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REGISTER OF REGULATIONS

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VIRGINIA REGISTER INFORMATION PAGE

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

ADOPTION, AMENDMENT, AND REPEAL OF REGULATIONS

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

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

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

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

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

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

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

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

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

FAST-TRACK RULEMAKING PROCESS

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

EMERGENCY REGULATIONS

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

STATEMENT

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

CITATION TO THE VIRGINIA REGISTER

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

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

Members of the Virginia Code Commission: **John S. Edwards**, Chair; **James M. LeMunyon**, Vice Chair, **Gregory D. Habeeb**; **Ryan T. McDougle**; **Pamela S. Baskerville**; **Robert L. Calhoun**; **Carlos L. Hopkins**; **E.M. Miller, Jr.**; **Thomas M. Moncure, Jr.**; **Christopher R. Nolen**; **Timothy Oksman**; **Charles S. Sharp**; **Mark J. Vucci**.

Staff of the Virginia Register: **Jane D. Chaffin**, Registrar of Regulations; **Karen Perrine**, Assistant Registrar; **Anne Bloomsburg**, Regulations Analyst; **Rhonda Dyer**, Publications Assistant; **Terri Edwards**, Operations Staff Assistant.

PUBLICATION SCHEDULE AND DEADLINES

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

February 2016 through April 2017

<u>Volume: Issue</u>	<u>Material Submitted By Noon*</u>	<u>Will Be Published On</u>
32:12	January 20, 2016	February 8, 2016
32:13	February 3, 2016	February 22, 2016
32:14	February 17, 2016	March 7, 2016
32:15	March 2, 2016	March 21, 2016
32:16	March 16, 2016	April 4, 2016
32:17	March 30, 2016	April 18, 2016
32:18	April 13, 2016	May 2, 2016
32:19	April 27, 2016	May 16, 2016
32:20	May 11, 2016	May 30, 2016
32:21	May 25, 2016	June 13, 2016
32:22	June 8, 2016	June 27, 2016
32:23	June 22, 2016	July 11, 2016
32:24	July 6, 2016	July 25, 2016
32:25	July 20, 2016	August 8, 2016
32:26	August 3, 2016	August 22, 2016
33:1	August 17, 2016	September 5, 2016
33:2	August 31, 2016	September 19, 2016
33:3	September 14, 2016	October 3, 2016
33:4	September 28, 2016	October 17, 2016
33:5	October 12, 2016	October 31, 2016
33:6	October 26, 2016	November 14, 2016
33:7	November 9, 2016	November 28, 2016
33:8	November 22, 2016 (Tuesday)	December 12, 2016
33:9	December 7, 2016	December 26, 2016
33:10	December 19, 2016 (Monday)	January 9, 2017
33:11	January 4, 2017	January 23, 2017
33:12	January 18, 2017	February 6, 2017
33:13	February 1, 2017	February 20, 2017
33:14	February 15, 2017	March 6, 2017
33:15	March 1, 2017	March 20, 2017
33:16	March 15, 2017	April 3, 2017

*Filing deadlines are Wednesdays unless otherwise specified.

PETITIONS FOR RULEMAKING

TITLE 12. HEALTH STATE BOARD OF HEALTH Initial Agency Notice

Title of Regulation: 12VAC5-408. Certificate of Quality Assurance of Managed Care Health Insurance Plan Licensees.

Statutory Authority: § 32.1-137.1 of the Code of Virginia.

Name of Petitioner: Medical Society of Virginia.

Nature of Petitioner's Request: The Medical Society of Virginia respectfully submits a petition for rulemaking, per § 2.2-4007 of the Code of Virginia, on behalf of our nearly 11,000 members. The Medical Society of Virginia (MSV) represents physician, medical student and physician assistant members and aims to make Virginia the best place to practice and receive medical care.

Specifically, MSV proposes amending 12VAC5-408-170: Provider credentialing and recredentialing. The purpose of these suggested changes is to update and streamline the credentialing and recredentialing process. Many physicians have expressed concern over the current process, as it takes significant time and resources away from delivering care to patients. MSV has engaged with key stakeholders including several health plans on this topic and have mutually agreed upon the proposed changes. As such, we hope the agency will consider these proposed changes eligible for the fast track regulatory process.

MSV appreciates the department's consideration of this request and looks forward to our continued work together to make Virginia the healthiest state in the nation.

MSV Proposed Changes to Provider Credentialing and Recredentialing:

12VAC5-408-170. Provider Credentialing and Recredentialing.

A. The MCHIP licensee shall establish and maintain a comprehensive credentialing verification program to ensure its providers meet the minimum standards of professional licensure or certification. Written supporting documentation for providers who have completed their residency or fellowship requirements for their specialty area more than 12 months prior to the credentialing decision shall include:

1. Current valid license and history of licensure or certification;
2. Status of hospital privileges, if applicable;
3. Valid DEA certificate, if applicable;
4. Information from the National Practitioner Data Bank, as available;

5. Education and training, including post graduate training, if applicable;
6. Specialty board certification status, if applicable;
7. Practice or work history covering at least the past five years; and
8. Current, adequate malpractice insurance and malpractice history of at least the past five years.

B. The MCHIP licensee may grant provisional credentialing for providers who have completed their residency or fellowship requirements for their specialty area within 12 months prior to the credentialing decision. Written supporting documentation necessary to provisionally credential a practitioner shall include:

1. Primary source verification of a current, valid license to practice prior to granting the provisional status;
2. Written confirmation of the past five years of malpractice claims or settlements, or both, from the malpractice carrier or the results of the National Practitioner Data Bank query prior to granting provisional status; and
3. A completed application and signed attestation.

C. Providers provisionally credentialed may remain so for 60 calendar days.

D. Policies for credentialing and recredentialing shall include:

1. Criteria used to credential and recredential;
2. Process used to make credentialing and recredentialing decisions;
3. Type of providers, including network providers, covered under the credentialing and recredentialing policies;
4. Process for notifying providers of information obtained that varies substantially from the information provided by the provider;
5. Process for receiving input from participating providers to make recommendations regarding the credentialing and recredentialing process; ~~and~~

6. Process and timeframes for communicating credentialing application receipt, progress and decisions to the primary credentialing contact at the address, either electronic or physical, listed on the credentialing application; and

~~6- 7.~~ A requirement that the MCHIP licensee notify the applicant or his designee if permission is granted by the applicant within 60 calendar days of receipt of an application if information is missing or if there are other deficiencies in the application. The MCHIP licensee shall complete the credentialing process within 90 calendar days of the receipt of a complete and accurate application ~~all such information requested by the MCHIP licensee or, if~~

Petitions for Rulemaking

~~information is not requested from the applicant, within 120 calendar days of receipt of an application. The department may impose administrative sanctions upon an MCHIP licensee for failure to complete the credentialing process as provided herein if it finds that such failure occurs with such frequency as to constitute a general business practice. The current policies shall be made available to participating providers and applicants upon written request via publication on the MCHIP licensee's website or within the licensee's provider manual.~~

E. A provider fully credentialed by an MCHIP licensee, who changes his place of employment or his nonMCHIP licensee employer, shall, if within 60 calendar days of such change and if practicing within the same specialty, continue to be credentialed by that MCHIP licensee upon receipt by the MCHIP licensee of the following:

1. The effective date of the change;
2. The new tax ID number and copy of W-9, as applicable;
3. The name of the new practice, contact person, address, telephone and fax numbers; and
4. Other such information as may materially differ from the most recently completed credentialing application submitted by the provider to the MCHIP licensee. This provision shall not apply if the provider's prior place of employment or employer had been delegated credentialing responsibility by the MCHIP licensee. Nothing in this section shall be construed to require an MCHIP licensee to contract or recontract with a provider.

F. ~~The appropriate credentialing process applicant shall be considered to be participating with the MCHIP licensee on the effective date which, for the purposes of this section, is the date of credentialing committee approval or the date the applicant executes a contract with the MCHIP licensee as an individual or is subject to be governed by an existing contract with the MCHIP licensee, whichever occurs later. If credentialing provides information about the malpractice insurance and if that insurance is not effective until after these dates, the effective date will be the effective date of the malpractice insurance. Beginning on the effective date the provider shall be obligated to the terms and conditions of the contract and shall be entitled to be paid as a participating provider pursuant to the terms of the contract. The MCHIP licensee shall notify the applicant and the primary credentialing contact of the effective date in a reasonable timeframe; in the event of a negative decision, the communication will include instructions for appeal, if any.~~

~~completed before the provider:~~

- ~~1. Begins seeing covered persons;~~
- ~~2. Enters into the employment or contractual relationship with the MCHIP licensee; and~~

~~3. Is included in the listing of health care providers as a participating provider in any marketing and covered person materials.~~

G. The providers shall be recredentialed at least every three years. Recredentialing documentation shall include:

1. Current valid license or certification;
2. Status of hospital privileges, if applicable;
3. Current valid DEA registration, if applicable;
4. Specialty board eligibility or certification status, if applicable;
5. Data from covered person complaints and the results of quality reviews, utilization management reviews and covered persons satisfaction surveys, as applicable; and
6. Current, adequate malpractice insurance and history of malpractice claims and professional liability claims resulting in settlements or judgments.

H. All information obtained in the credentialing process shall be subject to review and correction of any erroneous information by the health care provider whose credentials are being reviewed. Nothing in the previous sentence shall require an MCHIP or MCHIP licensee to disclose to a provider, or any other person or party, information or documents: (i) that the MCHIP or the MCHIP licensee, itself, develops or causes to be developed as part of the MCHIP's credentialing process or (ii) that are privileged under applicable law. The department may require the MCHIP licensee to provide a copy of its credentialing policies.

I. Providers shall be required by the MCHIP licensee to notify the MCHIP of any changes in the status of any credentialing criteria.

J. The MCHIP licensee shall not refuse to initially credential or refuse to reverify the credentials of a health care provider solely because the provider treats a substantial number of patients who require expensive or uncompensated care.

