VIRGINIA REGISTER OF REGULATIONS

VOL. 34 ISS. 23 PUBLISHED EVERY OTHER WEEK BY THE VIRGINIA CODE COMMISSION JULY 9, 2018

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THE VIRGINIA REGISTER OF REGULATIONS (USPS 001-831) is published biweekly for $263.00 per year by Matthew Bender & Company, Inc., 3 Lear Jet Lane, Suite 102, P.O. Box 1710, Latham, NY 12110. Periodical postage is paid at Albany, NY and at additional mailing offices. POSTMASTER: Send address changes to The Virginia Register of Regulations, 136 Carlin Road, Conklin, NY 13748-1531.

VIRGINIA REGISTER INFORMATION PAGE

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

ADOPTION, AMENDMENT, AND REPEAL OF REGULATIONS

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

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

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

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

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

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

A regulation becomes effective at the conclusion of the 30-day final adoption period, or at any other later date specified by the promulgating agency, unless (i) a legislative objection has been filed, in which event the regulation, unless withdrawn, becomes effective on the date specified, which shall be after the expiration of the 21-day objection period; (ii) the Governor exercises his authority to require the agency to provide for additional public comment, in which event the regulation, unless withdrawn, becomes effective on the date specified, which shall be after the expiration of the period for which the Governor has provided for additional public comment; (iii) the Governor and the General Assembly exercise their authority to suspend the effective date of a regulation until the end of the next regular legislative session; or (iv) the agency suspends the regulatory process, in which event the regulation, unless withdrawn, becomes effective on the date specified, which shall be after the expiration of the 30-day public comment period and no earlier than 15 days from publication of the readopted action.

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

FAST-TRACK RULEMAKING PROCESS

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

EMERGENCY REGULATIONS

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

During the time the emergency status is in effect, the agency may proceed with the adoption of permanent regulations through the usual procedures. To begin promulgating the replacement regulation, the agency must (i) file the Notice of Intended Regulatory Action with the Registrar within 60 days of the effective date of the emergency regulation and (ii) file the proposed regulation with the Registrar within 180 days of the effective date of the emergency regulation. If the agency chooses not to adopt the regulations, the emergency status ends when the prescribed time limit expires.

STATEMENT

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

CITATION TO THE *VIRGINIA REGISTER*

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

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

PUBLICATION SCHEDULE AND DEADLINES

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

July 2018 through August 2019

Volume: Issue	Material Submitted By Noon*	Will Be Published On
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	September17, 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
35:8	November 19, 2018 **(Monday)**	December 10, 2018
35:9	December 5, 2018	December 24, 2018
35:10	December 14, 2018 **(Friday)**	January 7, 2019
35:11	January 2, 2019	January 21, 2019
35:12	January 16, 2019	February 4, 2019
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35:18	April 10, 2019	April 29, 2019
35:19	April 24, 2019	May 13, 2019
35:20	May 8, 2019	May 27, 2019
35:21	May 22, 2019	June 10, 2019
35:22	June 5, 2019	June 24, 2019
35:23	June 19, 2019	July 8, 2019
35:24	July 3, 2019	July 22, 2019
35:25	July 17, 2019	August 5, 2019
35:26	July 31, 2019	August 19, 2019

*Filing deadlines are Wednesdays unless otherwise specified.

TITLE 3. ALCOHOLIC BEVERAGES

ALCOHOLIC BEVERAGE CONTROL AUTHORITY

Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the Alcoholic Beverage Control Authority intends to consider amending **3VAC5-50, Retail Operations**. The purpose of the proposed action is to implement Chapters 173 and 334 of the 2018 Acts of Assembly, which create a confectionery license and authorize the licensee to prepare and sell, on the licensed premises for off-premises consumption, confectionery. The goal of the regulation is to provide a definition of "confectionery," clarify the restrictions regarding alcohol content and sales, and provide labeling requirements.

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

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

Public Comment Deadline: August 8, 2018.

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

VA.R. Doc. No. R18-5486; Filed June 20, 2018, 11:03 a.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 2. AGRICULTURE

DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES

Final Regulation

REGISTRAR'S NOTICE: The Commissioner of Agriculture and Consumer Services is claiming an exemption from the Administrative Process Act in accordance with § 2.2-4002 A 13 of the Code of Virginia, which excludes the commissioner and the board when promulgating regulations pursuant to § 3.2-5406 of the Code of Virginia including adopting (i) by reference any regulation under the federal acts as it pertains to Chapter 54 (§ 3.2-5400 et seq.) of Title 3.2 of the Code of Virginia, amending it as necessary for intrastate applicability and (ii) any regulation containing provisions no less stringent than those contained in federal regulation. The Department of Agriculture and Consumer Services will receive, consider, and respond to petitions by any interested person at any time with respect to reconsideration or revision.

Title of Regulation: **2VAC5-210. Rules and Regulations Pertaining to Meat and Poultry Inspection under the Virginia Meat and Poultry Products Inspection Act (amending 2VAC5-210-10).**

Statutory Authority: § 3.2-5406 of the Code of Virginia.

Effective Date: July 9, 2018.

Agency Contact: Barry Jones, Program Manager, Meat and Poultry Services, Department of Agriculture and Consumer Services, P.O. Box 1163, Richmond, VA 23218, telephone (804) 786-4569, FAX (804) 786-1003, TTY (800) 828-1120, or email barry.jones@vdacs.virginia.gov.

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

Summary:

The amendments update the publication date for Title 9, Chapter III, Subchapters A and E of the Code of Federal Regulations (CFR) from January 1, 2016, to January 1, 2018. The U.S. Department of Agriculture/Food Safety and Inspection Service (USDA/FSIS) updates Title 9, Chapter III on January 1 of each year. The USDA/FSIS revisions to the CFR that are incorporated by reference include (i) a provision stating that livestock owners, transporters, haulers, and other persons not employed by an official establishment will be held responsible if they commit acts involving inhumane handling of livestock in connection with slaughter when on the premises of an official establishment; (ii) the removal of a provision that permits establishments to set apart and hold for treatment veal calves that are unable to rise from recumbent position and walk because they are tired or cold; (iii) a requirement that all nonambulatory disabled cattle be promptly disposed of after they have been condemned; (iv) the removal of a provision that requires antemortem inspection to be conducted in pens; (v) an amendment to the definition and standard of identity for the "roaster" or "roasting chicken" poultry class to better reflect the characteristics of "roaster" chickens in the market today; and (vi) an update to the definition of "roaster" to remove the eight-week minimum age criterion and increase the ready-to-cook carcass weight from five pounds to five and one-half pounds.

Part I
Adoption by Reference

2VAC5-210-10. Adoption by reference.

The rules and regulations governing the meat and poultry inspection of the ~~United States~~ U.S. Department of Agriculture specified in this part, as contained in Title 9, Chapter III, Subchapters A and E of the Code of Federal Regulations, as it exists and has been published in the January 1, ~~2016~~ 2018, update with amendments and with administrative changes therein as needed to make them appropriate and applicable to intrastate operations and transactions subject to the Virginia Meat and Poultry Products Inspection Act, are hereby adopted by reference.

VA.R. Doc. No. R18-5455; Filed June 12, 2018, 9:55 a.m.

TITLE 3. ALCOHOLIC BEVERAGES

ALCOHOLIC BEVERAGE CONTROL AUTHORITY

Emergency Regulation

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

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

Effective Dates: July 1, 2018, through December 30, 2019.

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

Preamble:

Section 2.2-4011 A of the Code of Virginia states that regulations that an agency finds are necessitated by an emergency situation may be adopted upon consultation with the Attorney General, which approval shall be granted only after the agency has submitted a request stating in writing the nature of the emergency, and the necessity for such action shall be at the sole discretion of the Governor.

The emergency action implements the confectionery license created by Chapters 173 and 334 of the 2018 Acts of Assembly, which authorizes the licensee to prepare and sell on the licensed premises for off-premises consumption confectionery. The provisions require that the confectionery contain 5.0% or less alcohol by volume and that any alcohol contained in such confectionery shall not be in liquid form at the time such confectionery is sold. The regulation defines the term "confectionery" and includes labeling requirements for such confectionery.

3VAC5-50-250. Confectionery; definition; restrictions; labeling.

A. "Confectionery" means a general class of sweet foods and edibles, including baked goods and candies, having an alcohol content not more than 5.0% by volume.

B. Any alcohol contained in such confectionery shall not be in liquid form at the time such confectionery is sold. Such alcohol shall be fully integrated or blended into the confectionery product.

C. Any such confectionery shall only be sold to those individuals who can lawfully consume alcohol.

D. Any establishment licensed to sell confectioneries for off-premises consumption shall properly label the product with such label including:

1. Notice that the product contains alcohol;

2. Notice that the product can only be consumed off premises; and

3. Warning that the product should not be consumed by anyone under the age of 21.

VA.R. Doc. No. R18-5486; Filed June 20, 2018, 11:03 a.m.

TITLE 4. CONSERVATION AND NATURAL RESOURCES

MARINE RESOURCES COMMISSION

Final Regulation

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

Title of Regulation: **4VAC20-240. Pertaining to the Tangier Island Crab Scrape Sanctuary (adding 4VAC20-240-25).**

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

Effective Date: July 1, 2018.

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

Summary:

The amendments establish a seasonal bycatch allowance of female hard crabs, not to exceed three bushels per day, for crab scrape licensees during the months of August through October.

4VAC20-240-25. Bycatch allowance.

From August 1 through October 31, there shall be a limited daily bycatch allowance of up to three bushels of female hard crabs for valid peeler scrape licensees.

VA.R. Doc. No. R18-5555; Filed June 25, 2018, 11:19 a.m.

Final Regulation

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

Title of Regulation: **4VAC20-270. Pertaining to Crabbing (amending 4VAC20-270-40, 4VAC20-270-51).**

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

Effective Date: July 5, 2018.

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

Summary:

The amendments update dates for the 2018-2019 commercial crabbing season in Virginia waters.

4VAC20-270-40. Season limits.

A. In ~~2017~~ 2018, the lawful season for the commercial harvest of crabs by crab pot shall be March ~~1~~ 17 through November 30. In ~~2018~~ 2019, the lawful season for the commercial harvest of crabs by crab pot shall be March 17 through November 30. For all other lawful commercial gear used to harvest crabs, as described in 4VAC20-1040, the lawful seasons for the harvest of crabs shall be April 1 through October 31.

B. It shall be unlawful for any person to harvest crabs or to possess crabs on board a vessel, except during the lawful season, as described in subsection A of this section.

C. It shall be unlawful for any person knowingly to place, set, fish, or leave any hard crab pot in any tidal waters of Virginia from December 1, ~~2017~~ 2018, through March 16, ~~2018~~ 2019. It shall be unlawful for any person to knowingly ~~to~~ place, set, fish, or leave any lawful commercial gear used to harvest crabs, except any hard crab pot~~,~~ or any gear as described in 4VAC20-460-25, in any tidal waters of Virginia from November 1, ~~2017~~ 2018, through March 31, ~~2018~~ 2019.

D. It shall be unlawful for any person knowingly to place, set, fish, or leave any fish pot in any tidal waters from March 12 through March 16, except as provided in subdivisions 1 and 2 of this subsection.

1. It shall be lawful for any person to place, set, or fish any fish pot in those Virginia waters located upriver of the following boundary lines:

a. In the James River the boundary shall be a line connecting Hog Point and the downstream point at the mouth of College Creek.

b. In the York River the boundary lines shall be the Route 33 bridges at West Point.

c. In the Rappahannock River the boundary line shall be the Route 360 bridge at Tappahannock.

d. In the Potomac River the boundary line shall be the Route 301 bridge that extends from Newberg, Maryland to Dahlgren, Virginia.

2. This subsection shall not apply to legally licensed eel pots as described in 4VAC20-500-50.

E. It shall be unlawful for any person to place, set, or fish any number of fish pots in excess of 10% of the amount allowed by the gear license limit, up to a maximum of 30 fish pots per vessel, when any person on that vessel has set any crab pots.

1. This subsection shall not apply to fish pots set in the areas described in subdivision D 1 of this section.

2. This subsection shall not apply to legally licensed eel pots as described in 4VAC20-500.

3. This subsection shall not apply to fish pots constructed of a mesh less than one-inch square or hexagonal mesh.

4VAC20-270-51. Daily commercial harvester, vessel, and harvest and possession limits.

A. Any barrel used by a harvester to contain or possess any amount of crabs will be equivalent in volume to no more than 3 bushels of crabs.

B. From July 5, ~~2017~~ 2018, through October 31, ~~2017~~ 2018, and April 1, ~~2018~~ 2019, through July 4, ~~2018~~ 2019, any Commercial Fisherman Registration Licensee legally licensed for any crab pot license, as described in 4VAC20-270-50 B, shall be limited to the following maximum daily harvest and possession limits for any of the following crab pot license categories:

1. 10 bushels, or 3 barrels and 1 bushel, of crabs if licensed for up to 85 crab pots.

2. 14 bushels, or 4 barrels and 2 bushels, of crabs if licensed for up to 127 crab pots.

3. 18 bushels, or 6 barrels, of crabs if licensed for up to 170 crab pots.

4. 29 bushels, or 9 barrels and 2 bushels, of crabs if licensed for up to 255 crab pots.

5. 47 bushels, or 15 barrels and 2 bushels, of crabs if licensed for up to 425 crab pots.

C. From November 1, ~~2017~~ 2018, through November 30, ~~2017~~ 2018, and March 17, ~~2018~~ 2019, through March 31, ~~2018~~ 2019, any Commercial Fisherman Registration Licensee legally licensed for any crab pot license, as described in 4VAC20-270-50 B, shall be limited to the following maximum daily harvest and possession limits for any of the following crab pot license categories:

1. 8 bushels, or 2 barrels and 2 bushels, of crabs if licensed for up to 85 crab pots.

2. 10 bushels, or 3 barrels and 1 bushel, of crabs if licensed for up to 127 crab pots.

3. 13 bushels, or 4 barrels and 1 bushel, of crabs if licensed for up to 170 crab pots.

4. 21 bushels, or 7 barrels, of crabs if licensed for up to 255 crab pots.

5. 27 bushels, or 9 barrels, of crabs if licensed for up to 425 crab pots.

D. When a single harvester or multiple harvesters are on board any vessel, that vessel's daily harvest and possession

limit shall be equal to only one daily harvest and possession limit, as described in subsections B and C of this section, and that daily limit shall correspond to the highest harvest and possession limit of only one licensee on board that vessel.

E. When transporting or selling one or more legal crab pot licensee's crab harvest in bushels or barrels, any agent shall possess either the crab pot license of that one or more crab pot licensees or a bill of lading indicating each crab pot licensee's name, address, Commercial Fisherman Registration License number, date, and amount of bushels or barrels of crabs to be sold.

F. If any police officer finds crabs in excess of any lawful daily bushel, barrel, or vessel limit, as described in this section, that excess quantity of crabs shall be returned immediately to the water by the licensee or licensees who possess that excess over lawful daily harvest or possession limit. The refusal to return crabs, in excess of any lawful daily harvest or possession limit, to the water shall constitute a separate violation of this chapter.

G. When any person on board any boat or vessel possesses a crab pot license, it shall be unlawful for that person or any other person aboard that boat or vessel to possess a seafood buyers boat license and buy any crabs on any day.

VA.R. Doc. No. R18-5553; Filed June 25, 2018, 11:29 a.m.

Final Regulation

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

Title of Regulation: **4VAC20-450. Pertaining to the Taking of Bluefish (amending 4VAC20-450-30).**

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

Effective Date: July 1, 2018.

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

Summary:

The amendments establish the 2018 commercial bluefish quota as 860,518 pounds.

4VAC20-450-30. Commercial landings quota.

A. The commercial landings of bluefish shall be limited to ~~1,014,773~~ 860,518 pounds during the current calendar year.

B. When it is projected that 95% of the commercial landings quota has been realized, a notice will be posted to close commercial harvest and landings from the bluefish fishery within five days of posting.

C. It shall be unlawful for any person to harvest or land bluefish for commercial purposes after the closure date set forth in the notice described in subsection B of this section.

VA.R. Doc. No. R18-5554; Filed June 25, 2018, 11:13 a.m.

Final Regulation

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

Title of Regulation: **4VAC20-1140. Prohibition of Crab Dredging in Virginia Waters (amending 4VAC20-1140-20).**

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

Effective Date: July 5, 2018.

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

Summary:

The amendments close the season for crab dredging in Virginia waters December 1, 2018, through March 31, 2019.

4VAC20-1140-20. Crab dredging prohibited.

In accordance with the provisions of § 28.2-707 of the Code of Virginia, the crab dredging season of December 1, ~~2017~~ 2018, through March 31, ~~2018~~ 2019, is closed, and it shall be unlawful to use a dredge for catching crabs from the waters of the Commonwealth during that season.

VA.R. Doc. No. R18-5552; Filed June 25, 2018, 11:10 a.m.

TITLE 8. EDUCATION

COLLEGE OF WILLIAM AND MARY

Final Regulation

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

Title of Regulation: **8VAC115-40. Open Flames on Campus (adding 8VAC115-40-10 through 8VAC115-40-50).**

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

Effective Date: June 21, 2018.

Agency Contact: Carla Costello, ADA Coordinator and Compliance Investigator, College of William and Mary, 108 James Blair Hall, Williamsburg, VA 23185, telephone (757) 221-1254, or email cacostello@wm.edu.

Summary:

The regulation (i) establishes the limitations on the presence of open flames in university buildings or on university property and (ii) imposes the requirement for a permit for certain activities involving open burning or open flames.

CHAPTER 40
OPEN FLAMES ON CAMPUS

8VAC115-40-10. Definitions.

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

"Open flame" means any activity or device producing a flame, including candles, tiki torches, oil lanterns, butane or other gas burners, incense, campfires, bonfires, fire pits, and grills.

"University property" means any property, vehicle, or vessel owned, leased, or controlled by the College of William & Mary in Virginia, including the Virginia Institute of Marine Science.

8VAC115-40-20. Permit required for open burning and open flames; exceptions.

A. Open flames are prohibited on all university property, including within university buildings and facilities, except pursuant to a permit issued by the university.

B. Exceptions to the requirement for a permit are:

1. Activities taking place within the scope of academic coursework when under the supervision of the relevant faculty member;

2. Flames created for the transient purpose of lighting a cigarette, cigar, pipe, or similar smoking device, provided such activity is in an authorized location, such activity is otherwise lawful, and the burning or smoking elements are safely and responsibly disposed; and

3. Activities undertaken by university contractors whose contract has been approved by the office of Procurement Services and which contract authorizes open flames.

8VAC115-40-30. Permits.

Persons seeking to ignite an open flame must apply to the Environmental Health and Safety Office for a permit to perform the activity. Permits may be issued for a one-time event or activity, or on a recurring or ongoing basis.

Applicants must apply at least five working days in advance of the activity to ensure consideration. An applicant's history of compliance with previous permits will be considered in a decision to grant a permit.

Persons granted permits are required to comply with all conditions of the permit.

8VAC115-40-40. Person lawfully in charge.

In addition to individuals authorized by university policy, College of William & Mary police officers and representatives of the Environmental Health and Safety Office are lawfully in charge for the purposes of forbidding entry upon or extending permission to remain upon university property of those who are in violation of this prohibition.

8VAC115-40-50. Compliance with policy.

Persons who fail to obtain a permit or to comply with its conditions will be asked to extinguish the open flame or bring the activity into compliance with the term of the permit. Failure to comply with this request may result in arrest for trespass. Members of the university community are also subject to disciplinary action, including termination or expulsion.

VA.R. Doc. No. R18-5543; Filed June 18, 2018, 12:30 p.m.

TITLE 12. HEALTH

DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

Final Regulation

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

Titles of Regulations: **12VAC30-70. Methods and Standards for Establishing Payment Rates - Inpatient Hospital Services (amending 12VAC30-70-351).**

12VAC30-80. Methods and Standards for Establishing Payment Rates; Other Types of Care (amending 12VAC30-80-20, 12VAC30-80-30, 12VAC30-80-36).

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

Effective Date: August 8, 2018.

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

Summary:

The amendments (i) allow an exception of 100% inflation for certain Virginia freestanding children's hospitals in fiscal year 2017 and fiscal year 2018 per Item 306 GGGG of Chapter 1 of the 2018 Acts of Assembly, Special Session I (the budget bill) and (ii) incorporate language approved for the State Plan for Medical Assistance by the Centers for Medicare and Medicaid Services12VAC30-70-351. Updating rates for inflation.

