009, or postal mail at Department of Environmental Quality, Tidewater Regional Office, 5636 Southern Boulevard, Virginia Beach, VA 23462, from November 27, 2017, to December 26, 2017.

Proposed Enforcement Action for W. W. Realty Associates LLC

An enforcement action has been proposed for W. W. Realty Associates LLC for violations of the State Water Control Law in Chesapeake, Virginia. A description of the proposed action is available at the Department of Environmental Quality office named below or online at www.deq.virginia.gov. Jennifer Coleman, Esq. will accept comments by email at jennifer.coleman@deq.virginia.gov, FAX at (757) 518-2009, or postal mail at Department of Environmental Quality, Tidewater Regional Office, 5636 Southern Boulevard, Virginia Beach, VA 23462, from November 27, 2017, to December 27, 2017.

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/cumulatab.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.