K. The MCHIP licensee shall have policies and procedures for altering the conditions of the provider's participation with the MCHIP licensee. The policies shall include actions to be taken to improve performance prior to termination and an appeals process for instances when the MCHIP licensee chooses to alter the condition of provider participation based on issues of quality of care or service, except in circumstances where an covered person's health has been jeopardized. Providers shall have complete and timely access to all data and information used by the licensee to identify or determine the need for altering the conditions of participation.

L. The MCHIP licensee shall retain the right to approve new providers and sites based on quality issues, and to terminate or suspend individual providers. Termination or suspension of individual providers for quality of care considerations shall be

supported by documented records of noncompliance with specific MCHIP expectations and requirements for providers. The provider shall have a prescribed system of appeal of this decision available to them as prescribed in the contract between the MCHIP or its delegated service entity and the provider.

M. Providers shall be informed of the appeals process. Profession specific providers actively participating in the MCHIP plan shall be included in reviewing appeals and making recommendations for action.

N. The MCHIP licensee shall notify appropriate authorities when a provider's application or contract is suspended or terminated because of quality deficiencies by the health care provider whose credentials are being reviewed.

O. There shall be an organized system to manage and protect the confidentiality of personnel files and records. Records and documents relating to a provider's credentialing application shall be retained for at least seven years.

Agency Plan for Disposition of Request: In accordance with Virginia law, the petition has been filed with the Registrar of Regulations and will be published on February 8, 2016, and posted to the Virginia Regulatory Town Hall at www.townhall.virginia.gov. Comment on the petition will be accepted until March 9, 2016, and may be posted on the Town Hall or sent to the board. Following receipt of all comment on the petition, and within 90 days of March 9, 2016, the matter will be considered by the State Health Commissioner, acting on behalf of the board, in order to decide whether to grant the petition.

Public Comment Deadline: March 9, 2016.

Agency Contact: Erik Bodin, Director, Office of Licensure and Certification, Department of Health, 9960 Mayland Drive, Suite 401, Richmond, VA 23233, telephone (804) 367-2102, or email erik.bodin@vdh.virginia.gov.

VA.R. Doc. No. R16-13; Filed January 19, 2016, 1:03 p.m.

BOARD OF MEDICAL ASSISTANCE SERVICES

Initial Agency Notice

Title of Regulation: **12VAC30-20. Administration of Medical Assistance Services.**

Statutory Authority: § 32.1-325 of the Code of Virginia.

Name of Petitioner: Jeremiah J. Jewett, III.

Nature of Petitioner's Request: The petitioner requests that the Formal Appeals regulations be amended as follows: "The DMAS director shall issue the final agency case decision to the provider, with a copy to the hearing officer, within 60 days of receipt of the hearing officer's recommended decision."

Agency Plan for Disposition of Request: In accordance with Virginia law, the petition has been filed with the Registrar of Regulations and will be published on February 8, 2016, and posted to the Virginia Regulatory Town Hall at www.townhall.virginia.gov. Comment on the petition will be accepted until February 29, 2016. Following receipt of all comment on the petition, and within 90 days of February 29, 2016, the matter and any comments will be considered by the Director of the Department of Medical Assistance Services, acting on behalf of the board, in order to make a determination on the petition.

Public Comment Deadline: February 29, 2016.

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

VA.R. Doc. No. R16-14; Filed January 19, 2016, 12:11 p.m.

NOTICES OF INTENDED REGULATORY ACTION

TITLE 6. CRIMINAL JUSTICE AND CORRECTIONS

BOARD OF CORRECTIONS

Withdrawal of Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the Board of Corrections has WITHDRAWN the Notice of Intended Regulatory Action (NOIRA) for **6VAC15-80, Standards for Planning, Design, Construction and Reimbursement of Local Correctional Facilities**, which was published in [25:20 VA.R. 3474 June 8, 2009](#). The NOIRA has been replaced by a current action to repeal 6VAC15-80 and replace it with a new regulation, 6VAC15-81, as described in the NOIRA published in [32:8 VA.R. 1336 December 14, 2015](#).

Agency Contact: Jim Bruce, Agency Regulatory Coordinator, Department of Corrections, P.O. Box 26963, Richmond, VA 23261-6963, telephone (804) 887-8215, or email james.bruce@vadoc.virginia.gov.

VA.R. Doc. No. R09-1823; Filed January 14, 2016, 11:16 a.m.

TITLE 12. HEALTH

STATE BOARD OF HEALTH

Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the State Board of Health intends to consider promulgating a new regulation, **12VAC5-221, Virginia's Rules and Regulations Governing Cooperative Agreements**. The purpose of the proposed action is to implement Chapter 741 of the 2015 Acts of Assembly, which mandates that the new regulation include, at a minimum, provisions regarding (i) the review of applications for proposed cooperative agreements; (ii) the process by which applications for proposed cooperative agreements are approved or denied; (iii) post-approval monitoring; and (iv) a schedule establishing the amount of the annual fee that the commissioner is authorized to assess from the parties to a cooperative agreement. The emergency regulations contain provisions that meet these requirements. To address the unique health care challenges that exist in the southwest region of Virginia, the General Assembly enacted Chapter 741, which authorizes the Commissioner of Health to approve cooperative agreements that are beneficial to individuals served by the Southwest Virginia Health Authority and to actively supervise cooperative agreements to ensure compliance with the provisions that have been approved. The intent of this regulatory action is to promote and protect the health and safety of individuals within the Southwest Virginia Health Authority's geographic area by ensuring that any

cooperative agreements entered into by hospitals foster improvements in the quality of health care, moderate increases in health care cost, improve access to needed health care services, and promote improvements in population health status in the Southwest Virginia Health Authority's geographic area.

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

Statutory Authority: § 32.1-12 of the Code of Virginia; Chapter 741 of the 2015 Acts of Assembly.

Public Comment Deadline: March 9, 2016.

Agency Contact: Susan Puglisi, Policy Analyst, Department of Health, 9960 Mayland Drive, Suite 401, Richmond, VA 23233, telephone (804) 367-2157, FAX (804) 527-4502, or email susan.puglisi@vdh.virginia.gov.

VA.R. Doc. No. R16-4430; Filed January 18, 2016, 5:40 p.m.

Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the State Board of Health intends to consider amending **12VAC5-410, Regulations for the Licensure of Hospitals in Virginia**. The purpose of the proposed action is to amend the regulation to comply with § 32.1-127 B 18 of the Code of Virginia, enacted by Chapter 661 of the 2015 Acts of Assembly, which requires the board to adopt regulations requiring each hospital that provides obstetrical services to establish policies to follow when a stillbirth occurs. The policies must meet the guidelines pertaining to counseling patients and their families and other aspects of managing stillbirths as may specified by the board.

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

Statutory Authority: §§ 32.1-123 and 32.1-127 of the Code of Virginia.

Public Comment Deadline: March 11, 2016.

Agency Contact: Susan Puglisi, Policy Analyst, Department of Health, 9960 Mayland Drive, Richmond, VA 23233, telephone (804) 367-2157, FAX (804) 527-4502, or email susan.puglisi@vdh.virginia.gov.

VA.R. Doc. No. R16-4620; Filed January 11, 2016, 10:08 a.m.

TITLE 16. LABOR AND EMPLOYMENT

SAFETY AND HEALTH CODES BOARD

Withdrawal of Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the Safety and Health Codes Board has WITHDRAWN the Notice of Intended Regulatory Action for **16VAC25-185, Confined Space Standard for**

Agriculture, which was published in [24:11 VA.R. 1342-1343 February 4, 2008](#).

Agency Contact: Regina P. Cobb, Agency Management Analyst Senior, Department of Labor and Industry, Main Street Centre, 600 East Main Street, Richmond, VA 23219, telephone (804) 786-0610, FAX (804) 786-8418, TTY (804) 786-2376, or email cobb.regina@dol.gov.

VA.R. Doc. No. R08-1045; Filed January 20, 2016, 11:30 a.m.



TITLE 22. SOCIAL SERVICES

STATE BOARD OF SOCIAL SERVICES

Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the State Board of Social Services intends to consider amending **22VAC40-111, Standards for Licensed Family Day Homes**. The purpose of the proposed action is to align the regulation with the federal Child Care and Development Block Grant Act of 2014, which requires 10 health and safety topics to be addressed for providers receiving federal child care and development funds. The intent is to align requirements of licensed programs with requirements for providers receiving child care and development funds; this includes unregulated and unlicensed programs. Amending the existing regulation to reflect federal health and safety standards will provide additional protections of the health, safety, and welfare of children in care.

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

Statutory Authority: §§ 63.2-217 and 63.2-1734 of the Code of Virginia.

Public Comment Deadline: March 9, 2016.

Agency Contact: Sharon Smith-Basey, Program Consultant, Department of Social Services, 801 East Main Street, Richmond, VA 23219, telephone (804) 726-7037, FAX (804) 726-7132, or email sharon.basey@dss.virginia.gov.

VA.R. Doc. No. R16-4604; Filed January 11, 2016, 12:25 p.m.

Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the State Board of Social Services intends to consider amending **22VAC40-185, Standards for Licensed Child Day Centers**. The purpose of the proposed action is to align the regulation with the federal Child Care and Development Block Grant Act of 2014, which requires 10 health and safety topics to be addressed for providers receiving federal child care and development funds. The intent is to align requirements of licensed programs with requirements for providers receiving child care and development funds; this includes unregulated and unlicensed programs. Amending the existing regulation to reflect federal

health and safety standards will provide additional protections of the health, safety, and welfare of children in care. The agency has a pending regulatory action to repeal 22VAC40-185 and replace it with a new regulation, as part of a comprehensive review and update.

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

Statutory Authority: §§ 63.2-217 and 63.2-1734 of the Code of Virginia.

Public Comment Deadline: March 9, 2016.