A. Each July, the Virginia moving average values as compiled and published by Global Insight (or its successor), under contract with the department shall be used to update the base year standardized operating costs per case, as determined in 12VAC30-70-361, and the base year standardized operating costs per day, as determined in 12VAC30-70-371, to the midpoint of the upcoming state fiscal year. The most current table available prior to the effective date of the new rates shall be used to inflate base year amounts to the upcoming rate year. Thus, corrections made by Global Insight (or its successor), in the moving averages that were used to update rates for previous state fiscal years shall be automatically incorporated into the moving averages that are being used to update rates for the upcoming state fiscal year.

B. The inflation adjustment for hospital operating rates, disproportionate share hospitals (DSH) payments, and graduate medical education payments shall be eliminated for fiscal year (FY) 2010. The elimination of the inflation adjustments shall not be applicable to rebasing in FY 2011.

C. In FY 2011, hospital operating rates shall be rebased; however the 2008 base year costs shall only be increased 2.58% for inflation. For FY 2011 there shall be no inflation adjustment for graduate medical education (GME) or freestanding psychiatric facility rates. The inflation adjustment shall be eliminated for hospital operating rates, GME payments, and freestanding psychiatric facility rates for FY 2012. The inflation adjustment shall be 2.6% for inpatient hospitals, including hospital operating rates, GME payments, DSH payments, and freestanding psychiatric facility rates for FY 2013, and 0.0% for the same facilities for FY 2014, FY 2015, and FY 2016. For FY 2017, the inflation adjustment for inpatient hospital operating rates, GME, DSH, and freestanding psychiatric hospitals shall be 50% of the adjustment calculated in subsection A of this section. In FY 2018, the inflation adjustment for inpatient hospital operating rates, GME, DSH, and freestanding psychiatric hospitals shall be eliminated for inpatient hospitals. A full inflation adjustment payment shall be made in both FY 2017 and FY 2018 to Virginia freestanding children's hospitals with greater than 50% Medicaid utilization in 2009.

12VAC30-80-20. Services that are reimbursed on a cost basis.

A. Payments for services listed in this section shall be on the basis of reasonable cost following the standards and principles applicable to the Title XVIII Program with the exception provided for in subdivision D 1 e of this section. The upper limit for reimbursement shall be no higher than payments for Medicare patients ~~on a facility by facility basis~~ in accordance with 42 CFR 447.321 ~~and 42 CFR 447.325~~. In no instance, however, shall charges for beneficiaries of the program be in excess of charges for private patients receiving services from the provider. The professional component for emergency room physicians shall continue to be uncovered as a component of the payment to the facility.

B. Reasonable costs will be determined from the filing of a uniform Centers for Medicare and Medicaid Services-approved cost report by participating providers. The cost reports are due not later than 150 days after the provider's fiscal year end. If a complete cost report is not received within 150 days after the end of the provider's fiscal year, DMAS or its designee shall take action in accordance with its policies to assure that an overpayment is not being made. All cost reports shall be reviewed and reconciled to final costs within 180 days of the receipt of a completed cost report. The cost report will be judged complete when DMAS has all of the following:

1. Completed cost reporting form provided by DMAS, with signed certification;

2. The provider's trial balance showing adjusting journal entries;

3. The provider's financial statements including, but not limited to, a balance sheet, a statement of income and expenses, a statement of retained earnings (or fund balance), and a statement of changes in financial position;

4. Schedules that reconcile financial statements and trial balance to expenses claimed in the cost report;

5. Depreciation schedule or summary;

6. Home office cost report, if applicable; and

7. Such other analytical information or supporting documents requested by DMAS when the cost reporting forms are sent to the provider.

C. Item 398 D of the 1987 Appropriation Act (as amended), effective April 8, 1987, eliminated reimbursement of return on equity capital to proprietary providers.

D. The services that are cost reimbursed are:

1. For dates of service prior to January 1, 2014, outpatient hospital services, including rehabilitation hospital outpatient services and excluding laboratory services.

a. Definitions. The following words and terms when used in this section shall have the following meanings when applied to emergency services unless the context clearly indicates otherwise:

"All-inclusive" means all emergency department and ancillary service charges claimed in association with the emergency room visit, with the exception of laboratory services.

"DMAS" means the Department of Medical Assistance Services consistent with Chapter 10 (§ 32.1-323 et seq.) of Title 32.1 of the Code of Virginia.

"Emergency hospital services" means services that are necessary to prevent the death or serious impairment of the health of the recipient. The threat to the life or health of the recipient necessitates the use of the most accessible hospital available that is equipped to furnish the services.

"Recent injury" means an injury that has occurred less than 72 hours prior to the emergency department visit.

b. Scope. DMAS shall differentiate, as determined by the attending physician's diagnosis, the kinds of care routinely rendered in emergency departments and reimburse for nonemergency care rendered in emergency departments at a reduced rate.

(1) With the exception of laboratory services, DMAS shall reimburse at a reduced and all-inclusive reimbursement rate for all services rendered in emergency departments that DMAS determines were nonemergency care.

(2) Services determined by the attending physician to be emergencies shall be reimbursed under the existing methodologies and at the existing rates.

(3) Services performed by the attending physician that may be emergencies shall be manually reviewed. If such services meet certain criteria, they shall be paid under the methodology for subdivision 1 b (2) of this subsection. Services not meeting certain criteria shall be paid under the methodology of subdivision 1 b (1) of this subsection. Such criteria shall include, but not be limited to:

(a) The initial treatment following a recent obvious injury.

(b) Treatment related to an injury sustained more than 72 hours prior to the visit with the deterioration of the symptoms to the point of requiring medical treatment for stabilization.

(c) The initial treatment for medical emergencies including indications of severe chest pain, dyspnea, gastrointestinal hemorrhage, spontaneous abortion, loss of consciousness, status epilepticus, or other conditions considered life threatening.

(d) A visit in which the recipient's condition requires immediate hospital admission or the transfer to another facility for further treatment or a visit in which the recipient dies.

(e) Services provided for acute vital sign changes as specified in the provider manual.

(f) Services provided for severe pain when combined with one or more of the other guidelines.

(4) Payment shall be determined based on ICD diagnosis codes and necessary supporting documentation. As used here, the term "ICD" is defined in 12VAC30-95-5.

(5) DMAS shall review on an ongoing basis the effectiveness of this program in achieving its objectives and for its effect on recipients, physicians, and hospitals. Program components may be revised subject to achieving program intent, the accuracy and effectiveness of the ICD code designations, and the impact on recipients and providers. As used here, the term "ICD" is defined in 12VAC30-95-5.

c. Limitation of allowable cost. Effective for services on and after July 1, 2003, reimbursement of Type Two hospitals for outpatient services shall be at various percentages as noted in subdivisions 1 c (1) and 1 c (2) of this subsection of allowable cost, with cost to be determined as provided in subsections A, B, and C of this section. For hospitals with fiscal years that do not begin on July 1, outpatient costs, both operating and capital, for the fiscal year in progress on that date shall be apportioned between the time period before and the time period after that date, based on the number of calendar months in the cost reporting period, falling before and after that date.

(1) Type One hospitals.

(a) Effective July 1, 2003, through June 30, 2010, hospital outpatient operating reimbursement shall be at 94.2% of allowable cost and capital reimbursement shall be at 90% of allowable cost.

(b) Effective July 1, 2010, through September 30, 2010, hospital outpatient operating reimbursement shall be at 91.2% of allowable cost and capital reimbursement shall be at 87% of allowable cost.

(c) Effective October 1, 2010, through June 30, 2011, hospital outpatient operating reimbursement shall be at 94.2% of allowable cost and capital reimbursement shall be at 90% of allowable cost.

(d) Effective July 1, 2011, hospital outpatient operating reimbursement shall be at 90.2% of allowable cost and capital reimbursement shall be at 86% of allowable cost.

(2) Type Two hospitals.

(a) Effective July 1, 2003, through June 30, 2010, hospital outpatient operating and capital reimbursement shall be 80% of allowable cost.

(b) Effective July 1, 2010, through September 30, 2010, hospital outpatient operating and capital reimbursement shall be 77% of allowable cost.

(c) Effective October 1, 2010, through June 30, 2011, hospital outpatient operating and capital reimbursement shall be 80% of allowable cost.

(d) Effective July 1, 2011, hospital outpatient operating and capital reimbursement shall be 76% of allowable cost.

d. The last cost report with a fiscal year end on or after December 31, 2013, shall be used for reimbursement for dates of service through December 31, 2013, based on this section. Reimbursement shall be based on charges reported for dates of service prior to January 1, 2014. Settlement will be based on four months of runout from the end of the provider's fiscal year. Claims for services paid after the cost report runout period will not be settled.

e. Payment for direct medical education costs of nursing schools, paramedical programs and graduate medical education for interns and residents.

(1) Direct medical education costs of nursing schools and paramedical programs shall continue to be paid on an allowable cost basis.

(2) Effective with cost reporting periods beginning on or after July 1, 2002, direct graduate medical education (GME) costs for interns and residents shall be reimbursed on a per-resident prospective basis. See 12VAC30-70-281 for prospective payment methodology for graduate medical education for interns and residents.

2. Rehabilitation agencies or comprehensive outpatient rehabilitation.

a. Effective July 1, 2009, rehabilitation agencies or comprehensive outpatient rehabilitation facilities that are operated by community services boards or state agencies shall be reimbursed their costs. For reimbursement methodology applicable to all other rehabilitation agencies, see 12VAC30-80-200.

b. Effective October 1, 2009, rehabilitation agencies or comprehensive outpatient rehabilitation facilities operated by state agencies shall be reimbursed their costs. For reimbursement methodology applicable to all other rehabilitation agencies, see 12VAC30-80-200.

3. Supplement payments to Type One hospitals for outpatient services.

a. In addition to payments for services set forth elsewhere in the State Plan, DMAS makes supplemental payments to qualifying state government owned or operated hospitals for outpatient services furnished to Medicare members on or after July 1, 2010. To qualify for a supplement payment, the hospital must be part of the state academic health system or part of an academic health system that operates under a state authority.

b. The amount of the supplemental payment made to each qualifying hospital shall be equal to the difference between the total allowable cost and the amount otherwise actually paid for the services by the Medicaid program based on cost settlement.

c. Payment for furnished services under this section shall be paid at settlement of the cost report.

4. Supplemental payments for private hospital partners of Type One hospitals. Effective for dates of service on or after October 25, 2011, quarterly supplemental payments shall be issued to qualifying private hospitals for outpatient services rendered during the quarter.

a. In order to qualify for the supplemental payment, the hospital shall be enrolled currently as a Virginia Medicaid provider and shall be owned or operated by a private entity in which a Type One hospital has a nonmajority interest.

b. Reimbursement methodology.

(1) Hospitals not participating in the Medicaid disproportionate share hospital (DSH) program shall receive quarterly supplemental payments for the outpatient services rendered during the quarter. Each quarterly payment distribution shall occur not more than two years after the year in which the qualifying hospital's entitlement arises. The annual supplemental payments in a fiscal year shall be the lesser of:

(a) The difference between each qualifying hospital's outpatient Medicaid billed charges and Medicaid payments the hospital receives for services processed for fee-for-service Medicaid individuals during the fiscal year; or

(b) $1,894 per Medicaid outpatient visit for state plan rate year 2012. For future state plan rate years, this number shall be adjusted by inflation based on the Virginia moving average values as compiled and published by Global Insight (or its successor) under contract with the department.

(2) Hospitals participating in the DSH program shall receive quarterly supplemental payments for the outpatient services rendered during the quarter. Each

quarterly payment distribution shall occur not more than two years after the year in which the qualifying hospital's entitlement arises. The annual supplemental payments in a fiscal year shall be the lesser of:

(a) The difference between each qualifying hospital's outpatient Medicaid billed charges and Medicaid payments the hospital receives for services processed for fee-for-service Medicaid individuals during the fiscal year;

(b) $1,894 per Medicaid outpatient visit for state plan rate year 2012. For future state plan rate years, this number shall be adjusted by inflation based on the Virginia moving average values as compiled and published by Global Insight (or its successor) under contract with the department; or

(c) The difference between the limit calculated under § 1923(g) of the Social Security Act and the hospital's DSH payments for the applicable payment period.

c. Limit. Maximum aggregate payments to all qualifying hospitals in this group shall not exceed the available upper payment limit per state fiscal year.

12VAC30-80-30. Fee-for-service providers.

A. Payment for the following services, except for physician services, shall be the lower of the state agency fee schedule (12VAC30-80-190 has information about the state agency fee schedule) or actual charge (charge to the general public)~~:~~ Except as otherwise noted in this section, state developed fee schedule rates are the same for both governmental and private individual practitioners. Fee schedules and any annual or periodic adjustments to the fee schedules are published on the DMAS website at http://www.dmas.virginia.gov.

1. Physicians' services. Payment for physician services shall be the lower of the state agency fee schedule or actual charge (charge to the general public).

2. Dentists' services.

3. Mental health services including: (i) community mental health services, (ii) services of a licensed clinical psychologist, (iii) mental health services provided by a physician, or (iv) peer support services.

a. Services provided by licensed clinical psychologists shall be reimbursed at 90% of the reimbursement rate for psychiatrists.

b. Services provided by independently enrolled licensed clinical social workers, licensed professional counselors or licensed clinical nurse specialists-psychiatric shall be reimbursed at 75% of the reimbursement rate for licensed clinical psychologists.

4. Podiatry.

5. Nurse-midwife services.

6. Durable medical equipment (DME) and supplies.

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

"DMERC" means the Durable Medical Equipment Regional Carrier rate as published by the Centers for Medicare and Medicaid Services at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSched/DMEPOS-Fee-Schedule.html.

"HCPCS" means the Healthcare Common Procedure Coding System, Medicare's National Level II Codes, HCPCS 2006 (Eighteenth edition), as published by Ingenix, as may be periodically updated.

a. Obtaining prior authorization shall not guarantee Medicaid reimbursement for DME.

b. The following shall be the reimbursement method used for DME services:

(1) If the DME item has a DMERC rate, the reimbursement rate shall be the DMERC rate minus 10%. For dates of service on or after July 1, 2014, DME items subject to the Medicare competitive bidding program shall be reimbursed the lower of:

(a) The current DMERC rate minus 10% or

(b) The average of the Medicare competitive bid rates in Virginia markets.

(2) For DME items with no DMERC rate, the agency shall use the agency fee schedule amount. The reimbursement rates for DME and supplies shall be listed in the DMAS Medicaid Durable Medical Equipment (DME) and Supplies Listing and updated periodically. The agency fee schedule shall be available on the agency website at www.dmas.virginia.gov.

(3) If a DME item has no DMERC rate or agency fee schedule rate, the reimbursement rate shall be the manufacturer's net charge to the provider, less shipping and handling, plus 30%. The manufacturer's net charge to the provider shall be the cost to the provider minus all available discounts to the provider. Additional information specific to how DME providers, including manufacturers who are enrolled as providers, establish and document their cost or costs for DME codes that do not have established rates can be found in the relevant agency guidance document.

c. DMAS shall have the authority to amend the agency fee schedule as it deems appropriate and with notice to providers. DMAS shall have the authority to determine alternate pricing, based on agency research, for any code that does not have a rate.

d. The reimbursement for incontinence supplies shall be by selective contract. Pursuant to § 1915(a)(1)(B) of the Social Security Act and 42 CFR 431.54(d), the Commonwealth assures that adequate services or devices shall be available under such arrangements.

e. Certain durable medical equipment used for intravenous therapy and oxygen therapy shall be bundled under specified procedure codes and reimbursed as determined by the agency. Certain services or durable medical equipment such as service maintenance agreements shall be bundled under specified procedure codes and reimbursed as determined by the agency.

(1) Intravenous therapies. The DME for a single therapy, administered in one day, shall be reimbursed at the established service day rate for the bundled durable medical equipment and the standard pharmacy payment, consistent with the ingredient cost as described in 12VAC30-80-40, plus the pharmacy service day and dispensing fee. Multiple applications of the same therapy shall be included in one service day rate of reimbursement. Multiple applications of different therapies administered in one day shall be reimbursed for the bundled durable medical equipment service day rate as follows: the most expensive therapy shall be reimbursed at 100% of cost; the second and all subsequent most expensive therapies shall be reimbursed at 50% of cost. Multiple therapies administered in one day shall be reimbursed at the pharmacy service day rate plus 100% of every active therapeutic ingredient in the compound (at the lowest ingredient cost methodology) plus the appropriate pharmacy dispensing fee.

(2) Respiratory therapies. The DME for oxygen therapy shall have supplies or components bundled under a service day rate based on oxygen liter flow rate or blood gas levels. Equipment associated with respiratory therapy may have ancillary components bundled with the main component for reimbursement. The reimbursement shall be a service day per diem rate for rental of equipment or a total amount of purchase for the purchase of equipment. Such respiratory equipment shall include oxygen tanks and tubing, ventilators, noncontinuous ventilators, and suction machines. Ventilators, noncontinuous ventilators, and suction machines may be purchased based on the individual patient's medical necessity and length of need.

(3) Service maintenance agreements. Provision shall be made for a combination of services, routine maintenance, and supplies, to be known as agreements, under a single reimbursement code only for equipment that is recipient owned. Such bundled agreements shall be reimbursed either monthly or in units per year based on the individual agreement between the DME provider and DMAS. Such bundled agreements may apply to, but not necessarily be limited to, either respiratory equipment or apnea monitors.

7. Local health services.

8. Laboratory services (other than inpatient hospital). The agency's rates for clinical laboratory services were set as of July 1, 2014, and are effective for services on or after that date.

9. Payments to physicians who handle laboratory specimens, but do not perform laboratory analysis (limited to payment for handling).

10. X-ray services.

11. Optometry services.

12. Reserved.

13. Home health services. Effective June 30, 1991, cost reimbursement for home health services is eliminated. A rate per visit by discipline shall be established as set forth by 12VAC30-80-180.

14. Physical therapy; occupational therapy; and speech, hearing, language disorders services when rendered to noninstitutionalized recipients.

15. Clinic services, as defined under 42 CFR 440.90, except for services in ambulatory surgery clinics reimbursed under 12VAC30-80-35.

16. Supplemental payments for services provided by Type I physicians.

a. In addition to payments for physician services specified elsewhere in this chapter, DMAS provides supplemental payments to Type I physicians for furnished services provided on or after July 2, 2002. A Type I physician is a member of a practice group organized by or under the control of a state academic health system or an academic health system that operates under a state authority and includes a hospital, who has entered into contractual agreements for the assignment of payments in accordance with 42 CFR 447.10.

b. Effective July 2, 2002, the supplemental payment amount for Type I physician services shall be the difference between the Medicaid payments otherwise made for Type I physician services and Medicare rates. Effective August 13, 2002, the supplemental payment amount for Type I physician services shall be the difference between the Medicaid payments otherwise made for physician services and 143% of Medicare rates. Effective January 3, 2012, the supplemental payment amount for Type I physician services shall be the difference between the Medicaid payments otherwise made for physician services and 181% of Medicare rates. Effective January 1, 2013, the supplemental payment amount for Type I physician services shall be the

difference between the Medicaid payments otherwise made for physician services and 197% of Medicare rates. Effective April 8, 2014, the supplemental payment amount for Type I physician services shall be the difference between the Medicaid payments otherwise made for physician services and 201% of Medicare rates.

c. The methodology for determining the Medicare equivalent of the average commercial rate is described in 12VAC30-80-300.

d. Supplemental payments shall be made quarterly no later than 90 days after the end of the quarter.

e. Payment will not be made to the extent that the payment would duplicate payments based on physician costs covered by the supplemental payments.

17. Supplemental payments for services provided by physicians at Virginia freestanding children's hospitals.

a. In addition to payments for physician services specified elsewhere in this chapter, DMAS provides supplemental payments to Virginia freestanding children's hospital physicians providing services at freestanding children's hospitals with greater than 50% Medicaid inpatient utilization in state fiscal year 2009 for furnished services provided on or after July 1, 2011. A freestanding children's hospital physician is a member of a practice group (i) organized by or under control of a qualifying Virginia freestanding children's hospital, or (ii) who has entered into contractual agreements for provision of physician services at the qualifying Virginia freestanding children's hospital and that is designated in writing by the Virginia freestanding children's hospital as a practice plan for the quarter for which the supplemental payment is made subject to DMAS approval. The freestanding children's hospital physicians also must have entered into contractual agreements with the practice plan for the assignment of payments in accordance with 42 CFR 447.10.

b. Effective July 1, 2011, the supplemental payment amount for freestanding children's hospital physician services shall be the difference between the Medicaid payments otherwise made for freestanding children's hospital physician services and 143% of Medicare rates as defined in the supplemental payment calculation described in the Medicare equivalent of the average commercial rate methodology (see 12VAC30-80-300), subject to the following reduction. Final payments shall be reduced on a prorated basis so that total payments for freestanding children's hospital physician services are $400,000 less annually than would be calculated based on the formula in the previous sentence. Effective July 1, 2015, the supplemental payment amount for freestanding children's hospital physician services shall be the difference between the Medicaid payments otherwise made for freestanding children's hospital physician services and 178% of Medicare rates as defined in the supplemental payment calculation for Type I physician services. Payments shall be made on the same schedule as Type I physicians.

18. Supplemental payments for services provided by physicians affiliated with Eastern Virginia Medical Center.

a. In addition to payments for physician services specified elsewhere in this chapter, the Department of Medical Assistance Services provides supplemental payments to physicians affiliated with Eastern Virginia Medical Center for furnished services provided on or after October 1, 2012. A physician affiliated with Eastern Virginia Medical Center is a physician who is employed by a publicly funded medical school that is a political subdivision of the Commonwealth of Virginia, who provides clinical services through the faculty practice plan affiliated with the publicly funded medical school, and who has entered into contractual arrangements for the assignment of payments in accordance with 42 CFR 447.10.

b. Effective October 1, 2015, the supplemental payment amount shall be the difference between the Medicaid payments otherwise made for physician services and 137% of Medicare rates. The methodology for determining the Medicare equivalent of the average commercial rate is described in 12VAC30-80-300.

c. Supplemental payments shall be made quarterly, no later than 90 days after the end of the quarter.

19. Supplemental payments for services provided by physicians at freestanding children's hospitals serving children in Planning District 8.

a. In addition to payments for physician services specified elsewhere in this chapter, DMAS shall make supplemental payments for physicians employed at a freestanding children's hospital serving children in Planning District 8 with more than 50% Medicaid inpatient utilization in fiscal year 2014. This applies to physician practices affiliated with Children's National Health System.

b. The supplemental payment amount for qualifying physician services shall be the difference between the Medicaid payments otherwise made and 178% of Medicare rates but no more than $551,000 for all qualifying physicians. The methodology for determining allowable percent of Medicare rates is based on the Medicare equivalent of the average commercial rate described in this chapter.

c. Supplemental payments shall be made quarterly no later than 90 days after the end of the quarter. Any quarterly payment that would have been due prior to the

approval date shall be made no later than 90 days after the approval date.

20. Supplemental payments to nonstate government-owned or operated clinics.

a. In addition to payments for clinic services specified elsewhere in the regulations, DMAS provides supplemental payments to qualifying nonstate government-owned or government-operated clinics for outpatient services provided to Medicaid patients on or after July 2, 2002. Clinic means a facility that is not part of a hospital but is organized and operated to provide medical care to outpatients. Outpatient services include those furnished by or under the direction of a physician, dentist or other medical professional acting within the scope of his license to an eligible individual. Effective July 1, 2005, a qualifying clinic is a clinic operated by a community services board. The state share for supplemental clinic payments will be funded by general fund appropriations.

b. The amount of the supplemental payment made to each qualifying nonstate government-owned or government-operated clinic is determined by:

(1) Calculating for each clinic the annual difference between the upper payment limit attributed to each clinic according to subdivision 20 d of this subsection and the amount otherwise actually paid for the services by the Medicaid program;

(2) Dividing the difference determined in subdivision 20 b (1) of this subsection for each qualifying clinic by the aggregate difference for all such qualifying clinics; and

(3) Multiplying the proportion determined in subdivision 20 b (2) of this subsection by the aggregate upper payment limit amount for all such clinics as determined in accordance with 42 CFR 447.321 less all payments made to such clinics other than under this section.

c. Payments for furnished services made under this section will be made annually in a lump sum during the last quarter of the fiscal year.

d. To determine the aggregate upper payment limit referred to in subdivision 20 b (3) of this subsection, Medicaid payments to nonstate government-owned or government-operated clinics will be divided by the "additional factor" whose calculation is described in 12VAC30-80-190 B 2 in regard to the state agency fee schedule for Resource Based Relative Value Scale. Medicaid payments will be estimated using payments for dates of service from the prior fiscal year adjusted for expected claim payments. Additional adjustments will be made for any program changes in Medicare or Medicaid payments.

21. Personal assistance services (PAS) for individuals enrolled in the Medicaid Buy-In program described in 12VAC30-60-200. These services are reimbursed in accordance with the state agency fee schedule described in 12VAC30-80-190. The state agency fee schedule is published on the DMAS website at http://www.dmas.virginia.gov.

B. Hospice services payments must be no lower than the amounts using the same methodology used under Part A of Title XVIII, and take into account the room and board furnished by the facility, equal to at least 95% of the rate that would have been paid by the state under the plan for facility services in that facility for that individual. Hospice services shall be paid according to the location of the service delivery and not the location of the agency's home office.

12VAC30-80-36. Fee-for-service providers: outpatient hospitals.

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

"Enhanced ambulatory patient group" or "EAPG" means a defined group of outpatient procedures, encounters, or ancillary services that incorporates International Classification of Diseases (ICD) diagnosis codes, Current Procedural Terminology (CPT) codes, and Healthcare Common Procedure Coding System (HCPCS) codes.

"EAPG relative weight" means the expected average costs for each EAPG divided by the relative expected average costs for visits assigned to all EAPGs.

"Base year" means the state fiscal year for which data is used to establish the EAPG base rate. The base year will change when the EAPG payment system is rebased and recalibrated. In subsequent rebasings, DMAS shall notify affected providers of the base year to be used in this calculation.

"Cost" means the reported cost as described in 12VAC30-80-20 A and B.

"Cost-to-charge ratio" equals the hospital's total costs divided by the hospital's total charges. The cost-to-charge ratio shall be calculated using data from cost reports from hospital fiscal years ending in the state fiscal year used as the base year.

"Medicare wage index" means the Medicare wage index published annually in the Federal Register by the Centers for Medicare and Medicaid Services. The indices used in this section shall be those in effect in the base year.

B. Effective January 1, 2014, the prospective enhanced ambulatory patient group (EAPG) based payment system described in this subsection shall apply to reimbursement for outpatient hospital services (with the exception of laboratory

services referred to the hospital but not associated with an outpatient hospital visit, which will be reimbursed according to the laboratory fee schedule).

1. The payments for outpatient hospital visits shall be determined on the basis of a hospital-specific base rate per visit multiplied by the relative weight of the EAPG (and the payment action) assigned for each of the services performed during a hospital visit.

2. The EAPG relative weights shall be the weights determined and published periodically by DMAS and shall be consistent with applicable Medicaid reimbursement limits and policies. The weights shall be updated at least every three years.

3. The statewide base rate shall be equal to the total costs described in this subdivision divided by the wage-adjusted sum of the EAPG weights for each facility. The wage-adjusted sum of the EAPG weights shall equal the sum of the EAPG weights multiplied by the labor percentage times the hospital's Medicare wage index plus the sum of the EAPG weights multiplied by the nonlabor percentage. The base rate shall be determined for outpatient hospital services at least every three years so that total expenditures will equal the following:

a. When using base years prior to January 1, 2014, for all services, excluding all laboratory services and emergency services described in subdivision 3 c of this subsection, a percentage of costs as reported in the available cost reports for the base period for each type of hospital as defined in 12VAC30-70-221.

(1) Type One hospitals. Effective January 1, 2014, hospital outpatient operating reimbursement shall be calculated at 90.2% of cost, and capital reimbursement shall be at 86% of cost inflated to the rate year.

(2) Type Two hospitals. Effective January 1, 2014, hospital outpatient operating and capital reimbursement shall be calculated at 76% of cost inflated to the rate year.

When using base years after January 1, 2014, the percentages described in subdivision 3 a of this subsection shall be adjusted according to subdivision 3 c of this subsection.

b. Laboratory services, excluding laboratory services referred to the hospital but not associated with a hospital visit, are calculated at the fee schedule in effect for the rate year.

c. Services rendered in emergency departments determined to be nonemergencies as prescribed in 12VAC30-80-20 D 1 b shall be calculated at the nonemergency reduced rate reported in the base year for base years prior to January 1, 2014. For base years after January 1, 2014, the cost percentages in subdivision 3 a of this subsection shall be adjusted to reflect services paid at the nonemergency reduced rate in the last year prior to January 1, 2014.

4. Inflation adjustment to base year costs. Each July, the Virginia moving average values as compiled and published by Global Insight (or its successor), under contract with DMAS, shall be used to update the base year costs to the midpoint of the rate year. The most current table available prior to the effective date of the new rates shall be used to inflate base year amounts to the upcoming rate year. Thus, corrections made by Global Insight (or its successor) in the moving averages that were used to update rates for previous state fiscal years shall be automatically incorporated into the moving averages that are being used to update rates for the upcoming state fiscal year. Inflation shall be applied to the costs identified in subdivision 3 a of this subsection. The inflation adjustment for state fiscal year 2017 shall be 50% of the full inflation adjustment calculated according to this section. There shall be no inflation adjustment for state fiscal year 2018. A full inflation adjustment shall be made in both fiscal year 2017 and fiscal year 2018 to Virginia freestanding children's hospitals with greater than 50% Medicaid utilization in 2009.

5. Hospital-specific base rate. The hospital-specific base rate per case shall be adjusted for geographic variation. The hospital-specific base rate shall be equal to the labor portion of the statewide base rate multiplied by the hospital's Medicare wage index plus the nonlabor percentage of the statewide base rate. The labor percentage shall be determined at each rebasing based on the most recently reliable data. For rural hospitals, the hospital's Medicare wage index used to calculate the base rate shall be the Medicare wage index of the nearest metropolitan wage area or the effective Medicare wage index, whichever is higher. A base rate differential of 5.0% shall be established for freestanding Type Two children's hospitals. The base rate for non-cost-reporting hospitals shall be the average of the hospital-specific base rates of in-state Type Two hospitals.

6. The total payment shall represent the total allowable amount for a visit including ancillary services and capital.

7. The transition from cost-based reimbursement to EAPG reimbursement shall be transitioned over a four-year period. DMAS shall calculate a cost-based base rate at January 1, 2014, and at each rebasing during the transition.

a. Effective for dates of service on or after January 1, 2014, DMAS shall calculate the hospital-specific base rate as the sum of 75% of the cost-based base rate and 25% of the EAPG base rate.

b. Effective for dates of service on or after July 1, 2014, DMAS shall calculate the hospital-specific base rate as

the sum of 50% of the cost-based base rate and 50% of the EAPG base rate.

c. Effective for dates of service on or after July 1, 2015, DMAS shall calculate the hospital-specific base rate as the sum of 25% of the cost-based base rate and 75% of the EAPG base rate.

d. Effective for dates of service on or after July 1, 2016, DMAS shall calculate the hospital-specific base rate as the EAPG base rate.

8. To maintain budget neutrality during the first six years of the transition to EAPG reimbursement, DMAS shall compare the total reimbursement of hospital claims based on the parameters in subdivision 3 of this subsection to EAPG reimbursement every six months based on the six months of claims ending three months prior to the potential adjustment. If the percentage difference between the reimbursement target in subdivision 3 of this subsection and EAPG reimbursement is greater than 1.0%, plus or minus, DMAS shall adjust the statewide base rate by the percentage difference the following July 1 or January 1. The first possible adjustment would be January 1, 2015, using reimbursement between January 1, 2014, and October 31, 2014.

C. The enhanced ambulatory patient group (EAPG) grouper version used for outpatient hospital services shall be determined by DMAS. Providers or provider representatives shall be given notice prior to implementing a new grouper.

D. The primary data sources used in the development of the EAPG payment methodology are the DMAS hospital computerized claims history file and the cost report file. The claims history file captures available claims data from all enrolled, cost-reporting general acute care hospitals. The cost report file captures audited cost and charge data from all enrolled general acute care hospitals. The following table identifies key data elements that are used to develop the EAPG payment methodology. DMAS may supplement this data with similar data for Medicaid services furnished by managed care organizations if DMAS determines that it is reliable.

Data Elements for EAPG Payment Methodology	
Data Elements	Source
Total charges for each outpatient hospital visit	Claims history file
Number of groupable claims lines in each EAPG	Claims history file
Total number of groupable claim lines	Claims history file
Total charges for each outpatient hospital revenue line	Claims history file
Total number of EAPG assignments	Claims history file
Cost-to-charge ratio for each hospital	Cost report file
Medicare wage index for each hospital	Federal Register

VA.R. Doc. No. R18-5387; Filed June 18, 2018, 9:43 a.m.

TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF DENTISTRY

Proposed Regulation

Title of Regulation: **18VAC60-21. Regulations Governing the Practice of Dentistry (adding 18VAC60-21-101 through 18VAC60-21-106).**

Statutory Authority: §§ 54.1-2400 and 54.1-2708.4 of the Code of Virginia.

Public Hearing Information:

July 27, 2018 - 9 a.m. - Department of Health Professions, Perimeter Center, 9960 Mayland Drive, 2nd Floor, Richmond, VA 23233

Public Comment Deadline: September 7, 2018.

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.

Basis: Regulations are promulgated under the general authority of § 54.1-2400 of the Code of Virginia, which provides the Board of Dentistry the authority to promulgate regulations to administer the regulatory system. In addition, the board has been mandated to adopt regulations related to prescribing of opioids by § 54.1-2708.4 of the Code of Virginia.

Purpose: The purpose of the regulatory action is the establishment of requirements for prescribing of controlled substances containing opioids to address the overdose and addiction crisis in the Commonwealth. The goal is to provide dentists 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.

Substance: Regulations for the management of acute pain include requirements for the evaluation of the patient,

limitations on quantity and dosage, and recordkeeping. Management of chronic pain requires either referral to a pain management specialist or adherence to regulations of the Board of Medicine. All dentists who prescribe Schedules II through IV drugs are required to take two hours of continuing education on pain management.

Issues: The primary advantage to the public is a reduction in the amount of opioid medication that is available in our 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. There are no disadvantages to the public; dentists prescribing for chronic pain must follow the regulations as those for Board of Medicine. 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.

The Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. Pursuant to Chapters 291[1] and 682[2] of the 2017 Acts of Assembly, the Board of Dentistry (Board) proposes a new regulation for the prescription of opioids in the management of acute and chronic pain. This regulation will replace an emergency regulation that became effective on April 24, 2017, and that is currently set to expire on October 23, 2018.

Result of Analysis. There are 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 2017 Acts of the Assembly became law. Each Chapter requires the Board of Dentistry to promulgate regulations for prescription of opioids.

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."

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."

This proposed regulation will apply to all dentists.

Requirements in the Proposed Regulation.

Requirements for Evaluation of the Patient in Prescribing for Acute Pain: For the evaluation of the patient, the regulation (section 102) requires that the dentist: (1) consider nonpharmacologic and non-opioid treatment for pain prior to treatment with opioids, (2) take a health history, (3) perform a physical examination appropriate for the complaint, (4) assess the patient's history and risk of substance abuse, and (5) query the state's Prescription Monitoring Program (PMP) as set forth in § 54.1-2522.1. Section 54.2522.1 requires queries when initiating a new course of treatment in which an opioid prescription is anticipated to last more than seven consecutive days. That section also provides that a prescriber may make additional queries "as may be required by routine prescribing practices."

Requirements for Treatment of Acute Pain with Opioids: The Board proposes to limit opioid prescriptions for all acute care to the lowest effective dose, and for no more than seven days unless extenuating circumstances are clearly documented. The Board also proposes to require that, "practitioners shall carefully consider and document in the medical record the reasons to exceed 50 MME/day"[3] 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." Dentists will be required to prescribe naloxone[4] "when risk factors of prior overdose, substance misuse, doses in excess of 120 MME/day, or concomitant benzodiazepine is present." Finally, dentists will also be required to limit co-prescribing of drugs that may increase the risk of accidental overdose when taken with opioids.

If another prescription for an opioid is to be written beyond seven days, the Board also proposes (in section 103) to require that the patient be re-evaluated and that a check of the PMP be run for the patient's prescription history. The Board 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 the Treatment of Chronic Pain: For treatment of chronic pain, the Board proposes to require that dentists either refer a patient to a medical doctor who is a pain management specialist or comply with the Board of Medicine's regulation, 18VAC85-21-60 through 18VAC85-21-120. Board staff reports that although very few dentists treat chronic pain, oral and maxillofacial surgeons may occasionally treat chronic pain.

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 restrictions on medicine dosages, preferences for non-opioid treatments, and use of the PMP. Except for the estimated costs directly resulting from mandatory drug testing (listed in Board of Medicine rules for treatment of chronic pain), 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 abuse, including drug addiction, savings or cost avoidance could be achieved from reduction in expenditures on the treatment of, and consequences from, substance abuse. 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 pain[5] or a shift to illicit drugs.[6]

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. This regulation proposes to require PMP queries as set forth in § 54.1-2522.1 of the Code of Virginia prior to initiating treatment with opioids and PMP queries "if another prescription for an opioid is to be written beyond seven days." To the extent that the regulation is also interpreted to require PMP checks for all prescriptions, as a "routine prescribing practice" (rather than just prescriptions anticipated to last more than seven continuous days), practitioners may incur additional time costs for running those queries. 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 for dental practices; 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 dentists in an acute care setting perform a risk assessment for substance misuse 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 abuse, costs would be incurred for their time to perform such assessments.

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 2016 Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain,[7] 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.

Direct Benefits and Costs of Rules for Treating Chronic Pain: Very few dentists will likely treat chronic pain. To the extent that they do, they will be required to follow Board of Medicine rules for such treatment. An analysis of the benefits and costs for the Board of Medicine's rules for chronic pain treatment can be found on the Virginia Regulatory Town Hall.[8]

Businesses and Entities Affected. These proposed regulatory changes will affect all 7,127 dentists currently licensed in the Commonwealth as well as any individuals who will be licensed as dentists in the future. Board staff report that the vast majority of these dentists are small businesses. These proposed regulations will also affect all dental patients who require acute or chronic pain management. Health insurance providers may also be affected.

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

Projected Impact on Employment. To the extent that these proposed regulatory changes lead to fewer individuals being effectively treated for chronic pain, employee absenteeism may increase, which would tend to depress total productivity. To the extent that this regulation reduces rates of addiction, thereby allowing former addicts to hold employment, productivity may 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. Small business dentists will likely incur increased costs associated with book keeping, staff wages, increased documentation requirements, and new drug testing requirements for chronic pain patients that will be enforced. 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. It is unclear to what extent these costs or savings may be passed on to insurance companies, patients, or other third parties.

Alternative Method that Minimizes Adverse Impact. Allowing dentists the discretion as to whether and how often to use drug testing would likely decrease the costs listed above. As noted above, the CDC only recommends that practitioners "consider" drug testing on an annual basis after the initial screen. For both the initial UDS and subsequent testing, however, it appears that the CDC concludes that practitioners should retain the discretion to determine whether to administer a test. The CDC notes that the recommendation to use drug testing is a Category B recommendation, which is one where "different choices will be appropriate for different patients, so clinicians must help patients arrive at a decision consistent with patient values and preferences, and specific clinical situations."[9]

Adverse Impacts:

Businesses: Dentists 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. It is unclear to what extent these costs may be passed on to insurance companies, patients, or other third parties.

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

Other Entities: To the extent that dentists treat chronic-pain patients, this proposed regulation may lead to those patients, or their insurance companies, incurring increased annual costs on account of drug testing requirements. To the extent that treatment by oral and maxillofacial surgeons is covered by health insurance or dental insurance, the Commonwealth of Virginia may incur increased costs on account of these proposed regulatory changes, including employee health benefits, and the Department of Medical Assistance Services may incur increased costs for Medicaid patients who are in treatment for chronic pain.

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Dowell Deborah, Tamara M Haegerich, Roger Chou. CDC Guideline for Prescribing Opioids for Chronic Pain. United States. 2016. MMWR Recomm Rep 2016; 65 (No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1.

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

[2]http://leg1.state.va.us/cgi-bin/legp504.exe?171+ful+CHAP0682.

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

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

[5]Institute 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.

[6]Today's fentanyl crisis: Prohibition's Iron Law, revisited, International Journal of Drug Policy 46 (2017) 156–159.

[7]https://www.cdc.gov/drugoverdose/prescribing/guideline.html.

[8]http://townhall.virginia.gov/L/GetFile.cfm?File=C:\TownHall\docroot\26\4760\7981\EIA_DHP_7981_v2.pdf.