Agency Contact: Tatanishia Armstrong, Licensing Consultant, Department of Social Services, 801 East Main Street, Richmond, VA 23219, telephone (804) 726-7152 ext: 7, FAX (804) 726-7132, or email tatanishia.armstrong@dss.virginia.gov.

VA.R. Doc. No. R16-4596; Filed January 13, 2016, 7:57 a.m.

Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the State Board of Social Services intends to consider repealing **22VAC40-661, Child Care Program**, and adopting **22VAC40-665, Child Care Program**, to replace it. The purpose of the proposed action is to align Virginia's child care subsidy program requirements with the federal Child Care and Development Block Grant Act of 2014. The goals of this action are to broaden the purposes of the program by emphasizing child development; increase the number of children receiving healthy, safe, and quality care; and implement family-friendly policies. The new regulation will strengthen the child care subsidy program's dual role as both an early childhood development program and a work support program for low-income families. Key changes in the new regulation include, but are not limited to, supporting and protecting the health and safety of children in care through more consistent standards for child care providers and monitoring of those standards. The changes will also focus on improving the quality of care statewide through increased supports for child care providers and enabling eligible families to more easily access stable and continuous care.

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

Statutory Authority: § 63.2-217 of the Code of Virginia.

Public Comment Deadline: March 9, 2016.

Agency Contact: Mary Ward, Subsidy Manager, Department of Social Services, 801 East Main Street, Richmond, VA 23219, telephone (804) 726-7638, FAX (804) 726-7655, or email mary.ward@dss.virginia.gov.

VA.R. Doc. No. R16-4602; Filed January 11, 2016, 12:20 p.m.

REGULATIONS

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

Symbol Key

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

TITLE 4. CONSERVATION AND NATURAL RESOURCES

MARINE RESOURCES COMMISSION

Emergency Regulation

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

Statutory Authority: §§ 28.2-201 and 28.2-210 of the Code of Virginia.

Effective Dates: January 27, 2016, through February 25, 2016.

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.

Preamble:

The emergency amendments modify the landing dates, landing periods, possession limits, and landing limits for summer flounder commercially harvested outside of Virginia waters, and include (i) permitting the possession of a North Carolina vessel possession limit of summer flounder but prohibiting offloading any amount of that possession limit except pursuant to a transfer quota agreed to by the Commissioner of the Marine Resources Commission, (ii) changing the harvesting date of April 19 to May 7, (iii) increasing the 20-day period for landing to 30 days, and (iv) prohibiting landing more than a total of 5000 pounds of summer flounder during the second 30-day period.

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

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

1. Possess aboard any vessel in Virginia waters any amount of Summer Flounder in excess of 10% by weight of Atlantic croaker or the combined landings, on board a vessel, of black sea bass, scup, squid, scallops and Atlantic mackerel.
2. Possess aboard any vessel in Virginia waters any amount of Summer Flounder in excess of 1,500 pounds landed in combination with Atlantic croaker.
3. Fail to sell the vessel's entire harvest of all species at the point of landing.

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

~~B. C.~~ C. From the second Wednesday in March through ~~April 19~~ May 7, it shall be unlawful for any person harvesting Summer Flounder outside of Virginia waters to do any of the following:

1. Possess aboard any vessel in Virginia waters any amount of Summer Flounder in excess of the combined total of the Virginia landing limit described in ~~subdivision subdivisions 3 and 4~~ of this subsection and the amount of the legal North Carolina landing limit or trip limit.

2. Land Summer Flounder in Virginia for commercial purposes more than twice during each consecutive ~~20-day~~ 30-day period, with the first ~~20-day~~ 30-day period beginning on the second Wednesday in March.

3. Land in Virginia more than a total of 7,500 pounds of Summer Flounder during ~~each consecutive 20-day~~ the first 30-day period, with the first ~~20-day~~ 30-day period beginning on the second Wednesday in March.

4. Land in Virginia more than a total of 5,000 pounds of summer flounder during the second 30-day period with the second 30-day period beginning on April 7.

~~4. 5.~~ Land in Virginia any amount of Summer Flounder more than once in any consecutive five-day period.

~~C. D.~~ D. From November 1 through December 31 of each year, or until it has been projected and announced that 85% of the allowable landings have been taken, it shall be unlawful for any person harvesting Summer Flounder outside of Virginia waters to do any of the following:

1. Possess aboard any vessel in Virginia waters any amount of Summer Flounder in excess of the combined total of the Virginia landing limit described in subdivisions 3 and 4 of this subsection and the amount of the legal North Carolina landing limit or trip limit.

2. Land Summer Flounder in Virginia for commercial purposes more than twice during each consecutive 30-day period, with the first 30-day period beginning on November 1.

3. Land in Virginia more than a total of 10,000 pounds of Summer Flounder during the first 30-day period, with the first 30-day period beginning on November 1.

4. Land in Virginia more than a total of 5,000 pounds of Summer Flounder during the second 30-day period with the second 30-day period beginning on December 1.

5. Land in Virginia any amount of Summer Flounder more than once in any consecutive five-day period.

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

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

~~F.~~ G. Any possession limit described in this section shall be determined by the weight in pounds of Summer Flounder as customarily packed, boxed and weighed by the seafood buyer or processor. The weight of any Summer Flounder in pounds found in excess of any possession limit described in this section shall be prima facie evidence of violation of this chapter. Persons in possession of Summer Flounder aboard any vessel in excess of the possession limit shall be in violation of this chapter unless that vessel has requested and been granted safe harbor. Any buyer or processor offloading or accepting any quantity of Summer Flounder from any vessel in excess of the possession limit shall be in violation of this chapter, except as described by subsection ~~I~~ J of this section. A buyer or processor may accept or buy Summer Flounder from a vessel that has secured safe harbor, provided that vessel has satisfied the requirements described in subsection ~~I~~ J of this section.

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

~~H.~~ I. It shall be unlawful for a licensed seafood buyer or federally permitted seafood buyer to fail to contact the Marine Resources Commission Operation Station prior to a vessel offloading Summer Flounder harvested outside of Virginia. The buyer shall provide to the Marine Resources Commission the name of the vessel, its captain, an estimate of the amount

in pounds of Summer Flounder on board that vessel, and the anticipated or approximate offloading time. Once offloading of any vessel is complete and the weight of the landed Summer Flounder has been determined, the buyer shall contact the Marine Resources Commission Operations Station and report the vessel name and corresponding weight of Summer Flounder landed. It shall be unlawful for any person to offload from a boat or vessel for commercial purposes any Summer Flounder during the period of 9 p.m. to 7 a.m.

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

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

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

VA.R. Doc. No. R16-4627; Filed January 27, 2016, 3:22 p.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: **4VAC20-720. Pertaining to Restrictions on Oyster Harvest (amending 4VAC20-720-40).**

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

Effective Date: February 1, 2016.

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 amendment changes the dates of part of the open oyster harvest season for the James River Area and the Thomas Rock Area (James River) from March 1, 2016, through March 31, 2016, to January 1, 2016, through January 31, 2016.

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4VAC20-720-40. Open oyster harvest season and areas.

A. It shall be unlawful for any person to harvest oysters from public and unassigned grounds outside of the seasons and areas set forth in this section.

B. It shall be unlawful to harvest clean cull oysters from the public oyster grounds and unassigned grounds except during the lawful seasons and from the lawful areas as described in the following subdivisions of this subsection.

1. James River Seed Area, including the Deep Water Shoal State Replenishment Seed Area: October 1, 2015, through April 30, 2016.
2. Milford Haven: December 1, 2015, through February 29, 2016.
3. Rappahannock River Area 9: November 1, 2015, through December 31, 2015.
4. Little Wicomico River: October 1, 2015, through December 31, 2015.
5. Coan River: October 1, 2015, through December 31, 2015.
6. Yeocomico River: October 1, 2015, through December 31, 2015.
7. Nomini Creek: October 1, 2015, through December 31, 2015.
8. Mobjack Bay Area: January 1, 2016, through January 31, 2016.
9. Rappahannock River Rotation Area 5: October 1, 2015, through November 30, 2015.
10. Rappahannock River Rotation Area 3: November 1, 2015, through December 31, 2015.
11. Great Wicomico River Area: December 1, 2015, through January 31, 2016.
12. Upper Chesapeake Bay - Blackberry Hangs Area: December 1, 2015, through January 31, 2016.
13. James River Area and the Thomas Rock Area (James River): November 1 2015, through December 31, 2015, and ~~March~~ January 1, 2016, through ~~March~~ January 31, 2016.
14. Pocomoke and Tangier Sounds Rotation Area 1: December 1, 2015, through February 29, 2016.
15. Pocomoke Sound Area - Public Ground 10: November 2, 2015, through November 13, 2015.
16. Pocomoke Sound Area - Public Ground 9: November 16, 2015, through November 27, 2015.
17. Deep Rock Area: December 1, 2015, through February 29, 2016.
18. Seaside of the Eastern Shore (for clean cull oysters only): November 1, 2015, through March 31, 2016.

C. It shall be unlawful to harvest seed oysters from the public oyster grounds or unassigned grounds, except during the lawful seasons. The harvest of seed oysters from the

lawful areas is described in the following subdivisions of this subsection.

1. James River Seed Area: October 1, 2015, through May 31, 2016.
2. Deep Water Shoal State Replenishment Seed Area: October 1, 2015, through May 31, 2016.

VA.R. Doc. No. R16-4613; Filed January 27, 2016, 3:25 p.m.



TITLE 12. HEALTH

STATE BOARD OF HEALTH

Final Regulation

Titles of Regulations: **12VAC5-90. Regulations for Disease Reporting and Control (adding 12VAC5-90-215).**

12VAC5-120. Regulations for Testing Children for Elevated Blood-Lead Levels (repealing 12VAC5-120-10 through 12VAC5-120-90).

Statutory Authority: §§ 32.1-12, 32.1-35, and 32.1-46.1 of the Code of Virginia.

Effective Date: March 11, 2016.