[9]CDC Guideline, page 4.

Agency's Response to Economic Impact Analysis: The Board of Dentistry and the Department of Health Professions do not concur with the result of the analysis that "there is insufficient data to accurately compare the magnitude of the benefits versus the costs." We believe it 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 (CPDs) 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 economic impact analysis (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/research-reports/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 regulations there has been a drop in morphine milligram equivalents (MME). 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 (CDC) indicates 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 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.

Summary:

The proposed regulatory action adopts requirements for the prescribing of opioids and products containing buprenorphine pursuant to Chapters 291 and 682 of the 2017 Acts of Assembly. Provisions for the management of acute pain include requirements for the evaluation of the patient, limitations on quantity and dosage, and recordkeeping. A dentist who manages a patient with chronic pain must either refer the patient to a pain management specialist or adhere to the regulations of the Board of Medicine. All dentists who prescribe Schedules II through IV controlled substances are required to complete two hours of continuing education in pain management. The proposed regulations replace emergency regulations currently in effect.

Part III
Prescribing for Pain Management

18VAC60-21-101. Definitions.

The following words and terms when used in this part 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.

"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.

"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.

18VAC60-21-102. Evaluation of the patient in prescribing for acute pain.

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 dentist shall follow the regulations for prescribing and treating with opioids in 18VAC60-21-103 and 18VAC60-21-104.

B. Prior to initiating treatment with a controlled substance containing an opioid for a complaint of acute pain, the dentist shall perform a health 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 abuse.

18VAC60-21-103. Treatment of acute pain with opioids.

A. Initiation of opioid treatment for all patients with acute pain shall include the following:

1. A prescription for an opioid shall be a short-acting opioid in the lowest effective dose for the fewest number of days, not to exceed seven days as determined by the manufacturer's directions for use, unless extenuating circumstances are clearly documented in the patient record.

2. The dentist shall carefully consider and document in the patient record the reasons to exceed 50 MME per day.

3. Prior to exceeding 120 MME per day, the dentist shall refer the patient to or consult with a pain management

specialist and document in the patient record the reasonable justification for such dosage.

4. Naloxone shall be prescribed for any patient when there is any risk factor of prior overdose, substance abuse, or doses in excess of 120 MME per day, and shall be considered when concomitant use of benzodiazepine is present.

B. If another prescription for an opioid is to be written beyond seven days, the dentist shall:

1. Reevaluate the patient and document in the patient record the continued need for an opioid prescription; and

2. Check the patient's prescription history in the Prescription Monitoring Program.

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

18VAC60-21-104. Patient recordkeeping requirement in prescribing for acute pain.

The patient 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, including date, type, dosage, strength, and quantity prescribed.

18VAC60-21-105. Prescribing of opioids for chronic pain.

If a dentist treats a patient for whom an opioid prescription is necessary for chronic pain, the dentist shall either:

1. Refer the patient to a medical doctor who is a pain management specialist; or

2. Comply with regulations of the Board of Medicine, 18VAC85-21-60 through 18VAC85-21-120, if the dentist chooses to manage the chronic pain with an opioid prescription.

18VAC60-21-106. Continuing education required for prescribers.

Any dentist who prescribes Schedules II through IV controlled substances after April 24, 2017, shall obtain two hours of continuing education on pain management, which must be taken by March 31, 2019. Thereafter, any dentist who prescribes Schedules II through IV controlled substances shall obtain two hours of continuing education on pain management every two years. Continuing education hours required for prescribing of controlled substances may be included in the 15 hours required for renewal of licensure.

VA.R. Doc. No. R17-5064; Filed June 15, 2018, 12:27 p.m.

BOARD OF MEDICINE

Final 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.

Effective Date: August 8, 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.

Summary:

The 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. Provisions for the management of acute pain include requirements for the evaluation of the patient, limitations on quantity and dosage, and medical recordkeeping. Provisions 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. Provisions 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. Changes since the proposed regulation was published include (i) adding treatment for pain associated with sickle cell as an exception to the regulations, (ii) adding information regarding the nature of tramadol each time that drug is listed, and (iii) changing the requirement for drug testing following the first year of chronic pain management to be consistent with that of the Centers for Disease Control and Prevention.

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

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) [sickle cell, (iii)] a patient in hospice care, or [~~(iii)~~ (iv)] 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 [(an atypical opioid)], 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;

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 [(an atypical opioid)], 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~~ thereafter randomly at the discretion of the practitioner but] at least [~~every six months thereafter~~ once a year].

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 waivered 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.

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 [(an atypical opioid)], 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, [and] 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 June 15, 2018, 12:29 p.m.

BOARD OF NURSING

Proposed Regulation

Titles of Regulations: **18VAC90-30. Regulations Governing the Licensure of Nurse Practitioners (amending 18VAC90-30-220).**

18VAC90-40. Regulations for Prescriptive Authority for Nurse Practitioners (amending 18VAC90-40-10; adding 18VAC90-40-150 through 18VAC90-40-290).

Statutory Authority: §§ 54.1-2400 and 54.1-2957 of the Code of Virginia.

Public Hearing Information:

July 19, 2018 - 10 am - Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Suite 201, Board Room 2, Richmond, VA 23233

Public Comment Deadline: September 7, 2018.

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

Basis: Regulations are promulgated under the general authority of § 54.1-2400 of the Code of Virginia, which provides the Boards of Nursing and Medicine the authority to promulgate regulations to administer the regulatory system.

In addition, Chapters 291 and 682 of the 2017 Acts of Assembly require adoption of regulations for the prescribing of opioids and products containing buprenorphine.

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. The goal is to provide prescribers with definitive rules to follow so they may feel more assured of their ability to treat pain in an appropriate manner to avoid under-prescribing or over-prescribing.

Substance: The regulations establish the practitioners to whom the rules apply and exceptions or nonapplicability. Provisions for the management of acute pain include requirements for the evaluation of the patient, limitations on quantity and dosage, and medical recordkeeping. Provisions 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. Provisions 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 our 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 and nurse practitioners 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.

The Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. The Board of Nursing (Board) proposes amendments to regulations that govern the licensure and prescriptive authority for nurse practitioners that will set rules 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.[1] These proposed regulations will replace emergency regulations that became effective May 8, 2017 and that are currently set to expire on November 7, 2018.

Result of Analysis. There are 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 legislation enacted by the 2017 General Assembly which required the Boards of Medicine and Dentistry to adopt regulations governing opioid prescription, 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. Each Chapter requires the Boards of Medicine and Dentistry to promulgate regulations for prescription of opioids.

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 containing an opioid 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 containing an opioid may be prescribed for a period of greater than three months."

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."

Although the Board of Nursing is not required to promulgate regulations under these Chapters, the Board of Nursing proposes regulations that are mostly consistent with those adopted by the Board of Medicine in order to "address the opioid crisis in Virginia"[2] and to make rules for prescribing consistent across prescribers.

Each proposed regulation includes exemptions to the new prescribing rules, specifying the circumstances under which they do not apply.[3] However, because of drafting differences these exemptions are presented in different ways. The Board of Medicine's action proposed an entirely new Chapter, and the exemptions apply to each part therein. In contrast, the Board of Nursing's action proposes amendments to two existing Chapters, and the exemptions apply only to certain parts therein. Accordingly, the exemptions do not apply to Part VII (Prescribing of Buprenorphine). Board staff state that this has no substantive effect, because buprenorphine can only be used for office-based opioid addiction treatment.

Requirements in the Proposed Regulation.

Requirements for Acute Pain Treatment: For the treatment of acute pain, the Board proposes to require that the prescriber: (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 period[4] 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 nonpharmacologic[5] and non-opioid treatments[6] "prior to treatment with opioids." Second, practitioners will be required to query the state's Prescription Monitoring Program (PMP), as set forth in § 54.1-2522.1, which requires queries when initiating a new course of treatment in which an opioid prescription is anticipated to last more than seven consecutive days. That section also provides that a prescriber may make additional queries "as may be required by routine prescribing practices." For acute pain treatment, a query will occur prior to initiating treatment. 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"[7] 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 naloxone[8] "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-product[9] 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 U.S. Food and Drug Administration, 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 buprenorphine, preferences for non-opioid treatments, and use of the PMP. Except for the estimated costs directly resulting from mandatory drug testing, and potential savings from decreased use of opioids in the state's Medicaid program, there are 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.[10] 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 pain[11] or a shift to illicit drugs.[12]

Direct Benefits and Costs of Drug Testing: Drug testing, typically through a urine drug screen (UDS) appears to confer direct benefits on practitioners and a subset of patients, if confirmed test results are used to correctly refer them for substance misuse treatment or identify non-adherence to their treatment plan. As noted by the Centers for Disease Control and Prevention's (CDC) 2016 Guideline for Prescribing Opioids for Chronic Pain ("Guideline"), a UDS can: provide information about drug use that is not reported by the patient, including controlled substances and illicit drugs that increase risk for overdose when combined with opioids such as nonprescribed opioids, benzodiazepines, and heroin; assist clinicians in identifying when patients are not taking opioids prescribed for them, which might in some cases indicate diversion or other clinically important issues such as difficulties with adverse effects; and provide useful information about patients assumed not to be using unreported drugs.[13] 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."[14]

Monitoring urine toxicology also can help practitioners comply with federal Drug Enforcement Agency requirements, which require practitioners to minimize abuse and diversion.[15]

However, quantitative data on the value of these benefits does not appear to be readily available. Moreover, because false positive and false negative test results are known to occur (discussed below), full realization of the benefits of UDS may require utilization of both an initial immunoassay (dipstick) test in a practitioner's office followed by a confirmatory gas chromatography/mass spectrometry or high-performance liquid chromatography test (collectively referred to as GC/MS in this analysis) in a laboratory.

In order to quantify the costs of drug testing, the number of patients that 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.[16] 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."[17] 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),[18] that indicates that 3 to 4 percent of the adult population were prescribed longer-term opioid therapy.[19] (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.

Table 1

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.[20] 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 test results have been reported for certain antibiotics (quinolones and ofloxacin), certain antidepressants and antipsychotics, the hypertension medication Verapamil, as well as over-the-counter medications containing dextromethorphan, ibuprofen and naproxen.[21]

Although re-testing is recommended by the CDC's Guideline, testing without confirmatory GC/MS testing may have unintended adverse 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."[22]

Of note, the CDC Guideline also only recommends initial drug testing before treatment, and states that clinicians should "consider" drug testing on an annual basis thereafter:

> "While experts agreed that clinicians should use urine drug testing before initiating opioid therapy for chronic pain, they disagreed on how frequently urine drug testing should be conducted during long-term opioid therapy. Most experts agreed that urine drug testing at least annually for all patients was reasonable."

For both the initial UDS and subsequent testing, however, it appears that the CDC concludes that practitioners should retain the discretion to determine whether to administer a test. The CDC notes that the recommendation to use drug testing is a Category B recommendation, which is one where "different choices will be appropriate for different patients, so clinicians must help patients arrive at a decision consistent with patient values and preferences, and specific clinical situations."[23]

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."[24] 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.[25] When urine tests have unexpected results, the CDC Guideline recommends 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."[26] 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.[27]

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 (positive or negative) cannot be explained. Board staff report that these actions could include referral for substance abuse counseling or release from care (with the patient being given a reasonable amount of time to find a new health care practitioner).[28] Although board staff noted that the retesting could be accomplished by administering another dipstick test, repeated dipstick tests may not yield different results. For instance, unexpected positive test results can be caused by various classes of non-narcotic prescription and over-the-counter medications, and unexpected negative results can result from individual rapid metabolism rates. In instances where unexpected results are caused by confounding factors (rather than random test error), repeated dipstick test would be unlikely to yield different results. Additionally, the CDC Guideline calls for use of GC/MS testing to confirm dipstick test results.

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."

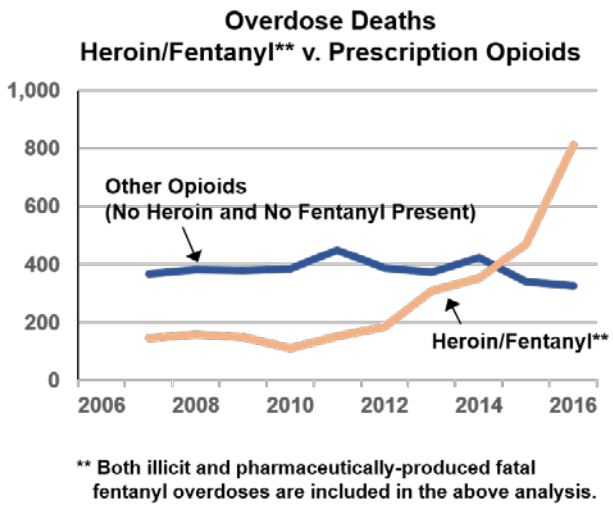
Board staff appear to agree with this guidance, adding that a patient could also be released from care if they do not comply with the treatment plan.[29] However, the Board has stated that patients should not be abandoned. As noted in a letter from the Board to practitioners:

> "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."[30]

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. Thus certain patients may stop pursuing opioid therapy, including those who test positive for unexpected substances and those who do not.[31] 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,"[32] 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."[33] Thus an additional unintended consequence of the regulations may be a shift in demand from legal prescriptions to illegal street drugs, including heroin and illicitly-produced fentanyl (in combination or separately). As noted in a recent issue of the International Journal of Drug Policy, "prescribing restrictions forced a minority of dependent users to more potent and available street heroin."[34] The federal Drug Enforcement Administration notes that "fentanyl can serve as substitute for heroin in opioid dependent individuals."[35]

As noted by the Board, "the purpose of the regulations is, in part, to assist physicians in treating opioid dependent patients."[36] 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."[37] (This trend is illustrated in the figure below.) Notwithstanding the increase in deaths from fentanyl, on average more than 400 fatalities still result in part from prescription opioids each year.[38]



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) reports 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.[39]

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 disproportionally 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. 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 the regulation is also interpreted to require PMP checks for all prescriptions, as a "routine prescribing practice" (rather than just prescriptions anticipated to last more than seven continuous days), practitioners may incur additional time costs for running those queries.

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. Additionally, to the extent that use of the PMP lowers the number of doses of opioids, the new requirement will provide the benefit of reducing the risk from use of opioids. The Department of Health Professions (DHP), citing the CDC, indicates that individuals taking greater than 90 MME/day are at a higher risk of overdose and death. DHP

adds that since the adoption of emergency regulation, PMP data indicate that "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."[40]

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 practitioners in an acute care setting perform a risk assessment for substance misuse[41] on all patients who may be prescribed opioids may not presently be a part of standard patient care. To the extent that practitioners 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 6,547 nurse practitioners licensed in the Commonwealth as well as their employers. Board staff reports that many nurse practitioners are employed by large entities that would not qualify as small businesses. Some nurse practitioners are employed by small medical practices that would qualify as small businesses. 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. 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, the changes contained in this proposed regulation will likely affect at least hundreds of thousands of chronic care patients in Virginia, and may affect as many as several million, depending upon the extent to which they seek opioid therapy.

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

Projected Impact on Employment. To the extent that these proposed regulatory changes lead to fewer individuals being effectively treated for chronic pain, employee absenteeism may increase, which would tend to depress total productivity. To the extent that this regulation reduces rates of addiction, which may allow former addicts to hold employment, 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. To the extent that these firms include nurse practitioners who would be affected by these proposed regulation, they will likely 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. Allowing doctors, and the nurse practitioners who work with them, the discretion as to whether and how often to use drug testing would likely decrease the costs listed above. As noted above, the CDC only recommends that practitioners "consider" drug testing on an annual basis after the initial screen.

Adverse Impacts:

Businesses. Doctors who employ nurse practitioners may incur increased costs and 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, will likely incur 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 Department of Human Resource Management reports that the Commonwealth of Virginia will likely incur increased employee health benefits costs because of these proposed regulatory changes, including additional costs for drug testing. The Department of Medical Assistance Services

(DMAS) may incur increased costs for Medicaid patients who are in treatment for chronic pain or who are undergoing addiction treatment with buprenorphine. These latter costs may be offset to some degree by reductions in expenditures on prescription opioids, according to DHP, which reports that DMAS has experienced "an annual reduction in drug spending on opioids of approximately $466,000."[42] The Department of Corrections may incur increased costs for drug testing and limitations on prescribing of buprenorphine for prisoners housed in prisons statewide.

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[1]This regulation was developed by a regulatory advisory panel (RAP) chaired by the president of the Board of Medicine and including two addiction specialists, a pain management specialist, and the Chief Medical Officer for the Department of Medical Assistance Services. The RAP met in January 2017 to draft regulations, which were then recommended by the Legislative Committee of the Board of Medicine in late January. The Committee of the Joint Boards of Nursing and Medicine reviewed the draft regulations at its meeting in February 2017, prior to their adoption by the Board of Medicine and the Board of Nursing.

[2]http://townhall.virginia.gov/l/GetFile.cfm?File=C:\TownHall\docroot\27\4797\8063\AgencyStatement_DHP_8063_v1.pdf.

[3]The exemptions are (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 and (3) a patient enrolled in a clinical trial authorized by state or federal law.

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

[5]These treatments can include such things as physical therapy, chiropractic care and acupuncture.

[6]The Centers for Disease Control and Prevention's 2016 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.

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

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

[9]Buprenorphine 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.

[10]Florence, 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.

[11]Institute 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.

[12]Today's fentanyl crisis: Prohibition's Iron Law, revisited, International Journal of Drug Policy 46 (2017) 156–159.

[13]CDC Guideline, pages 30-31; https://www.cdc.gov/drugoverdose/prescribing/guideline.html.

[14]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.

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

[16]Nahin, 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).

[17]Institutes of Medicine 2011 (p. 62).

[18]Boudreau, et al., Trends in De-facto Long-term Opioid Therapy for Chronic Non-Cancer Pain, Pharmacoepidemiol Drug Safety. 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."

[19]Defined 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.

[20]A 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.

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

[22]Brahm, et al.

[23]CDC Guideline, page 4.

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

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

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

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

[28]Board staff reports that the "reasonable time" would vary according to the availability of other health care options but would be at least 30 days.

[29]In 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.

[30]https://www.dhp.virginia.gov/medicine/newsletters/OpioidPrescribingBuprenorphine03142017.pdf.

[31]Krishnamurthy 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.

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

[33]Today's fentanyl crisis: Prohibition's Iron Law, revisited, International Journal of Drug Policy 46 (2017) 156–159.

[34]Fentanyl in the US heroin supply: A rapidly changing risk environment, International Journal of Drug Policy 46 (2017) 107–111.

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

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

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

[38]The OCME notes that drug-related deaths often have more than one drug causing or contributing to death. Therefore, some of the deaths attributed to prescription opioids and fentanyl may have multiple drugs on board.

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

[40]http://townhall.virginia.gov/L/GetFile.cfm?File=C:\TownHall\docroot\26\4760\7981\EIARes_DHP_7981_v1.pdf.

[41]The term "substance misuse" is not defined in the proposed regulation.

[42]http://townhall.virginia.gov/L/GetFile.cfm?File=C:\TownHall\docroot\26\4760\7981\EIARes_DHP_7981_v1.pdf.

Agency's Response to Economic Impact Analysis: The Boards of Nursing and Medicine and the Department of Health Professions do not concur with the result of the analysis 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 it 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 (CPDs) 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 economic impact analysis (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/research reports/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). 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 (CDC) indicate that individuals taking greater than 90 MME per 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 per 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 an 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 Assistanc 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 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.

Summary:

The proposed amendments establish the practitioners to whom the regulations apply and exceptions or nonapplicability. Provisions for the management of acute pain include requirements for the evaluation of the patient, limitations on quantity and dosage, and recordkeeping. Provisions 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. Provisions 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. The proposed amendments replace emergency regulations currently in effect.

Part IV
Disciplinary Provisions

18VAC90-30-220. Grounds for disciplinary action against the license of a licensed nurse practitioner.