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

Summary:

The amendments incorporate the testing and risk determination criteria for identifying children with elevated blood lead levels into 12VAC5-90 and repeal 12VAC5-120, the existing regulation pertaining to blood lead level testing of children.

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.

Part IX

Protocol for Identification of Children with Elevated Blood Lead Levels

12VAC5-90-215. Schedule and criteria for and confirmation of blood lead testing and information to be provided.

A. Schedule for testing. Every child shall be tested to determine the blood lead level at 12 months and 24 months of age if the health care provider determines that the child meets any of the criteria listed in subsection B of this section. Children 25 months through 72 months of age who present for medical care and meet any of criteria of subsection B of this section shall also be tested if they have either not previously been tested for blood lead level or were previously tested but experienced a change since testing that has resulted

in an increased risk of lead exposure based on the criteria listed in subsection B of this section.

B. Criteria for testing.

1. The child is eligible for or receiving benefits from Medicaid or the Special Supplemental Nutrition Program for Women, Infants and Children (WIC);
2. The child is living in or regularly visiting a house, apartment, dwelling, structure, or child care facility built before 1960;
3. The child is living in or regularly visiting a house, apartment, dwelling, structure, or child care facility built before 1978 that has (i) peeling or chipping paint or (ii) recent (within the last six months) ongoing or planned renovations;
4. The child is living in or regularly visiting a house, apartment, dwelling, or other structure in which one or more persons have blood lead testing yielding evidence of lead exposure;
5. The child is living with an adult whose job, hobby, or other activity involves exposure to lead;
6. The child is living near an active lead smelter, battery recycling plant, or other industry likely to release lead;
7. The child's parent, guardian, or other person standing in loco parentis requests the child's blood be tested due to any suspected exposure; or
8. The child is a recent refugee or immigrant or is adopted from outside of the United States.

C. Exceptions. A child who does not meet any of the schedule or criteria provided in subsection A or B of this section is considered to be at low risk, and testing is not required but may be conducted at the discretion of the health care provider. The testing requirement shall be waived if the parent, guardian, or other person standing in loco parentis of a child objects to the testing on the basis that the procedure conflicts with his religious tenets or practices.

D. Confirmation of blood lead levels. Blood lead level testing shall be performed on venous or capillary blood. Tests of venous blood performed by a laboratory certified by the federal Centers for Medicare & Medicaid Services in accordance with 42 USC § 263a, the Clinical Laboratory Improvement Amendment of 1988 (CLIA-certified), are considered confirmatory. Tests of venous blood performed by any other laboratory and tests of capillary blood shall be confirmed by a repeat blood test, preferably venous, performed by a CLIA-certified laboratory. Such confirmatory testing shall be performed in accordance with the following schedule:

1. Within one to three months if the result of the capillary test is at or above the CDC's reference value and up to 9 micrograms of lead per deciliter of whole blood ($\mu\text{g}/\text{dL}$).

2. Within one week to one month if the result of the capillary test is 10-44 $\mu\text{g}/\text{dL}$. The higher this test result, the more urgent the need for a confirmatory test.

3. Within 48 hours if the result of the capillary test is 45-59 $\mu\text{g}/\text{dL}$.

4. Within 24 hours if the result of the capillary test is 60-69 $\mu\text{g}/\text{dL}$.

5. Immediately as an emergency laboratory test if the result of the capillary test is 70 $\mu\text{g}/\text{dL}$ or higher.

E. Information to be provided. As part of regular well-check visits for all children, the health care provider shall make available to parents, guardians, or other persons standing in loco parentis information on the dangers of lead poisoning, potential sources of lead and ways to prevent exposure, and a list of available lead-related resources. When blood lead level testing is performed, the health care provider shall share the child's blood lead level test result with the child's parent, guardian, or other person standing in loco parentis and report to the local health department in accordance with the requirements of 12VAC5-90-80.

VA.R. Doc. No. R14-3897; Filed January 11, 2016, 10:10 a.m.

Emergency Regulation

Title of Regulation: **12VAC5-221. Virginia's Rules and Regulations Governing Cooperative Agreements (adding 12VAC5-221-10 through 12VAC5-221-150).**

Statutory Authority: § 32.1-12 of the Code of Virginia; Chapter 741 of the 2015 Acts of Assembly.

Effective Dates: January 18, 2016, through July 17, 2017.

Agency Contact: Susan Puglisi, Policy Analyst, Department of Health, 9960 Mayland Drive, Suite 401, Richmond, VA 23233, telephone (804) 367-2157, FAX (804) 527-4502, or email susan.puglisi@vdh.virginia.gov.

Preamble:

Chapter 741 of the 2015 Acts of Assembly mandates the Board of Health to promulgate regulations that at a minimum address the review of applications for proposed cooperative agreements, the process by which applications for proposed cooperative agreements shall be approved or denied, post-approval monitoring and a fee schedule establishing the amount of the annual fee per cooperative agreement. The second enactment clause of Chapter 741 further specifies that the regulations must be effective within 280 days of enactment. For that reason, the board is utilizing the emergency rulemaking process authorized by the Administrative Process Act in § 2.2-4011 of the Code of Virginia. The regulations contain provisions pertaining to definitions; a fee schedule; procedures for applying for a cooperative agreement, the Commissioner of Health's request for information, and the commissioner's review; ongoing monitoring; and annual reporting.

In drafting the emergency regulations, the Virginia Department of Health (VDH) consulted other jurisdictions,

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convened a regulatory advisory panel, and held a public hearing. Tennessee has a program that is similar to the program envisioned by Chapter 741 and is a neighboring jurisdiction to Southwest Virginia. For these reasons, VDH utilized regulations issued by Tennessee as a framework in drafting the emergency regulations. VDH convened a regulatory advisory panel of stakeholders consisting of hospital providers, health plans, physicians, and representatives from the Southwest Virginia Health Authority. The regulatory advisory panel met twice and provided feedback regarding a framework document that VDH incorporated into the emergency regulations. Finally, VDH held a public hearing in Abingdon, Virginia. Public comment received at the hearing was considered and where appropriate incorporated into the emergency regulations.

To address the unique health care challenges that exist in Southwest Virginia, the General Assembly through Chapter 741 has authorized the commissioner to approve cooperative agreements that are beneficial to individuals served by the Southwest Virginia Health Authority and to actively supervise cooperative agreements to ensure compliance with the provisions that have been approved. The intent of this regulatory action is to promote and protect the health and safety of individuals within the Southwest Virginia Health Authority's geographic area by ensuring any cooperative agreements entered into by hospitals foster improvements in the quality of health care, moderate increases in health care cost, improve access to needed health care services, and promote improvements in population health status in the Southwest Virginia Health Authority's geographic area. Chapter 741 mandates that this regulatory action include at a minimum provisions regarding (i) the review of applications for proposed cooperative agreements; (ii) the process by which applications for proposed cooperative agreements shall be approved or denied; (iii) post-approval monitoring; and (iv) a schedule establishing the amount of the annual fee that the commissioner is authorized to assess from the parties to a cooperative agreement. The emergency regulations contain provisions that meet these requirements.

CHAPTER 221

VIRGINIA'S RULES AND REGULATIONS GOVERNING COOPERATIVE AGREEMENTS

12VAC5-221-10. Purpose.

To address the unique health care challenges that exist in the Southwest Virginia community, the General Assembly authorized the commissioner to approve or deny an application for a cooperative agreement following receipt of a recommendation for approval by the authority. To the extent an approved cooperative agreement might be anticompetitive within the meaning and intent of state and federal antitrust laws, it is the intent of the Commonwealth with respect to

each participating locality to supplant competition with a regulatory program to permit cooperative agreements that are beneficial to citizens served by the authority. The commissioner is authorized to issue a letter authorizing cooperative agreement if he determines by a preponderance of the evidence that the benefits likely to result from the cooperative agreement outweigh the disadvantages likely to result from a reduction in competition. The commissioner is responsible for actively supervising the parties that receive the letter authorizing cooperative agreement to ensure compliance with the provisions that have been approved. Such intent is within the public policy of the Commonwealth to facilitate the provision of quality, cost-efficient medical care to residents of a participating locality.

12VAC5-221-20. Definitions.

"Applicant" means a party to a proposed cooperative agreement who submits an application to the authority pursuant to § 15.2-5384.1 of the Code of Virginia.

"Application" means the written materials submitted by applicants to the authority and the department in accordance with § 15.2-5384.1 of the Code of Virginia.

"Authority" means the political subdivision organized and operated pursuant to Chapter 53.1 (§ 15.2-5368 et seq.) of Title 15.2 of the Code of Virginia, or if such authority is abolished, the board, body, authority, department, or officer succeeding to the principal functions thereof or to whom the powers given by Chapter 53.1 of Title 15.2 of the Code of Virginia are given by law.

"Attorney General" means the Attorney General for the Commonwealth of Virginia.

"Commissioner" means the State Health Commissioner.

"Cooperative agreement" means an agreement among two or more hospitals for the sharing, allocation, consolidation by merger or other combination of assets, or referral of patients, personnel, instructional programs, support services, and facilities or medical, diagnostic, or laboratory facilities or procedures or other services traditionally offered by hospitals.

"Day" means a business day.

"Department" means the Virginia Department of Health.

"Hospital" includes any health center and health provider under common ownership with the hospital and means any and all providers of dental, medical, and mental health services, including all related facilities and approaches thereto and appurtenances thereof. Dental, medical, and mental health facilities includes any and all facilities suitable for providing hospital, dental, medical, and mental health care, including any and all structures, buildings, improvements, additions, extensions, replacements, appurtenances, lands, rights in lands, franchises, machinery, equipment, furnishing, landscaping, approaches, roadways, and other facilities necessary or desirable in connection therewith or incidental thereto (including, without limitation, hospitals; nursing homes; assisted living facilities; continuing care facilities;

self-care facilities; mental health facilities; wellness and health maintenance centers; medical office facilities; clinics; outpatient surgical centers; alcohol, substance abuse, and drug treatment centers; dental care clinics; laboratories; research facilities; sanitariums; hospices; facilities for the residence or care of the elderly, the handicapped, or the chronically ill; residential facilities for nurses, interns, and physicians; and any other kind of facility for the diagnosis, treatment, rehabilitation, prevention, or palliation of any human illness, injury, disorder, or disability) together with all related and supporting facilities and equipment necessary and desirable in connection therewith or incidental thereto, or equipment alone, including, without limitation, kitchen, laundry, laboratory, wellness, pharmaceutical, administrative, communications, computer and recreational facilities and equipment, storage space, mobile medical facilities, vehicles and other equipment necessary or desirable for the transportation of medical equipment or the transportation of patients. Dental, medical, and mental health facilities also includes facilities for graduate-level instruction in medicine or dentistry and clinics appurtenant thereto offering free or reduced rate dental, medical, or mental health services to the public.

"Letter authorizing cooperative agreement" means a document that is issued by the commissioner approving a cooperative agreement.

"Measure" means some number of factors or benchmarks, which may be binary, a range, or continuous factors.

"Participating locality" means any county or city in the LENOWISCO or Cumberland Plateau Planning District Commissions and the Counties of Smyth and Washington and the City of Bristol with respect to which an authority may be organized and in which it is contemplated that the authority will function.

"Party" means a hospital entering into a cooperative agreement.

"Plan of separation" means the written proposal submitted with an application to return the parties to a preconsolidation state, which includes a plan for separation of any combined assets, offering, provision, operation, planning, funding, pricing, contracting, utilization review or management of health services or any combined sharing, allocation, or referral of patients, personnel, instructional programs, support services and facilities or medical, diagnostic or laboratory facilities or procedures or other services traditionally offered by hospitals, including any parent or subsidiary at the time the consolidation occurs or thereafter.

"Primary service area" or "PSA" means the geographic area from which a hospital draws 75% of its patients as measured by the residential zip code of each patient.

"Secondary service area" or "SSA" means the geographic area from which a hospital draws an additional 15% of its patients, as measured by the residential zip code of each patient.

12VAC5-221-30. Separate applications.

A party shall submit an application for a letter authorizing cooperative agreement for each cooperative agreement the party is applying to enter into. This provision applies even in the event that the parties have an existing letter authorizing cooperative agreement issued by the commissioner. An amendment to a cooperative agreement shall require submission of a new application.

12VAC5-221-40. Application.

A. Parties within any participating locality may submit an application for a letter authorizing cooperative agreement to the authority. Information regarding the requirements of an application for a letter authorizing cooperative agreement submitted to the authority should be obtained through the authority.

B. At the time of submission to the authority, parties shall simultaneously submit a copy of the application to the commissioner and the Attorney General.

C. If the authority requires the applicant to submit additional information before determining that the application is complete, the parties shall simultaneously submit a copy of the additional information to the authority, the commissioner, and the Attorney General.

D. If the applicants believe the materials submitted contain proprietary information that is required to remain confidential, such information must be clearly identified and the applicants shall submit duplicate applications, one with full information for the commissioner's use and one redacted application available for release to the public. Proprietary information that is clearly identified by the applicants will be kept confidential by the department pursuant to subdivision 3 of § 2.2-3705.6 of the Code of Virginia.

12VAC5-221-50. Fee schedule.

A. Fees shall be remitted only by certified check, cashier's check, bank money order, or other methods approved by the department. Fees shall be made payable to the department.

B. The application fee shall be \$50,000 and shall be due to the department upon its receipt of a recommendation for approval from the authority.

C. If the commissioner should determine after review of the application that the actual cost incurred by the department is less than \$50,000, the applicant shall be reimbursed the amount that is greater than the actual cost. If the commissioner should determine that the actual cost incurred by the department is greater than \$50,000, the applicant shall pay any additional amounts due as instructed by the department. The application fee shall not exceed \$75,000.

12VAC5-221-60. Public hearing.

A. The authority shall, in conjunction with the commissioner, schedule a public hearing for each completed application submitted. The hearing shall be held no later than

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45 days after the receipt of a complete application by the authority.

B. The authority will publish and issue notice of the hearing in accordance with subsection C of § 15.2-5384.1 of the Code of Virginia.

C. The public hearing shall be open to the public in accordance with the provisions of the Virginia Freedom of Information Act (§ 2.2-3700 et. seq. of the Code of Virginia).

D. The public hearing shall be recorded by the Virginia Department of Health.

12VAC5-221-65. Public comment to the commissioner.

The public may submit written comments regarding the application to the commissioner. To ensure consideration by the commissioner, written comments must be received no later than 14 days after the authority adopts its recommendation on the application.

12VAC5-221-70. The commissioner's request for information.

A. Upon receipt of the authority's recommendation for approval, the commissioner and department may request supplemental information from the applicants.

B. To the extent the information is not present within the application, the commissioner shall request the following information:

1. A report or reports used for public information and education about the proposed cooperative agreement prior to the parties' submission of the application. The applicants shall document the efforts used to disseminate the report or reports. The report or reports shall include, but are not limited to:

a. A description of the proposed primary service area (PSA) and secondary service areas (SSA) and the services and facilities to be included in the cooperative agreement;

b. A description of how health services will change if the letter authorizing cooperative agreement is issued;

c. A description of improvements in patient access to health care including prevention services for all categories of payers and advantages patients will experience across the entire service area regarding costs, availability, and accessibility upon implementation of the cooperative agreement and/or findings from studies conducted by hospitals and other external entities, including health economists, and clinical services and population health experts, that describe how implementation of the proposed cooperative agreement will be effective with respect to resource allocation implications; efficient with respect to fostering cost containment, including, but not limited to, eliminating duplicative services; and equitable with respect to maintaining quality and competition in health services within the service area and assuring patient access to and

choice of insurers and providers within the health care system;

d. A description of any plans by the parties regarding existing or planned facilities that will impact access for patients to the services currently offered by the parties at their respective facilities, including expansions, closures, reductions in capacity, consolidation, and reduction or elimination of any services;

e. A description of the findings from community or population health assessments for the service areas regarding major health issues, trends, and health disparities, including comparisons to measures for the state and similar regional areas, and a description of how the health of the population will change if the letter authorizing cooperative agreement is issued; and

f. A description of the impact on the health professions workforce including long-term employment, wage levels, recruitment, and retention of health professionals.

2. A record of community stakeholder and consumer views of the proposed cooperative agreement collected through a public participatory process including meetings and correspondence. Transcripts or minutes of any meetings held during the public participatory process shall be included in the report.

3. A summary of the nature of the proposed cooperative agreement between the parties.

4. A signed copy of the cooperative agreement and a copy of the following:

a. A description of any consideration passing to any party, individual or entity under the cooperative agreement including the amount, nature, source, and recipient;

b. A detailed description of any merger, lease, operating or management contract, change of control or other acquisition or change, direct or indirect, in ownership of any party or of the assets of any party to the cooperative agreement;

c. A list of all services and products and of all hospitals and other service locations that are a subject of the cooperative agreement including those not located or provided within the boundaries of the Commonwealth of Virginia, and including, but not limited to, hospitals or other inpatient facilities, insurance products, physician practices, pharmacies, accountable care organizations, psychiatric facilities, nursing homes, physical therapy and rehabilitation units, home care agencies, wellness centers or services, surgical centers or services, dialysis centers or services, cancer centers or services, imaging centers or services, support services, and any other product, facility, or service; and

d. A description of each party's contribution of capital, equipment, labor, services, or other contribution of value to the transaction.

5. A detailed description of the current and proposed PSA and SSA for the parties, including the PSA and SSA of each party's hospitals, not limited to the boundaries of the Commonwealth of Virginia. If the proposed PSA and SSA differ from the service areas where the parties have conducted business over the five years preceding the application, a description of how and why the proposed PSA or SSA differs and why changes are proposed.

6. A description of the prior history of dealings between the parties for the last five years, including but not limited to, their relationship as competitors and any prior joint ventures, affiliations, or other collaborative agreements between the parties.

7. Documents sufficient to show the financial performance of each party to the transaction for each of the preceding five fiscal years including tax returns, debt, bond rating, and debt service; and copies of offering materials, subsequent filings such as continuing disclosure agreements and material event disclosures, and financial statements prepared by external certified public accountants, including management reports.

8. A copy of the current annual budget and budgets for the last five years for each party to the cooperative agreement. The budgets shall be in sufficient detail so as to determine the fiscal impact of the cooperative agreement on each party. The budgets shall be prepared in conformity with generally accepted accounting principles (GAAP) and all assumptions used shall be documented.

9. Projected budgets, including projected costs, revenues, profit margins, and operating ratios, of each party for each year for a period of five years after a letter authorizing cooperative agreement is issued. The budgets shall be prepared in conformity with generally accepted accounting principles (GAAP) and all assumptions used shall be documented.

10. A detailed explanation of the projected effects including expected change in volume, price, and revenue as a result of the cooperative agreement, including:

a. Identification of all insurance contracts and payer agreements in place at the time of the application and a description of pending or anticipated changes that would require or enable the parties to amend their current insurance and payer agreements;

b. A description of how pricing for provider insurance contracts are calculated and the financial advantages accruing to insurers, insured consumers and the parties to the cooperative agreement if the letter authorizing cooperative agreement is issued including changes in percentage of risk-bearing contracts; and

c. Identification of existing and future business plans, reports, studies or other documents of each party that:

(1) Discuss each party's projected performance in the market, business strategies, capital investment plans,

competitive analyses, and financial projections, including any documents prepared in anticipation of the cooperative agreement; and

(2) Identify plans that will be altered, eliminated, or combined under the cooperative agreement.

11. A copy of the following policies under the proposed cooperative agreement:

a. A policy that assures no restrictions to Medicare and/or Medicaid patients;

b. Policies for free or reduced fee care for the uninsured and indigent;

c. Policies for bad debt write-off; and

d. Policies that require the parties to the cooperative agreement to maintain or exceed the existing level of charitable programs and services.