The boards may deny licensure or relicensure, revoke or suspend the license, or take other disciplinary action upon proof that the nurse practitioner:

1. Has had a license or multistate privilege to practice nursing in this Commonwealth or in another jurisdiction revoked or suspended or otherwise disciplined;

2. Has directly or indirectly represented to the public that the nurse practitioner is a physician, or is able to, or will practice independently of a physician;

3. Has exceeded the authority as a licensed nurse practitioner;

4. Has violated or cooperated in the violation of the laws or regulations governing the practice of medicine, nursing or nurse practitioners;

5. Has become unable to practice with reasonable skill and safety to patients as the result of a physical or mental illness or the excessive use of alcohol, drugs, narcotics, chemicals or any other type of material;

6. Has violated or cooperated with others in violating or attempting to violate any law or regulation, state or federal, relating to the possession, use, dispensing, administration or distribution of drugs; ~~or~~

7. Has failed to comply with continuing competency requirements as set forth in 18VAC90-30-105;

8. Has willfully or negligently breached the confidentiality between a practitioner and a patient. A breach of confidentiality that is required or permitted by applicable law or beyond the control of the practitioner shall not be considered negligent or willful; or

9. Has engaged in unauthorized use or disclosure of confidential information received from the Prescription Monitoring Program, the electronic system within the Department of Health Professions that monitors the dispensing of certain controlled substances.

Part I
General Provisions

18VAC90-40-10. 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 containing an opioid may be prescribed for no more than three months.

"Boards" means the Virginia Board of Medicine and the Virginia Board of Nursing.

"Certified nurse midwife" means an advanced practice registered nurse who is certified in the specialty of nurse midwifery and who is jointly licensed by the Boards of Medicine and Nursing as a nurse practitioner pursuant to § 54.1-2957 of the Code of Virginia.

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

"Committee" means the Committee of the Joint Boards of Nursing and Medicine.

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

"MME" means morphine milligram equivalent.

"Nonprofit health care clinics or programs" means a clinic organized in whole or in part for the delivery of health care services without charge or when a reasonable minimum fee is charged only to cover administrative costs.

"Nurse practitioner" means an advanced practice registered nurse who has met the requirements for licensure as a nurse practitioner as stated in 18VAC90-30.

"Practice agreement" means a written or electronic agreement jointly developed by the patient care team physician and the nurse practitioner for the practice of the nurse practitioner that also describes the prescriptive authority of the nurse practitioner, if applicable. For a nurse practitioner licensed in the category of certified nurse midwife, the practice agreement is a statement jointly developed with the consulting physician.

"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 V
Management of Acute Pain

18VAC90-40-150. Evaluation of the patient for acute pain.

A. The requirements of this part shall not apply to:

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

2. The treatment of acute 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.

B. 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.

C. 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 as a part of the initial evaluation.

18VAC90-40-160. 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 a patient with 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 per day.

2. Prior to exceeding 120 MME per 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 per day, or concomitant benzodiazepine are present.

C. Due to a higher risk of fatal overdose when opioids are used 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.

18VAC90-40-170. 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 VI
Management of Chronic Pain

18VAC90-40-180. Evaluation of the chronic pain patient.

A. The requirements of this part shall not apply to:

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

2. The treatment of 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.

B. 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;

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 histories 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.

C. Prior to initiating opioid analgesia 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.

18VAC90-40-190. 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 opioid treatment for all patients, the practitioner shall:

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

2. Prior to exceeding 120 MME per 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 per 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 if these medications are prescribed.

E. The practitioner shall regularly evaluate for opioid use disorder and 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.

18VAC90-40-200. 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 record in the medical records the presence or absence of any indicators for medication misuse or diversion and take appropriate action.

18VAC90-40-210. Informed consent and agreement for treatment of 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 screen 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.

18VAC90-40-220. 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 or 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 the 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. Practitioners 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 shall regularly evaluate for opioid use disorder and 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.

18VAC90-40-230. Additional consultation.

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

B. When a practitioner 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.

18VAC90-40-240. Medical records.

The prescriber shall keep current, accurate, and complete records in an accessible manner and 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 VII
Prescribing of Buprenorphine

18VAC90-40-250. General provisions.

A. Practitioners engaged in office-based opioid addiction treatment with buprenorphine shall have obtained a waiver from SAMHSA 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. Nurse practitioners who have obtained a SAMHSA waiver shall only prescribe buprenorphine for opioid addiction pursuant to a practice agreement with a SAMHSA-waivered 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.

18VAC90-40-260. Patient assessment and treatment planning.

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 practitioner.

18VAC90-40-270. Treatment with buprenorphine.

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.

B. Buprenorphine mono-product tablets may be administered directly to patients in federally licensed opiate 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 abuse counseling.

18VAC90-40-280. Special populations.

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, and 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 practitioner to be psychiatrically unstable shall be referred for psychiatric evaluation and treatment prior to initiating medication-assisted treatment.

18VAC90-40-290. 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.

VA.R. Doc. No. R17-5096; Filed June 15, 2018, 12:47 p.m.

BOARD OF PHARMACY

Proposed Regulation

Title of Regulation: **18VAC110-20. Regulations Governing the Practice of Pharmacy (amending 18VAC110-20-690, 18VAC110-20-700, 18VAC110-20-710; adding 18VAC110-20-735).**

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

Public Hearing Information:

August 23, 2018 - 9:30 a.m. - Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Suite 201, Richmond, VA 23233

Public Comment Deadline: September 7, 2018.

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

Basis: Regulations are promulgated under the general authority of § 54.1-2400 of the Code of Virginia, which provides the Board of Pharmacy the authority to promulgate regulations to administer the regulatory system. The specific authority of the board to issue controlled substance registrations (CSRs) to the entities specified in the amended regulations is found in §§ 54.1-3408 and 54.1-3423 of the Code of Virginia.

Purpose: The primary purpose of the proposed amendments to regulations for a controlled substances registration is to address the mental health needs and opioid crisis in the Commonwealth. The goal of the amendments allowing entities, such as community services boards, to serve as the point of contact for telemedicine is to increase access to psychiatric services in more rural parts of the state where those specialty practices are few and far between. The goal of the amendments allowing community trainers to obtain a CSR is to increase access to naloxone by allowing people other than pharmacists to dispense the drug. Some nonprofit organizations that are authorized by the Department of Behavioral Health and Developmental Services to provide training to persons in the community have been successful in obtaining resources to purchase naloxone at a reduced rate.

However, under current law, they cannot store it or dispense it. Allowing these community organizations to dispense the medication will promote access to this lifesaving drug.

In spite of recent efforts to facilitate access to naloxone, which has proven to save lives, the number of deaths related to opioid overdose continues to rise. The primary purpose of the proposed amendments is to increase access to naloxone by allowing people other than pharmacists to dispense the drug. Likewise, to address a problem with teleprescribing of psychiatric drugs by a clinic at the University of Virginia Hospital, the solution for continuation of those services appears to be issuance of a CSR to a community services board where the examination and treatment can occur in accordance with state and federal law and regulation, and the practitioner-patient relationship can be established for the purpose of prescribing. Both uses of a CSR are intended to address the critical needs for mental health treatment and dispensing of a medication that saves lives in an overdose crisis. Regulations are crafted to increase access to psychiatric medications and naloxone without unnecessarily and unduly compromising the board's requirements for drug safety and integrity.

Substance: This proposed action replaces emergency regulations, which were adopted to authorize issuance of a controlled substances registration to (i) persons who have been trained in the administration of naloxone in order to possess and dispense the drug to persons receiving training and (ii) an entity for the purpose of establishing a bona fide practitioner-patient relationship for prescribing when treatment is provided by telemedicine in accordance with federal rules. As applicable, regulations for controlled substances registrants are amended to include recordkeeping, security, and storage requirements.

Issues: The primary advantage to the public is the potential for more availability of naloxone for persons who have been trained in its use or for the possibility of telemedicine and teleprescribing for patients in underserved areas who may be receiving care via instrumentation and diagnostic equipment. There are no disadvantages to the public. There are no advantages or disadvantages to the agency.

The Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. Pursuant to Chapters 55 and 58 of the 2017 Acts of the Assembly, the Board of Pharmacy (Board) proposes to amend their regulation to allow the issuance of controlled substances registration to: "1) persons who have been trained in the administration of naloxone in order to possess and dispense the drug to persons receiving training and 2) an entity for the purpose of establishing a bona fide practitioner-patient relationship for prescribing when treatment is provided by telemedicine in accordance with federal rules." These proposed regulatory amendments will replace emergency amendments that became effective May 8, 2017 and that are currently set to expire on November 7, 2018.

Result of Analysis. Benefits likely outweigh costs for all proposed changes.

Estimated Economic Impact. In 2017, Chapters 55 and 58 became law. As reported by the Board of Pharmacy, Chapter 55:[1]

> "Allows a person who is authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone for use in opioid overdose reversal and who is acting on behalf of an organization that provides services to individuals at risk of experiencing opioid overdose or training in the administration of naloxone for overdose reversal and that has obtained a controlled substances registration from the Board of Pharmacy pursuant to § 54.1-3423 to dispense naloxone to a person who has completed a training program on the administration of naloxone for opioid overdose reversal, provided that such dispensing is (i) pursuant to a standing order issued by a prescriber, (ii) in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, and (iii) without charge or compensation. The bill also provides that dispensing may occur at a site other than that of the controlled substance registration, provided that the entity possessing the controlled substance registration maintains records in accordance with regulations of the Board of Pharmacy."

Chapter 58:[2]

> "Provides that a health care practitioner who performs or has performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment[3], for the purpose of establishing a bona fide practitioner-patient relationship may prescribe Schedule II through VI controlled substances to the patient, provided that the prescribing of such controlled substance is in compliance with federal requirements for the practice of telemedicine. The bill also authorizes the Board of Pharmacy to register an entity at which a patient is treated by the use of instrumentation and diagnostic equipment for the purpose of establishing a bona fide practitioner-patient relationship and is prescribed Schedule II through VI controlled substances to possess and administer Schedule II through VI controlled substances when such prescribing is in compliance with federal requirements for the practice of telemedicine and the patient is not in the physical presence of a practitioner registered with the U.S. Drug Enforcement Administration."

Both of these Chapters contain language requiring the Board to promulgate emergency regulations to implement their mandates. The Board promulgated emergency regulations that

became effective May 8, 2017, and that are currently set to expire on November 7, 2018.

The Board now proposes to promulgate regulatory amendments to replace the emergency amendments that are currently in place. The proposed language is identical to the emergency language that is currently effective. In addition to allowing the issuance of controlled substances registration to entities listed in Chapters 55 and 58, the Board's proposed regulation sets rules for recordkeeping as required by Chapter 55. Specifically, "persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal…" will have to maintain records that include: 1) the prescriber's standing order authorizing the trained individual to dispense naloxone; 2) invoices or other records showing receipt of naloxone;[4] 3) a manual or electronic log that records the name, strength, lot, expiration date and quantity of naloxone transferred from the controlled substances registration location to the off-site training location along with the date of transfer and the name of the trained individual approved by the Department of Behavioral Health and Developmental Services; and 4) records for dispensing of naloxone that when and to whom naloxone was dispensed. Records will have to be filed chronologically and maintained for at least two years.

Individuals who newly qualify for controlled substances registration, and who choose to get and maintain that registration, will incur an initial fee of $90 and a renewal fee of $90 every year thereafter. Additionally, individuals who are subject to the recordkeeping requirements proposed by the Board in this action will incur some recordkeeping costs that include time spent compiling records and, if records are in paper, copying costs. These costs will likely be outweighed by the benefits that will accrue to individuals who overdose on opioids and may have their lives saved because they have easier access to naloxone. Individuals in Southwest Virginia, where psychiatric and other medical services are less readily available, will likely benefit disproportionately from this proposed regulation and the statutory changes that authorize and require it.

Businesses and Entities Affected. This regulatory action will affect all individuals who will newly qualify for controlled substances registration as well as the patients they may help. Board staff reports that there are 1,168 controlled substances registrants in the Commonwealth, but that it is likely that only a few registrations have been issued under the emergency regulation that this proposed regulation will replace.

Localities Particularly Affected. Localities in Southwest Virginia will particularly benefit from this proposed regulation.

Projected Impact on Employment. These proposed regulatory changes are unlikely to affect employment in the Commonwealth.

Effects on the Use and Value of Private Property. These proposed regulatory changes are unlikely to affect the use or value of private property in the Commonwealth.

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. No small businesses are likely to incur any additional costs on account of these proposed regulatory changes.

Alternative Method that Minimizes Adverse Impact. No small businesses are likely to incur any additional costs on account of these proposed regulatory changes.

Adverse Impacts:

Businesses: No businesses are likely to incur any additional costs on account of these proposed regulatory changes.

Localities: Localities in the Commonwealth are unlikely to see any adverse impacts on account of these proposed regulatory changes.

Other Entities: No other entities are likely to be adversely affected by these proposed changes.

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[1]http://townhall.virginia.gov/l/viewmandate.cfm?mandateid=818.

[2]http://townhall.virginia.gov/l/viewmandate.cfm?mandateid=819.
http://townhall.virginia.gov/l/viewmandate.cfm?mandateid=839.

[3]Board staff reports that instrumentation can include physical medical equipment to do such things as measure blood pressure, temperature, etc. or may include the ability to connect via Skype so that the practitioner can meet face to face virtually with patients, depending on the applicable standard of care.

[4]These records can be maintained electronically.

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

Summary:

Pursuant to Chapters 55 and 58 of the 2017 Acts of Assembly, the proposed amendments authorize issuance of a controlled substances registration (i) to persons who have been trained in the administration of naloxone in order to possess and dispense the drug to persons receiving training and (ii) to an entity for the purpose of establishing a bona fide practitioner-patient relationship for prescribing when treatment is provided by telemedicine

in accordance with federal rules. The amendments include applicable recordkeeping, security, and storage requirements. The proposed amendments replace emergency regulations currently in effect.

18VAC110-20-690. Persons or entities authorized or required to obtain a controlled substances registration.

A. A person or entity ~~which~~ that maintains or intends to maintain a supply of ~~Schedule~~ Schedules II through Schedule VI controlled substances, other than manufacturers' samples, in accordance with provisions of the Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia) may apply for a controlled substances registration on forms approved by the board.

B. Persons or entities ~~which~~ that may be registered by the board shall include~~, but not be limited to,~~ hospitals without in-house pharmacies, nursing homes without in-house pharmacies that use automated drug dispensing systems, ambulatory surgery centers, outpatient clinics, alternate delivery sites, crisis stabilization units, persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal, and emergency medical services agencies provided such persons or entities are otherwise authorized by law and hold required licenses or appropriate credentials to administer the drugs for which the registration is being sought.

C. In determining whether to register an applicant, the board shall consider factors listed in subsections A and D of § 54.1-3423 of the Code of Virginia and compliance with applicable requirements of this chapter.

1. The proposed location shall be inspected by an authorized agent of the board prior to issuance of a controlled substances registration.

2. Controlled substances registration applications that indicate a requested inspection date~~,~~ or requests that are received after the application is filed~~,~~ shall be honored provided a 14-day notice is allowed prior to the requested inspection date.

3. Requested inspection dates that do not allow a 14-day notice to the board may be adjusted by the board to provide 14 days for the scheduling of the inspection.

4. Any person wishing to change an approved location of the drug stock, make structural changes to an existing approved drug storage location, or make changes to a previously approved security system shall file an application with the board and be inspected.

5. Drugs shall not be stocked within the proposed drug storage location or moved to a new location until approval is granted by the board.

D. The application shall be signed by a person who will act as a responsible party for the controlled substances. The responsible party may be a prescriber, nurse, pharmacist, ~~or~~ pharmacy technician for alternate delivery sites, a person authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal, or other person approved by the board who is authorized to administer the controlled substances.

E. The board may require a person or entity to obtain a controlled substances registration upon a determination that ~~Schedule~~ Schedules II through VI controlled substances have been obtained and are being used as common stock by multiple practitioners and that one or more of the following factors exist:

1. A federal, state, or local government agency has reported that the person or entity has made large purchases of controlled substances in comparison with other persons or entities in the same classification or category.

2. The person or entity has experienced a diversion, theft, or other unusual loss of controlled substances which requires reporting pursuant to § 54.1-3404 of the Drug Control Act.

3. The person or entity has failed to comply with recordkeeping requirements for controlled substances.

4. The person or entity or any other person with access to the common stock has violated any provision of federal, state, or local law or regulation relating to controlled substances.

F. The board may issue a controlled substance registration to an entity at which a patient is being treated by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically for the purpose of establishing a bona fide practitioner-patient relationship and is being prescribed Schedules II through VI controlled substances when such prescribing is in compliance with federal requirements for the practice of telemedicine and the patient is not in the physical presence of a practitioner registered with the U.S. Drug Enforcement Administration provided:

1. There is a documented need for such registration, and issuance of the registration of the entity is consistent with the public interest;

2. The entity is under the general supervision of a licensed pharmacist or a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine; and

3. The application is signed by a person who will act as the responsible party for the entity for the purpose of compliance with provisions of this subsection. The responsible party shall be a prescriber, nurse, pharmacist,

or other person who is authorized by provisions of § 54.1-3408 of the Code of Virginia to administer controlled substances.

18VAC110-20-700. Requirements for supervision for controlled substances registrants.

A. A practitioner licensed in Virginia shall provide supervision for all aspects of practice related to the maintenance and use of controlled substances as follows:

1. In a hospital or nursing home without an in-house pharmacy, a pharmacist shall supervise.

2. In an emergency medical services agency, the operational medical director shall supervise.

3. For any other type of applicant or registrant, a pharmacist or a prescriber whose scope of practice is consistent with the practice of the applicant or registrant and who is approved by the board may provide the required supervision.

B. The supervising practitioner shall approve the list of drugs ~~which~~ that may be ordered by the holder of the controlled substances registration; possession of controlled substances by the entity shall be limited to such approved drugs. The list of drugs approved by the supervising practitioner shall be maintained at the address listed on the controlled substances registration.

C. Access to the controlled substances shall be limited to (i) the supervising practitioner or to those persons who are authorized by the supervising practitioner and who are authorized by law to administer drugs in Virginia; (ii) such other persons who have successfully completed a training program for repackaging of prescription drug orders in a CSB, BHA, or PACE site as authorized in § 54.1-3420.2 of the Code of Virginia; ~~or~~ (iii) other such persons as designated by the supervising practitioner or the responsible party to have access in an emergency situation, or (iv) persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal. If approved by the supervising practitioner, pharmacy technicians may have access for the purpose of delivering controlled substances to the registrant, stocking controlled substances in automated dispensing devices, conducting inventories, audits and other recordkeeping requirements, overseeing delivery of dispensed prescriptions at an alternate delivery site, and repackaging of prescription drug orders retained by a CSB, BHA, or PACE site as authorized in § 54.1-3420.2 of the Code of Virginia. Access to stock drugs in a crisis stabilization unit shall be limited to prescribers, nurses, or pharmacists.

D. The supervising practitioner shall establish procedures for and provide training as necessary to ensure compliance with all requirements of law and regulation, including~~, but not limited to,~~ storage, security, and recordkeeping.

E. Within 14 days of a change in the responsible party or supervising practitioner assigned to the registration, either the responsible party or outgoing responsible party shall inform the board, and a new application shall be submitted indicating the name and license number, if applicable, of the new responsible party or supervising practitioner.

18VAC110-20-710. Requirements for storage and security for controlled substances registrants.

A. Drugs shall be stored under conditions ~~which~~ that meet USP-NF specifications or manufacturers' suggested storage for each drug.

B. Any drug ~~which~~ that has exceeded the expiration date shall not be administered; it shall be separated from the stock used for administration and maintained in a separate, locked area until properly disposed.

C. If a controlled substances registrant wishes to dispose of unwanted or expired ~~Schedule~~ Schedules II through VI drugs, he shall transfer the drugs to another person or entity authorized to possess and to provide for proper disposal of such drugs.

D. Drugs shall be maintained in a lockable cabinet, cart, device, or other area ~~which~~ that shall be locked at all times when not in use. The keys or access code shall be restricted to the supervising practitioner and persons designated access in accordance with 18VAC110-20-700 C.

E. In a facility not staffed 24 hours a day, the drugs shall be stored in a fixed and secured room, cabinet or area ~~which~~ that has a security device for the detection of breaking ~~which~~ that meets the following conditions:

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

2. The installation and device shall be based on accepted alarm industry standards.

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

4. The device shall fully protect all areas where prescription drugs are stored and shall be capable of detecting breaking by any means when activated.

5. Access to the alarm system shall be restricted to only designated and necessary persons, and the system shall be activated whenever the drug storage areas are closed for business.

6. An alarm system is not required for researchers, animal control officers, humane societies, alternate delivery sites as provided in 18VAC110-20-275, emergency medical services agencies stocking only intravenous fluids with no added drug, persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal, and teaching institutions possessing only Schedule VI drugs.

18VAC110-20-735. Requirements for dispensing of naloxone by trained individuals.

A. Persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and dispense naloxone for opioid overdose reversal pursuant to subsection Y of § 54.1-3408 of the Code of Virginia shall maintain the following records:

1. The prescriber's standing order issued in accordance with subsection Y of § 54.1-3408 of the Code of Virginia authorizing the trained individual to dispense naloxone.

2. Invoices or other records showing receipts of naloxone shall be maintained, but may be stored in an electronic database or record as an electronic image that provides an exact, clearly legible image of the document or in secured storage either on site or off site. All records in off-site storage or database shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

3. A manual or electronic log indicating the name, strength, lot, expiration date, and quantity of naloxone transferred to and from the controlled substances registration location to the off-site training location, along with date of transfer and the name of the trained individual approved by the Department of Behavioral Health and Developmental Services.

4. Record of dispensing indicating the name of the person receiving naloxone, address or contact information if available, date of dispensing, drug name, strength, quantity, lot number, expiration date, and the name of the trained individual approved by the Department of Behavioral Health and Developmental Services to dispense naloxone.

B. The naloxone shall be labeled with directions for use in accordance with the prescriber's standing order, date of dispensing, name of person receiving the drug, drug name and strength, and the name and the telephone number for the entity associated with the controlled substances registration.

C. The naloxone shall be stored and transported under appropriate storage conditions in accordance with the manufacturer's directions to protect it from adulteration.

D. In the event of a manufacturer recall, the supervising practitioner or responsible party associated with the controlled substances registration certificate shall ensure compliance with recall procedures as issued by the manufacturer, U.S. Food and Drug Administration, or board to ensure an affected drug is transferred to a person or entity authorized to possess the drug for return or destruction.

E. Except for a prescriber's standing order, which shall be maintained on site for a period of not less than two years from the date of the last dispensing, records shall be filed chronologically and maintained for a period of not less than two years from the date of transaction.

VA.R. Doc. No. R17-5048; Filed June 15, 2018, 12:56 p.m.

BOARD OF VETERINARY MEDICINE

Final Regulation

Title of Regulation: **18VAC150-20. Regulations Governing the Practice of Veterinary Medicine (adding 18VAC150-20-174).**

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

Effective Date: August 8, 2018.

Agency Contact: Leslie L. Knachel, Executive Director, Board of Veterinary Medicine, 9960 Mayland Drive, Suite 300, Richmond, VA 23233, telephone (804) 367-4468, FAX (804) 527-4471, or email leslie.knachel@dhp.virginia.gov.

Summary:

The amendments establish requirements for the prescribing by veterinarians of controlled substances containing opioids, including tramadol and buprenorphine. The regulation provides for the management of pain, including requirements (i) for the evaluation of the patient, limitations on quantity and dosage, and recordkeeping; (ii) for chronic conditions or terminal illnesses that require prescribing an opioid for more than 14 days, an allowance for prescribing a dosage, quantity, and formulation appropriate for an animal according to species and size; and (iii) for continuation of treatment and for the content of the medical record.

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

18VAC150-20-174. Prescribing of controlled substances for pain or chronic conditions.

A. Evaluation of the patient and need for prescribing a controlled substance for pain.

1. For the purposes of this section, a controlled substance shall be a Schedules II through V drug, as set forth in the Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia), which contains an opioid [, to include tramadol and buprenorphine].

2. Nonpharmacologic and non-opioid treatment for pain shall be given consideration prior to treatment with opioids. Prior to initiating treatment with a controlled substance, as defined, the prescriber shall perform a history and physical examination appropriate to the complaint and conduct an assessment of the patient's history as part of the initial evaluation.

3. If a controlled substance is necessary for treatment of [~~acute~~] pain, the veterinarian shall prescribe it in the lowest effective dose appropriate to the size and species of the animal for the least amount of time. The [initial] dose shall not exceed a 14-day supply.

B. If the prescribing is within the accepted standard of care, a veterinarian may prescribe a controlled substance containing an opioid for management of [~~chronic~~] pain, terminal illnesses, or certain chronic conditions, such as chronic heart failure, chronic bronchitis, osteoarthritis, collapsing trachea, or related conditions.

1. For prescribing a controlled substance for management of pain after the initial 14-day prescription [~~referenced in subsection A of this section~~], the patient shall be seen and evaluated for the continued need for an opioid. [For the prescribing of a controlled substance for terminal illnesses or certain chronic conditions, it is not required to see and reevaluate the patient for prescribing beyond 14 days.]

2. For any prescribing of a controlled substance beyond 14 days, the veterinarian shall develop a treatment plan for the patient, which shall include measures to be used to determine progress in treatment, further diagnostic evaluations or modalities that might be necessary, and the extent to which the pain or condition is associated with [~~physical~~] impairment.

3. For continued prescribing of a controlled substance, the patient shall be seen and reevaluated at least every six months, and the justification for such prescribing documented in the patient record.

C. Prior to prescribing or dispensing a controlled substance, the veterinarian shall document a discussion with the owner about the [~~known risks and benefits of opioid therapy, the~~] responsibility for the security of the drug and proper disposal of any unused drug.

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

E. [~~Prescribing of buprenorphine for outpatient administration shall only occur in accordance with the following:~~

~~1. The dosage, quantity, and formulation shall be appropriate for the patient; and~~

~~2. The prescription shall not exceed a seven-day supply. Any prescribing beyond seven days shall be consistent with an appropriate standard of care and only after a reexamination of the patient as documented in the patient record.~~

~~F.~~] The medical record for prescribing controlled substances shall include signs or presentation of the pain or condition, a presumptive diagnosis for the origin of the pain or condition, an examination appropriate to the complaint, a treatment plan, and the medication prescribed to include the date, type, dosage, and quantity prescribed.

VA.R. Doc. No. R17-5103; Filed June 15, 2018, 12:30 p.m.

TITLE 20. PUBLIC UTILITIES AND TELECOMMUNICATIONS

STATE CORPORATION COMMISSION

Final Regulation

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

Title of Regulation: **20VAC5-309. Rules for Enforcement of the Underground Utility Damage Prevention Act (amending 20VAC5-309-150).**

Statutory Authority: §§ 12.1-13 and 56-265.30 of the Code of Virginia.

Effective Date: July 1, 2018.

Agency Contact: Aaron Campbell, Associate General Counsel, State Corporation Commission, P.O. Box 1197, Richmond, VA 23218, telephone (804) 371-9117, FAX (804) 371-9734, or email aaron.campbell@scc.virginia.gov.

Summary:

The amendments allow for trenchless excavation across gravity fed sewer mains and combination storm/sanitary sewer system utility lines without exposing the facilities if (i) a video camera designed to pass through the underground facilities is able to communicate the location, depth, diameter, and condition of those facilities to the excavator and (ii) certain other safety and notification requirements are met. Other changes (i) clarify throughout the regulation that "project" means a trenchless excavation

project and (ii) modify the beginning of the required retention period for video documentation to "from the time of the notice of excavation" rather than "from the time of the bore."

AT RICHMOND, JUNE 12, 2018

PETITION OF
COLUMBIA GAS OF VIRGINIA, INC.

CASE NO. URS-2018-00005

For rulemaking to revise requirement
for trenchless excavation set forth in
20VAC5-309-150 of the Rules for
Enforcement of the Underground
Utility Damage Prevention Act

ORDER ADOPTING REGULATIONS

On January 23, 2018, Columbia Gas of Virginia ("Petitioner" or "CVA") filed a Petition for Rulemaking ("Petition") with the State Corporation Commission ("Commission").[1] The Petitioner requested that the Commission initiate a rulemaking for the limited purpose of revising 20VAC5-309-150 ("Rule 150") of the Commission's Rules for Enforcement of the Underground Utility Damage Prevention Act, 20VAC5-309-10 et seq., that prescribes requirements for trenchless excavation. The Petition included proposed language ("Proposed Rule") to be considered by the Commission.

The Petitioner stated that the Proposed Rule would (i) provide for greater flexibility when conducting trenchless excavation that crosses gravity fed sewer mains and combination storm/sanitary sewer system utility lines and (ii) enhance the safety and efficiency of conducting such excavations.[2] Specifically, CVA proposed the following modifications: (1) add a subsection "B" applicable to conducting trenchless excavations crossing gravity fed sewer mains or combinations of storm/sanitary sewer system utility lines where the exposing of such lines is not required, provided the company utilizes camera technology and other techniques detailed within the new subsection; and (2) add a subsection "C" that restricts the application of the new subsection "B" to gravity fed sewer mains or combination storm/sanitary systems considered "utility lines," as that term is defined in § 56-265.15 of the Underground Utility Damage Prevention Act.[3]

On March 5, 2018, the Commission entered an Order Establishing Proceeding ("Procedural Order") which, among other things, directed that notice of the Proposed Rule be given to interested persons and that such interested persons and the Commission Staff ("Staff") be provided an opportunity to file written comments on, propose modifications or supplements to, or request a hearing on the Proposed Rule. The Procedural Order directed the Commission's Division of Information Resources to provide a copy thereof to the Registrar of Regulations for publication in the Virginia Register of Regulations.[4] The Procedural Order further directed the Petitioner: (i) to serve a copy thereof upon each member of the Commission's Underground Utility Damage Prevention Advisory Committee and each entity listed in Attachment B of the Order[5] and (ii) to present the Petition formally at the Virginia Damage Prevention Conference to be held on April 24-26, 2018.[6]

On April 5, 2018, Staff filed comments proposing slightly revised language for consideration by the Commission that did not materially change the substance of the Proposed Rule. On May 17, 2018, the Virginia Cable Television Communications Association filed comments supporting the Petition as well as Staff's slightly revised language. Also on May 17, 2018, Washington Gas Light Company filed a letter supporting CVA's proposal. On May 21, 2018, Virginia Natural Gas, Inc., filed "clarifying comments regarding the proposed revisions to Rule 150," wherein it suggested a possible interpretation of the new language in the Proposed Rule related to documentation an excavator would receive from the utility line operator notifying of the proposed trenchless excavation.[7] On May 31, 2018, the Petitioner filed Reply Comments providing the Commission with additional background regarding dialogue with industry stakeholders that took place prior to CVA filing its Petition.[8] CVA stated that the Proposed Rule provides flexibility for an excavator and operator to develop notification processes tailored to their specific circumstances.[9] CVA also clarified that it is agreeable to Staff's suggested modifications to the Proposed Rule.[10]

NOW THE COMMISSION, having considered this matter, is of the opinion and finds that the Proposed Rule, incorporating the modifications suggested by Staff, should be approved.

Accordingly, IT IS ORDERED THAT:

(1) The Commission's Rules for Enforcement of the Underground Utility Damage Prevention Act, 20 VAC 5-309-10 et seq., hereby are adopted as shown in Attachment A to this Order and shall become effective as of July 1, 2018.

(2) A copy of these regulations as set out in Attachment A of this Order Adopting Regulations shall be forwarded to the Registrar of Regulations for publication in the Virginia Register.

(3) This case is dismissed.

AN ATTESTED COPY hereof shall be sent by the Clerk of the Commission to all persons on the official Service List in this matter. The Service List is available from the Clerk of the State Corporation Commission, c/o Document Control Center, 1300 E. Main Street, First Floor, Tyler Building, Richmond, Virginia 23219. A copy shall also be sent to the Commission's Office of General Counsel and Division Utility and Railroad Safety.

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[1]On December 15, 2017, CVA presented draft language for the proposed rulemaking at a regularly scheduled meeting of the Underground Damage Prevention Advisory Committee.

[2]Petition at 1.

[3]Id. at 4 and Attachment A.

[4]The Order Establishing Proceeding and the proposed regulation were published in the April 2, 2018 issue of the Virginia Register of Regulations.

[5]On March 30, 2018, the Petitioner filed a Certificate of Service stating that it had mailed a copy of the Procedural Order to each member of the Underground Damage Prevention Advisory Committee as well as each Virginia Local Natural Gas Distribution Company.

[6]On April 25, 2018, the Petitioner formally presented the Petition at the Virginia Damage Prevention Conference.

[7]Comments of Virginia Natural Gas, Inc., at 1-2.

[8]Comments of CVA at 4.

[9]Id. at 5.

[10]Id. at 2.

20VAC5-309-150. Requirement for trenchless excavation.

A. Any person conducting trenchless excavation shall take all reasonable steps necessary to protect and support underground utility lines. ~~These~~ Except as provided in subsection B of this section, these steps shall include [, but are not limited to] the following:

1. The excavator should verify that all utility lines in the area are marked;

2. The excavator shall ensure that bore equipment stakes are installed at a safe distance from marked utility lines;

3. When grounding rods are used, the excavator shall ensure that they are installed at a safe distance (at least 24 inches plus the width of the utility line, if known) away from the marked or staked location of utility lines;

4. The excavator shall ensure sufficient clearance is maintained between the bore path and any underground utility lines during pullback;

5. The excavator shall give special consideration to water and sewer systems within the area that cannot be located accurately;

6. Unless prohibited by other laws, ordinances, regulations, or rules of governmental and regulatory authorities having jurisdiction, the excavator shall expose all utility lines ~~which~~ that will be in the bore path by hand digging to establish the underground utility line's location prior to commencing bore. For a parallel type bore, unless prohibited by other laws, ordinances, regulations, or rules of governmental and regulatory authorities having jurisdiction, the excavator shall expose the utility line by hand digging at reasonable distances along the bore path;

7. The excavator shall ensure the drill head locating device is functioning properly and within its specification;

8. The excavator shall visually check the drill head as it passes through potholes, entrances, and exit pits; and

9. If the depth indicated by the locating device is lower than the bottom of the pothole or pit, the excavator shall cease boring until the ~~hole/pit~~ hole or pit can be hand excavated further to maintain a visual inspection of the drill head.

B. Notwithstanding the requirements of subdivision A 6 of this section, any person conducting trenchless excavation crossing any gravity fed sewer main or combination storm/sanitary sewer system utility lines need not expose such utility lines by hand digging if, in addition to meeting the other applicable requirements set forth in subsection A of this section, the following steps are taken:

1. Prior to commencing a [trenchless excavation] project, the excavator shall receive documentation from the utility line operator (such as, but not limited to, documentation through the permitting process) documenting that the operator has been notified of the proposed trenchless excavation and that trenchless excavation will be used to cross its underground utility line. The scope of a [trenchless excavation] project shall not exceed the scope of a single notice of excavation;

2. Prior to commencing the boring process, the excavator shall determine (i) the depth of the utility line through appropriate locating technology and (ii) the diameter and condition of the utility line using a sewer system camera with video recording capability;

3. The excavator shall ensure that a clearance of at least three feet is maintained between the bore path and the utility line;

4. Using the same type of video equipment identified in subdivision B 2 of this section, after the [~~bore~~ trenchless excavation project] has been completed, the excavator shall use a sewer system camera to determine the condition of the utility line and ensure that no cross bore or other damage has occurred;

5. The excavator shall immediately notify the utility line operator of any damage found; and

6. After the bore has been completed, the excavator shall make all video documentation available to the utility line operator and the division upon request. Such video documentation shall be maintained and made available for 12 months from the time of the [~~bore~~ notice of excavation].

C. The provisions of subsection B of this section shall apply only to gravity fed sewer mains or combination storm/sanitary systems that are considered "utility lines" as that term is defined in § 56-265.15 of the Act.

VA.R. Doc. No. R18-5415; Filed June 13, 2018, 11:50 a.m.

TITLE 22. SOCIAL SERVICES

DEPARTMENT FOR AGING AND REHABILITATIVE SERVICES

Notice of Extension of Emergency Regulation

Title of Regulation: **22VAC30-80. Auxiliary Grants Program (amending 22VAC30-80-10, 22VAC30-80-20, 22VAC30-80-30, 22VAC30-80-45 through 22VAC30-80-70; adding 22VAC30-80-35).**

Statutory Authority: §§ 51.5-131 and 51.5-160 of the Code of Virginia.

Expiration Date Extended Through: January 7, 2019.

The Governor approved the Department for Aging and Rehabilitative Services's request to extend this emergency regulation for six months as provided in § 2.2-4011 D of the Code of Virginia. Therefore, the emergency action will continue in effect through January 7, 2019. The second enactment clause of Chapter 567 of the 2016 Acts of Assembly directed the Commissioner of the Department for Aging and Rehabilitative Services to promulgate regulations for the provision of supportive housing for individuals receiving auxiliary grants. The emergency regulations were published in 33:10 VA.R. 1162-1166 January 9, 2017.

After the effective date of the emergency action, certain sections included in the emergency action were amended by a separate regulatory action pertaining to the receipt of third-party payments that became effective October 4, 2017 (34:1 VA.R. 147-151 September 4, 2017).

The extended emergency regulation, incorporating the amendments from the separate regulatory action, is set forth below.

Agency Contact: Tishaun Harris-Ugworji, Program Consultant, Department for Aging and Rehabilitative Services, 8004 Franklin Farms Drive, Richmond, VA 23229, telephone (804) 662-7531, or email tishaun.harrisugworji@dars.virginia.gov.

22VAC30-80-10. Definitions.

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

"Adult foster care" or "AFC" means a locally optional program that provides room and board, supervision, and special services to an individual who has a physical or mental health need. Adult foster care may be provided for up to three individuals by any one provider who is approved by the local department of social services.

"Assisted living care" means a level of service provided by an assisted living facility for individuals who may have physical or mental impairments and require at least moderate assistance with the activities of daily living. Included in this level of service are individuals who are dependent in behavior pattern (i.e., abusive, aggressive, disruptive) as documented on the Uniform Assessment Instrument.

"Assisted living facility" or "ALF" means, as defined in § 63.2-100 of the Code of Virginia, any congregate residential setting that provides or coordinates personal and health care services, 24-hour supervision, and assistance (scheduled and unscheduled) for the maintenance or care of four or more adults who are aged, infirm or disabled and who are cared for in a primarily residential setting, except (i) a facility or portion of a facility licensed by the State Board of Health or the Department of Behavioral Health and Developmental Services, but including any portion of such facility not so licensed; (ii) the home or residence of an individual who cares for or maintains only persons related to him by blood or marriage; (iii) a facility or portion of a facility serving infirm or disabled persons between the ages of 18 and 21, or 22 if enrolled in an educational program for the handicapped pursuant to § 22.1-214 of the Code of Virginia, when such facility is licensed by the department as a children's residential facility under Chapter 17 (§ 63.2-1700 et seq.) of Title 63.2 of the Code of Virginia, but including any portion of the facility not so licensed; and (iv) any housing project for persons 62 years of age or older or the disabled that provides no more than basic coordination of care services and is funded by the U.S. Department of Housing and Urban Development, by the U.S. Department of Agriculture, or by the Virginia Housing Development Authority. Included in this definition are any two or more places, establishments or institutions owned or operated by a single entity and providing maintenance or care to a combined total of four or more aged, infirm or disabled adults. Maintenance or care means the protection, general supervision and oversight of the physical and mental well-being of an aged, infirm or disabled individual. Assuming responsibility for the well-being of individuals residing in an ALF, either directly or through contracted agents, is considered "general supervision and oversight."

"Authorized payee" means the individual who may be a court-appointed conservator or guardian, a person with a valid power of attorney, or an authorized representative with the documented authority to accept funds on behalf of the individual. An authorized payee for the auxiliary grant shall not be (i) the licensee or (ii) the owner of, employee of, or an entity hired by or contracted by the ALF or AFC home.

"Authorized representative" means the person representing or standing in place of the individual receiving the auxiliary grant for the conduct of the auxiliary grant recipient's affairs (i.e., personal or business interests). "Authorized representative" may include a guardian, conservator, attorney-in-fact under durable power of attorney, trustee, or other person expressly named in writing by the individual as his agent. An authorized representative shall not be (i) the

licensee or (ii) the owner of, employee of, or an entity hired by or contracted by the ALF or AFC home unless the auxiliary grant recipient designates such a person to assist with financial management of his personal needs allowance as a choice of last resort because there is no other authorized representative willing or available to serve in this capacity.

"Auxiliary Grants Program" or "AG" means a state and locally funded assistance program to supplement income of an individual receiving Supplemental Security Income (SSI) or adult who would be eligible for SSI except for excess income, who resides in an ALF ~~or in~~, an AFC home, or a supportive housing setting with an established rate. The total number of individuals within the Commonwealth of Virginia eligible to receive AG in a supportive housing setting shall not exceed the number designated in the signed agreement between the department and the Social Security Administration.