12. A description of the plan to systematically integrate health care and preventive health services among the parties to the cooperative agreement in the proposed geographic service area that addresses the following:

a. A streamlined management structure, including a description of a single board of directors, centralized leadership, and operating structure;

b. Alignment of the care delivery decisions of the system with the interests of the community;

c. Clinical standardization;

d. Alignment of the cultural identities of the parties to the cooperative agreement

e. Any planned expansions, closures, reductions in capacity, consolidation, and reduction or elimination of any services;

f. Any plan for integration regarding health professions workforce development and the recruitment and retention of health professionals; and

g. Any plan for implementation of innovative or value-based payment models.

13. A description of the plan, including economic metrics, that details anticipated efficiencies in operating costs and shared services that can be gained only through the cooperative agreement including:

a. Proposed use of any cost saving to reduce prices borne by insurers and consumers;

b. Proposed use of cost savings to fund low-cost or no-cost services designed to achieve long-term population health improvements; and

c. Other proposed uses of savings to benefit advancement of health and quality of care and outcomes.

14. A description of the market and the competitive dynamics for health care services in the parties' respective service areas, including at a minimum:

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a. The identity of any nonparty hospital located in the PSA and SSA and any nonparty hospital outside of the PSA and SSA that also serves patients in the parties' PSA and SSA;

b. Estimates of the share of hospital services furnished by each of the parties and any nonparty hospitals;

c. Identification of whether any services or products of the proposed cooperative agreement are currently being offered or capable of being offered by any nonparty hospitals in the PSA and SSA and a description of how the proposed cooperative agreement will not exclude such nonparty hospitals from continued competitive and independent operation in the PSA and SSA;

d. A listing of the physicians employed by or under contract with each of the parties' hospitals in the PSA and SSA, including their specialties and office locations;

e. The identity of any potential entrants in the parties' PSA and SSA and the basis for any belief that such entry is likely within the two calendar years immediately following the date of the letter authorizing cooperative agreement is issued by the department; and

f. A list of each party's top 10 commercial insurance payers by revenue within the PSA and SSA.

15. A detailed description of each of the benefits that the parties propose will be achieved through the cooperative agreement. For each benefit include:

a. A description specifically describing how the parties intend to achieve the benefit;

b. A description of what the parties have done in the past with respect to achieving or attempting to achieve the benefits independently or through collaboration and how this may change if the cooperative agreement is granted;

c. An explanation of why the benefit can only be achieved through a cooperative agreement and not through other less restrictive arrangements; and

d. A description of how the parties propose that the commissioner measure and monitor achievement of the proposed benefit including:

(1) Proposed measures and suggested baseline values with rationale for each measure to be considered by the commissioner in developing a plan to monitor achievement of the benefit;

(2) The current and projected levels and the trajectory for each measure that would be achieved over the next five years under the cooperative agreement;

(3) The projected levels for each measure in five years in the absence of the cooperative agreement; and

(4) A plan for how the requisite data for assessing the benefit will be obtained.

16. A description of any potential adverse impact of the proposed cooperative agreement on (i) population health or

(ii) quality, availability, cost, or price of health care services to patients or payers.

17. A description of any commitments the parties are willing to make to address any potential adverse impacts resulting from the cooperative agreement. Each such commitment shall at a minimum include:

a. The parties' proposed benchmarks and metrics to measure achievement of the proposed commitments;

b. The parties' proposed plan to obtain and analyze data to evaluate the extent to which the commitments have been met, including how data shall be obtained from entities other than the parties; and

c. The parties' proposed consequences if they do not meet a commitment.

18. A plan of separation. The parties shall provide an independent opinion from a qualified organization verifying the plan of separation can be operationally implemented without undue disruption to essential health services provided by the parties.

19. A statement regarding the requirements for any certificate or certificates of public need resulting from the cooperative agreement.

20. A detailed description of the total cost to the parties resulting from the application for the cooperative agreement. Cost estimates should include costs for consultant, legal, and professional services; capital costs; financing costs; and management costs. The description should identify costs associated with the implementation of the cooperative agreement, including documentation of the availability of necessary funds. The description should identify which costs will be borne by each party.

21. An explanation of the reasons for the exclusion of any information set forth in this section. If the parties exclude an item because it is not applicable to the proposed cooperative agreement, an explanation of why the item is not applicable shall be provided.

22. A timetable for implementing all components of the proposed cooperative agreement and contact information for the person or persons authorized to receive notices, reports, and communications with respect to the letter authorizing cooperative agreement.

23. Records, reports, and documentation to support the information submitted pursuant to this section, including any additional supplemental information requested by the commissioner.

C. All supplemental information submitted to the commissioner shall be accompanied by a verified statement signed by the chairperson of the board of directors and chief executive officer of each party; or if one or more party is an individual, signed by the individual attesting to the accuracy and completeness of the enclosed information.

12VAC5-221-80. The commissioner's review.

A. The commissioner shall consult with the Attorney General when reviewing an application.

B. The commissioner may consult with the Federal Trade Commission when reviewing an application.

C. The commissioner may consult and coordinate with other affected jurisdictions when reviewing an application.

D. The commissioner shall consult with all other affected agencies of the Commonwealth when reviewing an application.

E. The commissioner in his review shall examine the record developed by the authority, the authority's recommendation for approval, and any additional information received from the parties. In addition, the commissioner may consider any other data, information, or advice available to him.

F. The commissioner shall not render a decision on the application until all supplemental information requested has been received.

G. The commissioner shall consider the following factors when conducting a review of an application:

1. Advantages.

a. Enhancement of the quality of hospital and hospital-related care, including mental health services and treatment of substance abuse, provided to citizens served by the authority, resulting in improved patient satisfaction;

b. Enhancement of population health status consistent with the regional health goals established by the authority;

c. Preservation of hospital facilities in geographical proximity to the communities traditionally served by those facilities to ensure access to care;

d. Gains in the cost-efficiency of services provided by the hospitals involved;

e. Improvements in the utilization of hospital resources and equipment;

f. Avoidance of duplication of hospital resources;

g. Participation in the state Medicaid program; and

h. Total cost of care.

2. Disadvantages.

a. The extent of any likely adverse impact of the proposed cooperative agreement on the ability of health maintenance organizations, preferred provider organizations, managed health care organizations, or other health care payers to negotiate reasonable payment and service arrangements with hospitals, physicians, allied health care professionals, or other health care providers;

b. The extent of any reduction in competition among physicians, allied health care professionals, other health care providers, or other persons furnishing goods or

services to, or in competition with, hospitals that is likely to result directly or indirectly from the proposed cooperative agreement;

c. The extent of any likely adverse impact on patients in the quality, availability, and price of health care services; and

d. The availability of arrangements that are less restrictive to competition and achieve the same benefits or a more favorable balance of benefits over disadvantages attributable to any reduction in competition likely to result from the proposed cooperative agreement.

H. The commissioner shall approve the application if he finds by a preponderance of the evidence that the benefits likely to result from the proposed cooperative agreement outweigh the disadvantages likely to result from a reduction in competition from the proposed cooperative agreement.

I. In the selection and application of the measures for reviewing the proposed benefits of the cooperative agreement, as well as during the monitoring and active supervision of any approved cooperative agreement, the commissioner shall:

1. Draw from consensus health and health care metrics, such as those being developed pursuant to the Virginia state innovation model development initiative and state population health improvement plan, to ensure the validity and consistency of the measure;

2. Use historical actual experience in the region to establish baseline performance and evaluate progress over time;

3. Consider recommendations on the measures and goals from the Technical Advisory Panel appointed pursuant to 12VAC5-221-120; and

4. Allow for flexibility, to the extent quantifiable goals or targets are specified, should environmental factors that are outside the control of the parties change significantly.

12VAC5-221-90. Action on an application.

A. The commissioner shall issue his decision in writing within 45 days of receipt of the authority's recommendation. However, if the commissioner has requested supplemental information from the applicants, the commissioner shall have 15 days, following receipt of the supplemental information, to issue a decision.

B. At the request of the applicants, the commissioner may delay issue of his decision to provide additional time to review the record.

C. The commissioner may condition approval of the letter authorizing cooperative agreement upon the applicants' commitment to achieving the improvements in population health, access to health care services, quality, and cost efficiencies identified by the applicants in support of their application. Such conditions may include, but are not limited to:

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1. A cap on the negotiated case-mix adjusted revenue per discharge by payer by product. The method for calculating such a case-mix shall be published on the Virginia Department of Health's Office of Licensure and Certification's website in a guidance document. The department may rely on third-party auditors to assist in determining the method for determining such caps, such caps' levels, and a plan for monitoring compliance;

2. A commitment to return a portion of the cost savings and efficiencies gained through the cooperative agreement to residents in the participating localities through specific proposed mechanisms;

3. An agreement that the parties shall not prevent or discourage health plans from directing or incentivizing patients to choose certain providers; the parties shall not have any contractual clauses or provisions that prevent health plans from directing or incentivizing patients;

4. An agreement that the parties shall not engage in the tying of sales of the health system's services with the health plan's purchase of other services from the health system;

5. An agreement that the parties shall not restrict a health plan's ability to make available to its health plan enrollees cost, quality, efficiency, and performance information to aid enrollees in evaluating and selecting providers in the health plan; and

6. A commitment that the parties shall not refuse to include certain provisions in contracts with health plans that have been utilized in health plan contracts in other parts of the Commonwealth in order to promote value-based health care, including but not limited to, bundled payments, pay for performance, utilization management, and other processes that reward improvements in quality and efficiency.

D. The commissioner's decision to approve or deny an application shall constitute a case decision pursuant to the Virginia Administrative Process Act (§ 2.2-4000 et. seq. of the Code of Virginia).

12VAC5-221-100. Ongoing and active supervision.

A. The commissioner shall maintain active and continuing supervision of the parties in accordance with the terms under this subsection and to ensure compliance with the cooperative agreement and the letter authorizing cooperative agreement.

B. Any party who receives a letter authorizing cooperative agreement shall submit any additional information that is requested by the department to establish benchmarks for ongoing monitoring and supervision. The department's request may include, but is not limited to (i) information on patient satisfaction, (ii) information on employee satisfaction, (iii) a charge master, (iv) information reflecting the contracted rates negotiated with nonphysician providers, (v) information reflecting the noncontracted rates negotiated with allied

health professionals, and (vi) information reflecting the noncontracted rates negotiated with other providers.

C. The department shall establish quantitative measures that will be used to evaluate the proposed and continuing benefits of the cooperative agreement.

1. The quantitative measures shall include measures of the cognizable benefits from the cooperative agreement in at least the following categories:

a. Population health;

b. Access to health services;

c. Economic;

d. Patient safety;

e. Patient satisfaction; and

f. Other cognizable benefits.

2. Each category may be comprised of measures for subcategories.

3. The Technical Advisory Panel and the parties to the cooperative agreement may make recommendations for the creation and evaluation of quantitative measures, but the department shall have the exclusive authority to add, modify, accept, or reject recommendations when creating or interpreting the quantitative measures.

D. A department representative may make periodic unannounced on-site inspections of the parties' facilities as necessary. If the department finds, after inspection, noncompliance with any provision of this chapter, any applicable state regulations, or the elements of the cooperative agreement or the letter authorizing cooperative agreement, the commissioner shall begin enforcement procedures in accordance with 12VAC5-221-130.

E. The parties shall make available to the department representative requested records and shall allow access to interview the agents, employees, contractors, and any other person under control, direction, or supervision of the parties.

F. Complaints received by the department with regard to noncompliance with the cooperative agreement or the letter authorizing cooperative agreement shall be investigated. When the investigation is complete, the parties and the complainant, if known, shall be notified of the findings of the investigation.

G. The commissioner may develop other mechanisms of monitoring the parties to determine compliance with the cooperative agreement and whether compliance continues to meet the requirements of § 15.2-5384.1 of the Code of Virginia. The commissioner may modify the mechanisms of monitoring the parties upon notice to the parties.

12VAC5-221-110. Annual reporting.

A. parties shall report annually to the commissioner on the extent of the benefits realized and compliance with any terms and conditions placed on their letter authorizing cooperative agreement. The report shall:

1. Describe the activities conducted pursuant to the cooperative agreement;

2. Include any actions taken in furtherance of commitments made by the parties or terms imposed by the commissioner as a condition for approval of the cooperative agreement;

3. Include information related to changes in price, cost, quality, access to care, and population health improvement;

4. Include actual costs, revenues, profit margins, and operating costs;

5. Include a charge master;

6. Include information reflecting the contracted rates negotiated with nonphysician providers, allied health professionals, and others;

7. Include any measures requested by the department based on the recommendations of the Technical Advisory Panel appointed pursuant to 12VAC5-221-120; and

8. Include the current status of the quantitative measures established under subsection C of 12VAC5-221-100 and the information requested by the department for benchmarks established in subsection B of 12VAC5-221-100.

B. The parties shall be required to update the parties' plan of separation annually and submit the updated plan of separation to the department. The parties shall provide an independent opinion from a qualified organization that states the plan of separation may be operationally implemented without undue disruption to essential health services provided by the parties.

C. The commissioner may require the parties to supplement the annual report with additional information to the extent necessary to ensure compliance with the cooperative agreement and the letter authorizing cooperative agreement.

D. All annual reports submitted pursuant to this section shall be certified audited by a third-party auditor.

E. The fee due with the filing of the annual report shall be \$20,000. If the commissioner should determine that the actual cost incurred by the department is greater than \$20,000, the parties shall pay any additional amounts due as instructed by the department. The annual filing fee shall not exceed \$75,000.

F. The commissioner shall issue a written decision and the basis for the decision on an annual basis as to whether the benefits of the cooperative agreement continue to outweigh the disadvantages attributable to a reduction in competition that have resulted from the cooperative agreement.

12VAC5-221-120. Technical Advisory Panel.

A. The commissioner shall appoint a Technical Advisory Panel to provide (i) initial recommendations to the commissioner as to the quality, cost, and access measures and benchmarks to be considered to objectively track the benefits and disadvantages of a cooperative agreement; and (ii) provide ongoing input to the commissioner on the evolution of these and other new measures and the progress of the

parties with respect to achievement of commitments with respect to these measures.

B. The Technical Advisory Panel shall consist of:

1. A representative of the Commissioner of Health who shall serve as chair of the panel;

2. The chief medical or quality officer or officers of the parties;

3. A chief medical or quality officer of a hospital or health system from other state market areas with no affiliation with the parties;

4. A chief medical or quality officer of a health plan that has subscribers in the affected area;

5. Experts in the area of health quality measurement and performance;

6. A consumer and employer representative from the affected area;

7. A representative from the Bureau of Insurance of the State Corporation Commission;

8. The chief financial officer or officers of the parties;

9. A chief financial officer of a hospital or health system from other state market areas with no affiliation with the parties; and

10. A chief financial officer of a health plan that has subscribers in the affected area.

C. The Technical Advisory Panel shall meet at least on an annual basis.

D. The Technical Advisory Panel shall identify evidence-based cost, quality, and access measures in areas including, but not limited to, population health, patient safety, health outcomes, patient satisfaction, access to care, and any other areas identified by the panel. The panel shall also make recommendations regarding how to best report performance on quality metrics.

E. The Technical Advisory Panel meetings shall be staffed by the Virginia Department of Health Office of Licensure and Certification.

12VAC5-221-130. Enforcement procedures.

A. If the commissioner has reason to believe that compliance with a cooperative agreement no longer meets the requirements of § 15.2-5384.1 of the Code of Virginia or this chapter, the commissioner shall initiate a proceeding to determine whether compliance with the cooperative agreement no longer meets the requirements of § 15.2-5384.1 of the Code of Virginia or this chapter.

B. In the course of such a proceeding, the commissioner is authorized to seek reasonable modifications to a letter authorizing cooperative agreement. Such modifications shall be with the consent of the parties.

C. The commissioner may revoke a letter authorizing cooperative agreement upon a finding that:

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1. The parties are not complying with the terms or conditions of the cooperative agreement or the letter authorizing cooperative agreement;

2. The cooperative agreement is not in substantial compliance with the terms of the parties' application or the letter authorizing cooperative agreement;

3. The benefits resulting from the cooperative agreement no longer outweigh the disadvantages attributable to the reduction in competition resulting from the cooperative agreement;

4. The commissioner's approval was obtained as a result of intentional material misrepresentation to the commissioner or as the result of coercion, threats, or intimidation toward any party to the cooperative agreement; or

5. The parties have failed to pay any fee required by the department or the authority.

D. The proceeding initiated by the commissioner under this section, and any judicial review thereof, shall be held in accordance with and governed by the Virginia Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).

12VAC5-221-140. Voluntary termination of cooperative agreement.

A. Any party shall file notice with the department within 30 days after terminating its participation in a cooperative agreement. The notice shall be sent in writing to the attention of the director of the department's Office of Licensure and Certification.

B. In the event of a termination of a cooperative agreement, the parties shall return the letter authorizing cooperative agreement to the department's Office of Licensure and Certification.

12VAC5-221-150. Official records.

A. The commissioner shall maintain on file all cooperative agreements that the commissioner has approved.

B. All records collected pursuant to this chapter shall be maintained in accordance with the Virginia Freedom of Information Act (§ 2.2-3700 et seq. of the Code of Virginia) and the Library of Virginia's record management program (§ 42.1-85 of the Code of Virginia).

C. All approved cooperative agreements and letters authorizing cooperative agreement shall be published on the Virginia Department of Health Office of Licensure and Certification website.

D. All reports collected pursuant to 12VAC5-221-110 shall be published on the Virginia Department of Health Office of Licensure and Certification website.

E. The commissioner shall make public his annual determination of compliance with a letter authorizing the cooperative agreement.

VA.R. Doc. No. R16-4430; Filed January 18, 2016, 5:40 p.m.

Final Regulation

REGISTRAR'S NOTICE: The following regulatory action is exempt from Article 2 of the Administrative Process Act in accordance with § 2.2-4006 A 4 c of the Code of Virginia, which excludes regulations that are necessary to meet the requirements of federal law or regulations, provided such regulations do not differ materially from those required by federal law or regulation. The State Board of Health will receive, consider, and respond to petitions by any interested person at any time with respect to reconsideration or revision.

Title of Regulation: **12VAC5-481. Virginia Radiation Protection Regulations (amending 12VAC5-481-451).**

Statutory Authority: § 32.1-229 of the Code of Virginia.

Effective Date: March 9, 2016.

Agency Contact: Steve Harrison, Director, Office of Radiological Health, Department of Health, 109 Governor Street, Richmond, VA 23219, telephone (804) 864-8151, FAX (804) 864-8155, or email steve.harrison@vdh.virginia.gov.

Summary:

The federal Nuclear Regulatory Commission adopted 10 CFR Part 37, Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material effective March 19, 2013, which required Virginia to adopt compatible regulations within three years of that date to maintain its status as an Agreement State. This action amends 12VAC5-481-451 to comply with this federal requirement. The amendments include definitions of Category 1 and Category 2 radioactive materials; requirements for background investigations and access authorization programs; protection of background information; physical protection requirements during use, which includes a security program and coordination with local law-enforcement agencies; physical protection in transit; and recordkeeping.

12VAC5-481-451. Increased controls and fingerprinting Physical protection of Category 1 and Category 2 quantities of radioactive material.

A. Any licensee who possesses or uses an aggregated quantity of Category 1 or Category 2 radioactive material equal to or in excess of those in subdivision 1 of this subsection shall establish a physical protection program that meets all requirements detailed in this section.