"Certification" means an official approval as designated on the form provided by the department and prepared by ~~the~~ an ALF or a supportive housing provider. Each ALF shall annually ~~certifying~~ certify that ~~the ALF~~ it has properly managed the personal funds and personal needs allowances of individuals residing in the ALF and is in compliance with program regulations and appropriate licensing regulations. Each supportive housing provider shall annually certify that it is in compliance with the regulations for the administration of the auxiliary grants programs (22VAC30-80).

"Department" means the Department for Aging and Rehabilitative Services.

"DBHDS" means the Department of Behavioral Health and Developmental Services.

"Established rate" means the rate as set forth in the appropriation act or as set forth to meet federal maintenance of effort requirements.

"Licensee" means any person, association, partnership, corporation, or governmental unit to whom a license to operate an ALF is issued in accordance with 22VAC40-72.

"Personal funds" means payments the individual receives, whether earned or unearned, including wages, pensions, Social Security benefits, and retirement benefits. "Personal funds" does not include personal needs allowance.

"Personal needs allowance" means a portion of the AG payment that is reserved for meeting the individual's personal needs. The amount is established by the Virginia General Assembly.

"Personal toiletries" means hygiene items provided to the individual by the ALF or AFC home including deodorant, razor, shaving cream, shampoo, soap, toothbrush, and toothpaste.

"Program" means the Auxiliary Grant Program.

"Provider" means an ALF that is licensed by the Department of Social Services or an AFC provider that is approved by a local department of social services or a supportive housing provider as defined in § 37.2-421.1 of the Code of Virginia.

"Provider agreement" means a ~~document~~ written agreement that ~~the ALF~~ ALFs and supportive housing providers must complete and submit to the department when requesting ~~to be approved for admitting~~ approval to admit individuals receiving AG.

"Qualified assessor" means an individual who is authorized by 22VAC30-110 to perform an assessment, reassessment, or change in level of care for an individual applying for AG or residing in an ALF or a supportive housing setting. For individuals receiving services from a community services board or behavioral health authority, a qualified assessor is an employee or designee of the community services board or behavioral health authority.

"Rate" means the established rate.

"Residential living care" means a level of service provided by an ALF for individuals who may have physical or mental impairments and require only minimal assistance with the activities of daily living. Included in this level of service are individuals who are dependent in medication administration as documented on the Uniform Assessment Instrument (UAI).

"Supportive housing" or "SH" means a residential setting with access to supportive services for an AG recipient in which tenancy as described in § 37.2-421.1 of the Code of Virginia is provided or facilitated by a provider licensed to provide mental health community support services, intensive community treatment, programs of assertive community treatment, supportive in-home services, or supervised living residential services that has entered into an agreement with the DBHDS pursuant to § 37.2-421.1 of the Code of Virginia.

"Third-party payment" means a payment made by a third party to an ALF or AFC home on behalf of an AG recipient for goods or services other than for food, shelter, or specific goods or services required to be provided by the ALF or AFC home as a condition of participation in the Auxiliary Grants Program in accordance with 22VAC30-80-45.

"Uniform Assessment Instrument" or "UAI" means the department-designated assessment form. It is used to record assessment information for determining the level of service that is needed.

22VAC30-80-20. Assessment.

A. In order to receive payment from the program for care in an ALF or in AFC home, an individual applying for AG shall have been assessed by a qualified assessor using the UAI in accordance with 22VAC30-110 and determined to need residential or assisted living care or AFC.

B. As a condition of eligibility for the program, a UAI shall be completed on an individual prior to admission, except for an emergency placement as documented and approved by a Virginia adult protective services worker; at least once annually; and whenever there is a significant change in the individual's level of care, and a determination is made that the individual needs residential or assisted living care in an ALF or AFC home.

C. The ALF or AFC provider is prohibited from charging a security deposit or any other form of compensation for providing a room and services to the individual. The collection or receipt of money, gift, donation or other consideration from or on behalf of an individual for any services provided is prohibited.

D. In order to receive payment from the AG program for care in the SH setting, an individual shall be evaluated by a qualified assessor in accordance with § 51.5-160 E of the Code of Virginia. Eligible individuals shall be notified of the SH setting option and the availability of approved SH providers at the time of their annual level of care assessment.

22VAC30-80-30. Basic services in an assisted living facility or an adult foster care home.

A. The rate established under the program for the ALF setting shall cover the following services:

1. Room and board.

a. A furnished room in accordance with 22VAC40-72-730;

b. Housekeeping services based on the needs of the individual;

c. Meals and snacks provided in accordance with 22VAC40-72 including, but not limited to food service, nutrition, number and timing of meals, observance of religious dietary practices, special diets, menus for meals and snacks, and emergency food and water. A minimum of three well-balanced meals shall be provided each day. When a diet is prescribed for an individual by his physician, it shall be prepared and served according to the physician's orders. Basic and bedtime snacks shall be made available for all individuals desiring them and shall be listed on the daily menu. Unless otherwise ordered in writing by the individual's physician, the daily menu, including snacks, for each individual shall meet the guidelines of the U.S. Department of Agriculture's Food ~~Guide Pyramid~~ guidance system or the dietary allowances of the Food and Nutritional Board of the National Academy of Sciences, taking into consideration the age, sex, and activity of the resident. Second servings shall be provided, if requested, at no additional charge. At least one meal each day shall include a hot main dish; and

d. Clean bed linens and towels as needed by the individual and at least once a week.

2. Maintenance and care.

a. Minimal assistance as defined in 22VAC40-72-10 with personal hygiene including bathing, dressing, oral hygiene, hair grooming and shampooing, care of clothing, shaving, care of toenails and fingernails or arranging for such assistance if the resident's medical condition precludes facility from providing the service, arranging for haircuts as needed, and care of needs associated with menstruation or occasional bladder or bowel incontinence that occurs less than weekly;

b. Medication administration as required by licensing regulations including insulin injections;

c. Provision of personal toiletries including toilet paper;

d. Minimal assistance with the following:

(1) Care of personal possessions;

(2) Care of personal needs allowance if requested by the individual and provider policy allows this practice, and in compliance with 22VAC40-72-140 and 22VAC40-72-150~~, Standards for Licensed Assisted Living Facilities~~;

(3) Use of the telephone;

(4) Arranging nonmedical transportation;

(5) Obtaining necessary personal items and clothing;

(6) Making and keeping appointments; and

(7) Correspondence;

e. Securing health care and transportation when needed for medical treatment;

f. Providing social and recreational activities in accordance with 22VAC40-72-520; and

g. General supervision for safety.

B. The AFC provider shall adhere to the standards in 22VAC30-120-40.

22VAC30-80-35. Basic services in supportive housing settings.

A. The rate established under the program for SH, as defined in 22VAC30-80-10, shall cover a residential setting with access to SH services that include:

1. Development of individualized SH service plans;

2. Access to skills training;

3. Assistance with accessing available community-based services and supports;

4. Initial identification and ongoing review of the level of care needs; and

5. Ongoing monitoring of services described in the individual's individualized SH plan.

B. The residential setting covered under the program for SH, as defined in 22VAC30-80-10, shall be the least restrictive and most integrated setting practicable for the individual and shall:

1. Comply with federal habitability standards;

2. Provide cooking and bathroom facilities in each unit;

3. Afford dignity and privacy to the individual; and

4. Include rights of tenancy pursuant to the Virginia Residential Landlord and Tenant Act (§ 55-248.2 et seq. of the Code of Virginia).

22VAC30-80-45. Conditions of participation in the program.

A. Provider agreement for ALF.

1. As a condition of participation in the program, the ALF provider is required to complete and submit to the department a signed provider agreement as stipulated in ~~subdivision 2 of~~ this ~~subsection~~ section. The agreement is to be submitted prior to the ALF accepting AG payment for qualified individuals. A copy of the ALF's current license must be submitted with the provider agreement.

2. The ALF provider shall agree to the following conditions in the provider agreement to participate in the program:

a. Provide services in accordance with all laws, regulations, policies, and procedures that govern the provision of services in the facility;

b. Submit an annual certification form by October 1 of each year;

c. Care for individuals with AG in accordance with the requirements in this chapter at the current established rate;

d. Refrain from charging the individual, his family, or his authorized personal representative a security deposit or any other form of compensation as a condition of admission or continued stay in the facility;

e. Accept the established rate as payment in full for services rendered;

f. Account for the personal needs allowances in a separate bank account and apart from other facility funds and issue a statement to each individual regarding his account balance that includes any payments deposited or withdrawn during the previous calendar month;

g. Provide a 60-day written notice to the regional licensing office in the event of the facility's closure or ownership change;

h. Provide written notification of the date and place of an individual's discharge or the date of an individual's death to the local department of social services determining the individual's AG eligibility and to the qualified assessor within 10 days of the individual's discharge or death; and

i. Return to the local department of social services determining the individual's AG eligibility, all AG funds received after the death or discharge date of an individual in the facility.

B. As a condition of participation in the program, the AFC provider shall be approved by a local department of social services and comply with the requirements set forth in 22VAC30-120.

C. Provider agreement for SH. As a condition of participating in the AG program, the SH provider shall enter an agreement with DBHDS pursuant to § 37.2-421.1 of the Code of Virginia. The SH provider shall submit a copy of the executed agreement and a copy of its current DBHDS license prior to the SH provider receiving payments from the AG program on behalf of qualified individuals. The SH provider shall provide SH services for each individual in accordance with § 37.2-421.1 of the Code of Virginia and all other applicable laws, regulations, and policies and procedures.

~~C.~~ D. ALFs and AFC homes providing services to AG recipients may accept third-party payments made by persons or entities for the actual costs of goods or services that have been provided to the AG recipient. The department shall not include such payments as income for the purpose of determining eligibility for or calculating the amount of an AG provided that the payment is made:

1. Directly to the ALF or AFC home by the third party on behalf of the individual after the goods or services have been provided;

2. Voluntarily by the third party, and not in satisfaction of a condition of admission, continued stay, or provision of proper care and services, unless the AG recipient's physical needs exceed the services required to be provided by the ALF as a condition of participation in the auxiliary grant program; and

3. For specific goods or services provided to the individual other than food, shelter, or other specific goods or services required to be provided by the ALF or AFC home as a condition of participation in the AG program.

~~D.~~ E. Third-party payments shall not be used to pay for a private room in an ALF or AFC home.

~~E.~~ F. ALFs and AFC homes shall document all third-party payments received on behalf of an individual, including the source, amount, and date of the payment, and the goods or services for which such payments were made. Documentation related to the third-party payments shall be provided to the department upon request.

~~F.~~ G. ALFs and AFC homes shall provide each AG recipient and his authorized representative with a written list of the goods and services that shall be covered by the AG as defined in this chapter, including a clear statement that the facility shall not charge an individual or the individual's family or authorized representative additional amounts for goods or services included on such list. This statement shall be signed by the AG recipient or authorized representative as acknowledgment of receipt and shall be made available to the department upon request.

22VAC30-80-50. Establishment of rate.

The established rate for individuals authorized to reside in an ALF ~~or in~~, an AFC, or a supportive housing setting is the established rate as set forth in the appropriation act or as set forth by changes in the federal maintenance of effort formula. The AG payment is determined by adding the rate plus the personal needs allowance minus the individual's countable income. The effective date is the date of the individual's approval for AG by the local department of social services.

22VAC30-80-60. Reimbursement.

A. Any payments contributed toward the cost of ~~care~~ basic services as defined in 22VAC30-80-30 and 22VAC30-80-35 pending AG eligibility determination shall be reimbursed to the individual or contributing party by the ALF ~~or~~, AFC, or SH provider once eligibility for AG is established and that payment received. The payment shall be made payable to the individual, who will then reimburse ~~the provider for care~~ appropriate providers for basic services. If the individual is not capable of managing his finances, his authorized representative is responsible for reimbursing the provider.

B. In the event an ALF is closed, the facility shall prorate the rate up to the date of the individual's discharge and return the balance of the AG to the local department of social services that determined the individual's eligibility for the AG. If the facility maintained the individual's personal needs allowance, the facility shall provide a final accounting of the individual's personal needs allowance account within 60 days of the individual's discharge. Verification of the accounting and of the reimbursement to the individual shall be sent to the case management agency responsible for the individual's annual reassessment. In the event of the individual's death, the provider shall give to the individual's personal representative a final accounting of the individual's funds within 60 calendar days of the event. All AG funds received after the death or discharge date shall be returned to the local department of social services responsible for determining the individual's AG eligibility as soon as practicable.

C. Providers who do not comply with the requirements of this chapter may be subject to adverse action, which may include suspension of new AG program admissions or termination of provider agreements.

22VAC30-80-70. ALF certification and record requirements.

A. ~~ALFs~~ ALF and SH providers shall submit to the department an annual certification form by October 1 of each year for the preceding state fiscal year. The certification shall include the following: identifying information about the ~~ALF~~ provider, census information including a list of individuals who resided in the facility or SH setting and received AG during the reporting period and personal needs allowance accounting information if such personal needs accounting information is required by the setting. If a provider fails to submit an annual certification form, the provider will not be authorized to accept additional individuals with AG.

B. All information reported by an ALF or SH provider on the certification form shall be subject to audit by the department. Financial information that is not reconcilable to the provider's general ledger or similar records could result in establishment of a liability to the provider. Records shall be retained for three years after the end of the reporting period or until audited by the department, whichever is first.

C. All records maintained by an AFC provider, as required by 22VAC30-120, shall be made available to the department or the approving local department of social services upon request. All records are subject to audit by the department. Financial information that is not reconcilable to the provider's records could result in establishment of a liability to the provider. Records shall be retained for three years after the end of the reporting period or until audited by the department, whichever is first.

VA.R. Doc. No. R17-4816; Filed June 15, 2018, 11:51 a.m.

STATE BOARD OF SOCIAL SERVICES

Withdrawal of Proposed Regulation

Title of Regulation: **22VAC40-601. Supplemental Nutrition Assistance Program (adding 22VAC40-601-70).**

Statutory Authority: § 63.2-217 of the Code of Virginia; 7 CFR 271.4.

Notice is hereby given that the State Board of Social Services has WITHDRAWN the proposed regulatory action for 22VAC40-601, Supplemental Nutrition Assistance Program, that was published in 30:6 VA.R. 771-776 November 18, 2013.

Agency Contact: Celestine Jackson, Program Consultant, Department of Social Services, 801 East Main Street, Richmond, VA 23219, telephone (804) 726-7376, FAX (804) 726-7357, TTY (800) 828-1120, or email celestine.jackson@dss.virginia.gov.

VA.R. Doc. No. R11-2893; Filed June 22, 2018, 9:14 a.m.

EXECUTIVE ORDER NUMBER TEN (2018)

Declaration of a State of Emergency for the Commonwealth of Virginia Due to Severe Weather and Flooding

Importance of the Issue

On this date, June 8, 2018, I am declaring a state of emergency to exist for the Commonwealth of Virginia based on a series of severe thunderstorms that began impacting the Commonwealth on May 14, 2018, and continued through June 3, 2018. These storms produced damaging winds and resulted in severe flooding, downed trees, large-scale power outages, and loss of life.

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

Therefore, by virtue of the authority vested in me by § 44-146.17 of the Code of Virginia, as Governor and as Director of Emergency Management, and by virtue of the authority vested in me by Article V, Section 7 of the Constitution of Virginia and by § 44-75.1 of the Code of Virginia, as Governor and Commander-in-Chief of the armed forces of the Commonwealth, and subject always to my continuing and ultimate authority and responsibility to act in such matters, I hereby proclaim a state of emergency. Accordingly, I direct state and local government agencies to render appropriate assistance, to alleviate any conditions resulting from the situation, and to implement recovery and mitigation operations and activities so as to return impacted areas to pre-event conditions as much as possible.

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

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

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

C. Evacuation of areas threatened or stricken by effects of the severe weather and flooding, as appropriate. Pursuant to § 44-146.17(1) of the Code of Virginia, I reserve the right to direct and compel the evacuation of all or part of the populace therein from such areas and upon such timetable as the local governing body, in coordination with the VEST, acting on behalf of the State Coordinator of Emergency Management, shall determine. I authorize the control of ingress and egress at an emergency area, including the movement of persons within the area and the occupancy of premises therein upon such timetable as the local governing body, in coordination with the State Coordinator of Emergency Management and the VEST, shall determine. Violations of any order to citizens to evacuate shall constitute a violation of this Executive Order and are punishable as a Class 1 misdemeanor.

D. Activation, implementation, and coordination of appropriate mutual aid agreements and compacts, including the Emergency Management Assistance Compact (EMAC), and the authorization of the State Coordinator of Emergency Management to enter into any other supplemental agreements, pursuant to § 44-146.17(5) and § 44-146.28:1 of the Code of Virginia. The State Coordinator of Emergency Management is hereby designated as Virginia's authorized representative within the meaning of the Emergency Management Assistance Compact, § 44-146.28:1 of the Code of Virginia.

E. Provision of appropriate assistance, including temporary assignments of non-essential state employees to the Adjunct Emergency Workforce, shall be rendered by agencies of state government to respond to this situation.

F. Authorization of appropriate oversight boards, commissions, and agencies to waive and/or ease building code restrictions and permitting requirements, and to allow for emergency demolition, hazardous waste disposal, debris removal, emergency landfill sitting, and other operations and activities necessary to address immediate health and safety needs without regard to time-consuming procedures or formalities and without regard to application, permit fees, or royalties. All appropriate executive branch agencies are to exercise their discretion to the extent allowed by law to address any pending deadlines or expirations affected by or attributable to this emergency event.

G. Authorization for the heads of executive branch agencies, acting when appropriate on behalf of their regulatory boards, to waive any state requirements or regulation for which the federal government has issued a waiver of the corresponding federal or state regulation based on the impact of events related to this situation.

H. Activation of the statutory provisions in § 59.1-525 et seq. of the Code of Virginia related to price gouging.

I. Authorization of a maximum of $300,000 in state sum sufficient funds for state and local government's mission assignments authorized and coordinated through the Virginia Department of Emergency Management that are allowable as

defined by the Stafford Act, 42 USC § 5121 et seq. This funding is also available for state response and recovery operations and incident documentation.

J. Authorization of an amount estimated at $500,000 for matching funds for the Individuals and Household Program, authorized by the Stafford Act (when presidentially authorized), to be paid from state funds.

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

L. During this declared emergency, any person who holds a license, certificate, or other permit issued by any U.S. territory, state, or political subdivision thereof, evidencing the meeting of qualifications for professional, mechanical, or other skills, without compensation other than reimbursement for actual and necessary expenses, may render aid involving that skill in the Commonwealth during a disaster, and such person shall not be liable for negligently causing the death of, or injury to, any person or for the loss of, or damage to, the property of any person resulting from such service as set forth in the Code of Virginia § 44-146.23(C). Additionally, members and personnel of volunteer, professional, auxiliary, and reserve groups identified and tasked by the State Coordinator of Emergency Management for specific disaster-related mission assignments as representatives of the Commonwealth engaged in emergency services activities within the meaning of the immunity provisions of § 44-146.23(a) and (f) of the Code of Virginia, in the performance of their specific disaster-related mission assignments.

Upon my approval, the costs incurred by state agencies and other agents in performing mission assignments through the VEOC of the Commonwealth as defined herein and in § 44-146.28 of the Code of Virginia, other than costs defined in the paragraphs above pertaining to the Virginia National Guard and pertaining to the Virginia Defense Force, in performing these missions shall be paid from state funds.

Effective Date of this Executive Order

This Executive Order shall be effective May 14, 2018, and shall remain in full force and in effect until July 6, 2018, unless sooner amended or rescinded by further executive order.

Termination of the Executive Order is not intended to terminate any federal-type benefits granted or to be granted due to injury or death as a result of service under this Executive Order.

Given under my hand and under the Seal of the Commonwealth of Virginia, this 8th day of June, 2018.

/s/ Ralph S. Northam
Governor

STATE AIR POLLUTION CONTROL BOARD

Small Business Impact Review - Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the State Air Pollution Control Board conducted a small business impact review of **9VAC5-45, Consumer and Commercial Products**, and determined that this regulation should be retained in its current form. The State Air Pollution Control Board is publishing its report of findings dated May 25, 2018, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

This regulation continues to be needed. It provides sources with the most cost-effective means of fulfilling ongoing state and federal requirements that protect air quality. No comments were received that indicate a need to repeal or revise the regulation. The regulation's level of complexity is appropriate to ensure that the regulated entities are able to meet their legal mandates as efficiently and cost-effectively as possible. This regulation does not overlap, duplicate, or conflict with any state law or other state regulation.

In 2013, Articles 1 through 6 were reviewed as part of a revision to the regulations. Part I, Special Provisions, and Part II, Article 7 were last reviewed in 2014. Over time, it generally becomes less expensive to characterize, measure, and mitigate the regulated pollutants that contribute to poor air quality. This regulation continues to provide the most efficient and cost-effective means to determine the level and impact of excess emissions and to control those excess emissions.

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

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

Notice of Periodic Review and Small Business Impact Review

Pursuant to Executive Order 17 (2014) and §§ 2.2-4007.1 and 2.2-4017 of the Code of Virginia, the Department of Environmental Quality (DEQ) on behalf of the State Air Pollution Control Board is conducting a periodic review and small business impact review of **9VAC5-520, Biomass Energy Generator General Permit for a Pilot Test Facility**.

The review of this regulation will be guided by the principles in Executive Order 17 (2014). The purpose of this review is to determine whether this regulation should be repealed, amended, or retained in its current form. Public comment is sought on the review of any issue relating to this regulation, including whether the regulation (i) is necessary for the protection of public health, safety, and welfare or for the economical performance of important governmental functions; (ii) minimizes the economic impact on small businesses in a manner consistent with the stated objectives of applicable law; and (iii) is clearly written and easily understandable.

The regulations may be viewed on the DEQ air regulation webpage at http://www.deq.virginia.gov/Programs/Air/Laws,Regulations,Guidance.aspx.

The comment period begins July 9, 2018, and ends July 30, 2018.

Comments may be submitted online to the Virginia Regulatory Town Hall at http://www.townhall.virginia.gov/L/Forums.cfm. Comments may also be sent to Gary Graham, Regulatory Analyst, Office of Regulatory Affairs, Department of Environmental Quality, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4103, FAX (804) 698-4319, or email gary.graham@deq.virginia.gov.

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

DEPARTMENT OF ENVIRONMENTAL QUALITY

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

Chesapeake Solar Project 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 Chesapeake. The project will be located on approximately 920 acres across multiple parcels off Shillelagh Road, approximately five miles south of Chesapeake. The northwest corner is located near 36.69 degrees latitude and -76.31 degrees longitude. The proposed project is anticipated to have a nameplate capacity of 150 megawatts and include 518,000 solar panels.

Contact Information: Mary E. Major, Department of Environmental Quality, 1111 East Main Street, Suite 1400, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-

4423, FAX (804) 698-4510, or email mary.major@deq.virginia.gov.

Core Solar SPV XIII LLC Withdrawal of Notice of Intent for Small Renewable Energy Project (Solar) Permit by Rule - Chesapeake

Core Solar SPV XIII LLC has withdrawn its notice of intent to submit the necessary documentation for a permit by rule for a small renewable energy project (solar) in Chesapeake pursuant to 9VAC15-60. The project was to be located on 908 acres across multiple parcels off Shillelagh Road, approximately five miles south of Chesapeake. The notice was previously published in the Virginia Register of Regulations on October 16, 2017.

Contact Information: Mary E. Major, Department of Environmental Quality, 1111 East Main Street, Suite 1400, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4423, FAX (804) 698-4510, 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 June 20, 2018. 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 Sixty-One (18)

Virginia Lottery's "Rev Up Sales Retailer Incentive Promotion" (effective July 3, 2018)

Director's Order Number Sixty-Two (18)

Virginia Lottery's "7-Eleven New Hot Entreé Promotion" (effective August 1, 2018)

Director's Order Number Sixty-Three (18)

Virginia Lottery's "7Rewards App Retailer Incentive Promotion" (effective June 27, 2018)

Director's Order Number Sixty-Four (18)

Virginia Lottery's "Hey Alexa Did We Win? Retailer Incentive Promotion" (effective August 1, 2018)

Director's Order Number Sixty-Five (18)

Virginia Lottery's "My Sheetz Birthday Retailer Incentive Promotion" (effective July 1, 2018)

Director's Order Number Sixty-Six (18)

Virginia Lottery's "Wawa Sports Partnership Retailer Incentive Promotion" (effective September 21, 2018)

Director's Order Number Sixty-Seven (18)

Virginia Lottery's "7-Eleven Mass Market Battle Madness Retailer Incentive Promotion" (effective September 1, 2018)

Director's Order Number Seventy-Three (18)

Virginia Lottery's Scratch Game 1896 "$5,555 Bonus Cash" Final Rules for Game Operation (effective June 18, 2018)

Director's Order Number Seventy-Eight (18)

Virginia Lottery "G.E.M. Rev Up Sales Retailer Incentive Promotion" (effective July 1, 2018)

Director's Order Number Seventy-Nine (18)

Virginia Lottery's FY19 eXTRA Chances Promotion Final Rules for Operation (effective June 25, 2018)

Director's Order Number Ninety-Five (18)

Virginia Lottery's Scratch Game 1916 "5X the Money" Final Rules for Game Operation (effective June 18, 2018)

DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

Notice of Intent to Amend the Virginia State Plan for Medical Assistance Pursuant to § 1902(a)(13) of the Social Security Act (USC § 1396a(a)(13))

Comment period: June 21, 2018, through July 20, 2018.

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

This notice is intended to satisfy the requirements of 42 CFR 447.205 and of § 1902(a)(13) of the Social Security Act, 42 USC § 1396a(a)(13). A copy of this notice is available for public review from Elizabeth Jones, Provider Reimbursement Division, DMAS, 600 Broad Street, Suite 1300, Richmond, VA 23219, or via email at beth.jones@dmas.virginia.gov.

DMAS is specifically soliciting input from stakeholders, providers, and beneficiaries on the potential impact of the proposed changes discussed in this notice. Comments or inquiries may be submitted, in writing, within 30 days of this notice publication to Ms. Jones, and such comments are available for review at the same address. Comments may also be submitted in writing on the Virginia Regulatory Town Hall public comment forum.

This notice is available for public review on the Virginia Regulatory Town Hall at http://www.townhall.virginia.gov, on the General Notices page, found at https://townhall.virginia.gov/L/generalnotice.cfm.

1. Graduate medical education (GME) incentive payments for new primary care and high need specialty residencies. The 2018 Acts of Assembly directs DMAS to provide supplemental payments to qualifying institutions for primary care and high-need specialty medical residencies. The supplemental payment for each qualifying residency slot shall be $100,000 annually minus any Medicare residency payment for which the sponsoring institution is eligible. Supplemental payments shall be made for up to four years for each qualifying resident. Payments shall be made quarterly following the same schedule used for other medical education payments. The current State Plan designates the number of residents for each institution for the first cohort (15 slots) beginning in July 2017. Effective July 1, 2018, the department is amending the State Plan to make supplemental payments to the following sponsoring institutions for the specified number of primary care residencies for up to four years: Sentara Norfolk General (one residency), Maryview Hospital (one residency), and Carilion Medical Center (six residencies). The department shall make supplemental payments to Carilion Medical Center for two psychiatry residencies and to Sentara Norfolk General for one OB/GYN residency, two psychiatric residencies, and one urology residency.

The expected increase in annual aggregate expenditures is $2.9 million for state fiscal year 2019 and $2.9 million for state fiscal year 2020.

2. Eliminate disproportionate share hospital (DSH) payment eligibility and increase indirect medical education (IME) payment for Children's National Medical Center. Effective July 1, 2018, the Department of Medical Assistance Services is amending the State Plan for Medical Assistance to eliminate eligibility for DSH for Children's National Medical Center, an out-of-state children's hospital, increase the reimbursement for IME for Children's National Medical center by the amount of DSH the hospital was eligible for in 2018, and reduce the Type Two DSH allotment by the same amount.

The expected change in annual aggregate expenditures is $0.

3. Establish supplemental inpatient and outpatient payments for Chesapeake Regional Hospital. The department is amending the State Plan for Medical Assistance to implement a supplemental inpatient and outpatient payment for Chesapeake Regional Hospital. The payment is determined as the difference between reimbursement with rates using an adjustment factor of 100% and the provider's current authorized reimbursement. The payment is subject to the inpatient and outpatient upper payment limits for non-state-government-owned hospitals. The department shall include in its contracts with managed care organizations a minimum fee schedule for Chesapeake Regional Hospital consistent with rates using an adjustment factor of 100%. The department shall adjust capitation payments to Medicaid managed care organizations to fund this minimum fee schedule.

The expected increase in annual aggregate expenditures is $6,037,352 in state fiscal year 2019 and $6,218,472 in state fiscal year 2020.

4. Establish supplemental payments for nursing homes owned by Type One hospitals. The department is amending the State Plan to make supplemental payments for nursing homes owned by Type One hospitals (consisting of state-owned teaching hospitals) as provided in the State Plan for Medical Assistance. The total supplemental payment shall be based on the difference between the upper payment limit of 42 CFR 447.272 as approved by CMS and all other Medicaid payments subject to such limit made to such nursing homes. The department shall include in its contracts with managed care organizations a minimum fee schedule for nursing homes owned by Type One hospitals consistent with the State Plan amendment. The department shall adjust capitation payments to Medicaid managed care organizations to fund this minimum fee schedule.

The expected increase in annual aggregate expenditures is $5,205,503 in state fiscal year 2019.

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

VIRGINIA WASTE MANAGEMENT BOARD

Small Business Impact Review - Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Virginia Waste Management Board conducted a small business impact review of **9VAC20-70, Financial Assurance Regulations for Solid Waste Disposal, Transfer and Treatment Facilities**, and determined that this regulation should be retained in its current form. The Virginia Waste Management Board is publishing its report of findings dated May 24, 2018, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

The current regulation continues to be needed. If a facility for the disposal, transfer, or treatment of solid waste is abandoned, the facility will need to be closed in a manner to minimize impacts to human health and the environment. This regulation requires owners and operators to provide funding to properly close the facility prior to operation of the facility. These requirements protect citizens of the Commonwealth from having to pay for the closure of these facilities if they are abandoned.

During the public comment period, an owner of a permitted composting facility requested the agency consider reducing

the regulatory requirements for owner-occupied facilities. The amount of financial assurance required to be provided is based on factors such as the facility size and the amount of solid waste managed at the facility. The amount of financial assurance required is based on the estimated costs related to properly close the facility. Owner-occupied facilities are required to meet the same standards as non-owner-occupied facilities.

The regulations contain many different ways to demonstrate financial assurance. These options may make the regulation appear to be complex to some readers, but the multiple financial assurance mechanisms included in the regulation provide additional flexibility to the regulated community, including small businesses.

Federal regulations (40 CFR Part 258) require owners and operators of municipal solid waste landfill units to provide financial assurance. Virginia law requires solid waste treatment, transfer, or disposal facilities to demonstrate financial assurance. Virginia's regulations do not conflict with federal law or regulations or with state law.

This regulation was last amended in 2013. Financial mechanisms used to demonstrate financial assurance have not changed since that time. The regulations continue to meet the requirements of state law and are being retained. The regulation includes multiple mechanisms for the regulated community to use to demonstrate financial assurance. The inclusion of multiple mechanisms is beneficial to small businesses.

Contact Information: Melissa Porterfield, Office of Regulatory Affairs, Department of Environmental Quality, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4238, FAX (804) 698-4019, or email melissa.porterfield@deq.virginia.gov.

Notice of Periodic Review and Small Business Impact Review

Pursuant to Executive Order 17 (2014) and §§ 2.2-4007.1 and 2.2-4017 of the Code of Virginia, the Department of Environmental Quality is conducting a periodic review and small business impact review of **9VAC20-90, Solid Waste Management Permit Action Fees and Annual Fees**. The review of this regulation will be guided by the principles in Executive Order 17 (2014).

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

The comment period begins July 9, 2018, and ends July 30, 2018.

Comments may be submitted online to the Virginia Regulatory Town Hall at http://www.townhall.virginia.gov/L/Forums.cfm. Comments may also be sent to Melissa Porterfield, Office of Regulatory Affairs, Department of Environmental Quality, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4238, FAX (804) 698-4019, or email melissa.porterfield@deq.virginia.gov.

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

Small Business Impact Review - Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Virginia Waste Management Board conducted a small business impact review of **9VAC20-160, Voluntary Remediation Regulations**, and determined that this regulation should be retained in its current form. The Virginia Waste Management Board is publishing its report of findings dated May 29, 2018, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

The current regulation continues to be needed. This regulation facilitates voluntary cleanup of contaminated sites where remediation is not clearly mandated by the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), the Resource Conservation and Recovery Act (RCRA), the Virginia Waste Management Act, or other applicable authority. This voluntary program encourages remediation of contaminated sites in the Commonwealth. No public comments were received during the periodic review comment period.

The subject matter of the regulation is complex in nature, and the regulation details the requirements of the program. The Voluntary Remediation Regulations are a voluntary state regulation, and there is no corresponding federal regulation. Participants enter the program to voluntarily clean up contaminated sites where remediation is not clearly mandated by CERCLA, RCRA, Virginia Waste Management Act, State Water Control Law, or other authority. It provides a stream-lined approach for remediation projects by establishing minimum standards and procedures pertaining to eligibility, enrollment, reporting, remediation, and termination criteria.

This regulation was last amended in 2014 in response to changes in state law. Changes in technology and economic conditions since 2014 have not impacted the requirements of the regulation, and the agency is recommending the regulation stay in effect without change. The regulation is

beneficial to both the regulated community and the Commonwealth. The regulation facilitates voluntary cleanup of contaminated sites where remediation is not clearly mandated by the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), the Resource Conservation and Recovery Act (RCRA), the Virginia Waste Management Act, or other applicable authority. This voluntary program encourages remediation of sites in the Commonwealth. Entities may choose to participate in this program, and small businesses are not adversely impacted by this regulation.

Contact Information: Melissa Porterfield, Office of Regulatory Affairs, Department of Environmental Quality, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4238, FAX (804) 698-4019, or email melissa.porterfield@deq.virginia.gov.

Public Comment Opportunity - Former DC Department of Corrections Lorton Correctional Complex Statement of Basis

The Department of Environmental Quality (DEQ) has prepared a Statement of Basis (SB) on its proposed remedy for the former DC Corrections Lorton Correctional Facility (hereinafter referred to as the Site or the Facility) located at 8515 Silverbrook Road, Lorton, Virginia.

The Facility is subject to the Corrective Action Program under the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act (RCRA) of 1976, and the Hazardous and Solid Waste Amendments (HSWA) of 1984, 42 USC §§ 6901 et seq. (Corrective Action Program). The Corrective Action Program is designed to ensure that certain facilities subject to RCRA have investigated and cleaned up any releases of hazardous waste and hazardous constituents that have occurred at their respective facilities. For this Facility, DEQ retains primary authority in Virginia for the Corrective Action Program. DEQ has prepared this SB in cooperation with the U.S. Environmental Protection Agency (EPA). The administrative record (AR) for the Facility contains all documents, including data and quality assurance information.

DEQ's proposed remedy for the Facility consists of land use controls in the form of institutional controls. This SB highlights key information relied upon by DEQ in making its proposed decision.

Before DEQ makes a final decision on its proposal for the Facility, the public may participate in the remedy selection process by reviewing this SB and documents contained in the AR for the Facility. The AR contains all information considered by DEQ in reaching this proposed decision. The administrative record, including the SB, is available for review during normal business hours by contacting the staff contact listed at the end of this notice.

Interested parties are encouraged to review the AR and comment on DEQ's proposed remedy. The public comment period closes on July 16, 2018. Submit comments by mail, fax, or email to the staff contact listed below.

DEQ will hold a public meeting to discuss this proposed remedy upon request, which should also be made to the staff contact listed below. DEQ will respond to all relevant comments received during the comment period. If DEQ determines that new information warrants a modification to the proposed remedy, DEQ will modify the proposed remedy or select other alternatives based on such new information and public comments. DEQ will announce its final remedy and explain the rationale for any changes in a document entitled the Final Decision and Response to Comments (FDRTC). All persons who comment on this proposed remedy will receive a copy of the FDRTC. Others may obtain a copy by contacting Kurt Kochan at the address listed below.

Contact Information: Kurt Kochan, Department of Environmental Quality, 1111 East Main Street, Suite 1400, P.O. Box 1105, Richmond, VA 23218, telephone (703) 583-3825, FAX (703) 583-3821, or email kurt.kochan@deq.virginia.gov.

STATE WATER CONTROL BOARD

Notice of Periodic Review and Small Business Impact Review

Pursuant to Executive Order 17 (2014) and §§ 2.2-4007.1 and 2.2-4017 of the Code of Virginia, the Department of Environmental Quality is conducting a periodic review and small business impact review of **9VAC25-600, Designated Groundwater Management Areas**. The review of this regulation will be guided by the principles in Executive Order 17 (2014).

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

The comment period begins July 9, 2018, and ends July 30, 2018.

Comments may be submitted online to the Virginia Regulatory Town Hall at http://www.townhall.virginia.gov/L/Forums.cfm. Comments may also be sent to Melissa Porterfield, Office of Regulatory Affairs, Department of Environmental Quality, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4238, FAX

(804) 698-4019, or email melissa.porterfield@deq.virginia.gov.

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

Proposed Consent Special Order for Bell – Mer LLC

An enforcement action has been proposed for Bell – Mer LLC for violations at the Bailey Ridge Subdivision in Richmond County, Virginia. The State Water Control Board proposes to issue a special order by consent to Bell – Mer 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. Carla Pool will accept comments by email at carla.pool@deq.virginia.gov, FAX at (804) 698-4234, or postal mail at Department of Environmental Quality, Central Office, P.O. Box 1105, Richmond, VA 23218, from July 9, 2018, to August 8, 2018.

Proposed Consent Order for CG First Street LP, Gables Old Town North

An enforcement action has been proposed for CG First Street LP, Gables Old Town North for violations of the State Water Control Law and regulations at the CG First Street, Gables Old Town North, Waste Water Treatment Facility located at 525 Montgomery Street, Alexandria, Virginia. The State Water Control Board proposes to issue a consent order to resolve violations associated with the CG First Street, Gables Old Town North, Waste Water Treatment Facility. A description of the proposed action is available at the Department of Environmental Quality office named below or online at www.deq.virginia.gov. Mark Miller will accept comments by email at mark.miller@deq.virginia.gov or postal mail at Department of Environmental Quality, Northern Regional Office, 13901 Crown Court, Woodbridge, VA 22193, from July 10, 2018, through August 9, 2018.

Proposed Consent Order for McCarthy Building Companies Inc.

An enforcement action has been proposed for McCarthy Building Companies Inc. for the Essex Solar Center located at the intersection of Route 17 and Route 607 in Essex County, Virginia. The State Water Control Board proposes to issue a consent order to address noncompliance with State Water Control Law and regulations. The action contains corrective action and a civil charge. A description of the proposed action is available at the Department of Environmental Quality office named below or online at www.deq.virginia.gov. Frank Lupini will accept comments by email at frank.lupini@deq.virginia.gov, FAX at (804) 698-4277, or postal mail at Department of Environmental Quality, P.O. Box 1105, Richmond, VA 23218, from July 9, 2018, to August 9, 2018.

Proposed Consent Order for North Spring Behavioral Healthcare Inc.

An enforcement action has been proposed for North Spring Behavioral Healthcare Inc. for violations of the State Water Control Law and regulations associated with the North Spring Behavioral Healthcare Wastewater Treatment Plant located in Leesburg, Virginia. The State Water Control Board proposes to issue a consent order to resolve violations associated with the North Spring Behavioral Healthcare Wastewater Treatment Plant. A description of the proposed action is available at the Department of Environmental Quality office named below or online at www.deq.virginia.gov. Stephanie Bellotti will accept comments by email at stephanie.bellotti@deq.virginia.gov or postal mail at Department of Environmental Quality, Northern Regional Office, 13901 Crown Court, Woodbridge, VA 22193, from July 10, 2018, through August 9, 2018.

Proposed Consent Special Order for Virginia True Corporation

An enforcement action has been proposed for Virginia True Corporation for violations at the Virginia True Golf Course in Richmond County, Virginia. The State Water Control Board proposes to issue a special order by consent to Virginia True Corporation 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 July 9, 2018, to August 9, 2018.

VIRGINIA CODE COMMISSION

Notice to State Agencies

Contact Information: *Mailing Address:* Virginia Code Commission, Pocahontas Building, 900 East Main Street, 8th Floor, Richmond, VA 23219; *Telephone:* (804) 698-1810; *Email:* varegs@dls.virginia.gov.

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

Cumulative Table of Virginia Administrative Code Sections Adopted, Amended, or Repealed: A table listing regulation sections that have been amended, added, or repealed in the *Virginia Register of Regulations* since the

regulations were originally published or last supplemented in the print version of the Virginia Administrative Code is available at http://register.dls.virginia.gov/documents/cumultab.pdf.

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