1. Radionuclides of concern.

Radionuclide	Quantity of concern (TBq) ^{1,2}	Quantity of concern (Ci) ^{1,2}	Category 1 (TBq) ^{1,2}	Category 1 (Ci) ^{1,2}	Category 2 (TBq) ^{1,2}	Category 2 (Ci) ^{1,2}
Am-241	0.6	16	60	1,620	0.6	16.2
Am-241/Be	0.6	16	60	1,620	0.6	16.2
Cf-252	0.2	5.4	20	540	0.2	5.4
Cm-244	0.5	14	50	1,350	0.5	13.5
Co-60	0.3	8.1	30	810	0.3	8.1
Cs-137	1	27	100	2,700	1	27
Gd-153	10	270	1,000	27,000	10	270
Ir-192	0.8	22	80	2,160	0.8	21.6
Pm-147	400	11,000	40,000	1,080,000	400	10,800
Pu-238	0.6	16	60	1,620	0.6	16.2
Pu-239/Be	0.6	16	60	1,620	0.6	16.2
Ra-226	0.4	11	40	1,080	0.4	10.8
Se-75	2	54	200	5,400	2	54
Sr-90 (Y-90)	10	270	1,000	27,000	10	270
Tm-170	200	5,400	20,000	540,000	200	5,400
Yb-169	3	81	300	8,100	3	81
Combinations of radioactive materials listed above ³	See footnote below ⁴				See footnote 4 below	

¹The aggregate activity of multiple, collocated sources of the same radionuclides should be included when the total activity equals or exceeds the quantity of concern Category 1 or Category 2 threshold.

²The primary values used for compliance are TBq. The curie (Ci) values are rounded to two significant figures for informational purposes only.

³Radioactive materials are to be considered aggregated or collocated if breaching a common physical barrier (e.g., a locked door at the entrance to a storage room) would allow access to the radioactive material or devices containing the radioactive material.

⁴If several radionuclides are aggregated, the sum of the ratios of the activity of each source, i of radionuclide, n , $A(i,n)$, to the quantity of concern Category 1 or Category 2 threshold for radionuclide n , Q_n , listed for that radionuclide equals or exceeds one. [(aggregated source activity for radionuclide A) / (quantities of concern for radionuclide A)] + [(aggregated source activity for radionuclide B) / (quantities of concern for radionuclide B)] + etc... ≥ 1 .

2. A licensee that possesses radioactive waste that contains Category 1 or Category 2 quantities of radioactive material is exempt from the requirements of this section.

3. A licensee that possesses radioactive waste that contains discrete sources, ion-exchange resins, or activated material that weighs less than 2,000 kg (4,409 lbs) is not exempt from the requirements of this section. The licensee shall implement the following requirements to secure the radioactive waste:

a. Use continuous physical barriers that allow access to the radioactive waste only through established access control points;

b. Use a locked door or gate with monitored alarm at the access control point;

c. Assess and respond to each actual or attempted unauthorized access to determine whether an actual or attempted theft, sabotage, or diversion occurred; and

d. Immediately notify the local law-enforcement agency (LLEA) and request an armed response from the LLEA upon determination that there was an actual or attempted theft, sabotage, or diversion of the radioactive waste.

B. The following increased controls apply to licensees who, at any given time, possess radioactive sources greater than or equal to the quantities of concern of radioactive material listed in subsection A of this section.

1. In order to ensure the safe handling, use, and control of licensed material in use and in storage, each licensee shall control access at all times to radioactive material quantities of concern and devices containing such radioactive

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material (devices), and limit access to such radioactive material and devices to only approved individuals who require access to perform their duties.

a. ~~The licensee shall allow only trustworthy and reliable individuals, approved in writing by the licensee, to have unescorted access to radioactive material quantities of concern and devices. The licensee shall approve for unescorted access only those individuals with job duties that require access to such radioactive material and devices. Personnel who require access to such radioactive material and devices to perform a job duty, but who are not approved by the licensee for unescorted access, must be escorted by an approved individual.~~

b. ~~For individuals employed by the licensee for three years or less, and for nonlicensee personnel, such as physicians, physicists, housekeeping personnel, and security personnel under contract, trustworthiness and reliability shall be determined at a minimum, by verifying employment history, education, personal references and fingerprinting and the review of an FBI identification and criminal history records check. The licensee shall also, to the extent possible, obtain independent information to corroborate that provided by the employee (i.e., seeking references not supplied by the individual). For individuals employed by the licensee for longer than three years, trustworthiness and reliability shall be determined, at a minimum, by a review of the employees' employment history with the licensee and fingerprinting and an FBI identification and criminal history records check.~~

c. ~~Service provider licensee employees shall be escorted unless determined to be trustworthy and reliable by an NRC required background investigation. Written verification attesting to or certifying the person's trustworthiness and reliability shall be obtained from the licensee providing the service.~~

d. ~~The licensee shall document the basis for concluding that there is reasonable assurance that an individual granted unescorted access is trustworthy and reliable, and does not constitute an unreasonable risk for unauthorized use of radioactive material quantities of concern. The licensee shall maintain a list of persons approved for unescorted access to such radioactive material and devices by the licensee.~~

2. ~~In order to ensure the safe handling, use and control of licensed material in use and in storage, each licensee shall have a documented program to monitor and immediately detect, assess, and respond to unauthorized access to radioactive material quantities of concern and devices. Enhanced monitoring shall be provided during periods of source delivery or shipment, where the delivery or shipment exceeds 100 times the limits in subsection A of this section.~~

a. ~~The licensee shall respond immediately to any actual or attempted theft, sabotage, or diversion of such radioactive material or of the devices. The response shall include requesting assistance from a local law enforcement agency (LLEA).~~

b. ~~The licensee shall have a prearranged plan with LLEA for assistance in response to an actual or attempted theft, sabotage, or diversion of such radioactive material or of the devices that is consistent in scope and timing with a realistic potential vulnerability of the sources containing such radioactive material. The prearranged plan shall be updated when changes to the facility design or operation affect the potential vulnerability of the sources. Prearranged LLEA coordination is not required for temporary job sites.~~

e. ~~The licensee shall have a dependable means to transmit information between, and among, the various components used to detect and identify an unauthorized intrusion, to inform the assessor, and to summon the appropriate responder.~~

d. ~~After initiating appropriate response to any actual or attempted theft, sabotage, or diversion of radioactive material or of the devices, the licensee shall, as promptly as possible, notify the agency at (804) 864 8150 during normal business hours and (804) 674 2400 after hours and the NRC HQ Operations Center at (301) 816 5100.~~

e. ~~The licensee shall maintain documentation describing each instance of unauthorized access and any necessary corrective actions to prevent future instances of unauthorized access.~~

3. ~~Transportation:~~

a. ~~In order to ensure the safe handling, use, and control of licensed material in transportation for domestic highway and rail shipments by a carrier other than the licensee, for quantities that equal or exceed those in subsection A of this section but are less than 100 times those in subsection A of this section, per consignment, the licensee shall:~~

(1) ~~Use carriers that:~~

(a) ~~Use package tracking systems;~~

(b) ~~Implement methods to assure trustworthiness and reliability of drivers;~~

(c) ~~Maintain constant control and/or surveillance during transit; and~~

(d) ~~Have the capability for immediate communication to summon appropriate response or assistance.~~

(2) ~~Verify and document that the carrier employs the measures listed in subdivision (1) above.~~

(3) ~~Contact the recipient to coordinate the expected arrival time of the shipment.~~

(4) ~~Confirm receipt of the shipment.~~

~~(5) Initiate an investigation to determine the location of the licensed material if the shipment does not arrive on or about the expected arrival time. When, through the course of the investigation, it is determined the shipment has become lost, stolen, or missing, the licensee shall immediately notify the agency at (804) 864 8150 during normal working hours and (804) 674 2400 after hours and the NRC HQ Operations Center at (301) 816 5100. If after 24 hours of investigating, the location of the material still cannot be determined, the radioactive material shall be determined missing and the licensee shall immediately notify the agency at (804) 864 8150 during normal working hours and (804) 674 2400 after hours and the NRC HQ Operations Center at (301) 816 5100.~~

~~b. For domestic highway and rail shipments, prior to shipping licensed radioactive material that exceeds 100 times the quantities in subsection A of this section per consignment, the licensee shall:~~

~~(1) Notify the NRC (Director, Office of Nuclear Material Safety and Safeguards, U.S. NRC, Washington, DC 20555), in writing, at least 90 days prior to the anticipated date of shipment. The NRC will issue the Order to implement the Additional Security Measures (ASMs) for the transportation of Radioactive Material Quantities of Concern (RAM QC). The licensee shall not ship this material until the ASMs for the transportation of RAM QC are implemented or the licensee is notified otherwise, in writing, by the NRC.~~

~~(2) Once the licensee has implemented the ASMs for the transportation of RAM QC, the notification requirements of subdivision 1 of this subsection shall not apply to future shipments of licensed radioactive material that exceeds 100 times the quantities listed in subsection A of this section. The licensee shall implement the ASMs for the transportation of RAM QC.~~

~~e. If a licensee employs a Manufacturer/Distributor (M&D) licensee to take possession at the licensee's location of the licensed radioactive material and ship it under its M&D license, the requirements of subdivision a and b above shall not apply.~~

~~d. If the licensee is to receive radioactive material greater than or equal to the quantities listed in subsection A of this section, per consignment, the licensee shall coordinate with the originator to:~~

~~(1) Establish an expected time of delivery; and~~

~~(2) Confirm receipt of transferred radioactive material. If the material is not received at the expected time of delivery, notify the originator and assist in any investigation.~~

4. In order to ensure the safe handling, use, and control of licensed material in use and in storage, each licensee that possesses mobile or portable devices containing

radioactive material in quantities greater than or equal to the limits in subsection A of this section shall:

a. For portable devices, have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee.

b. For mobile devices:

(1) That are only moved outside of the facility (e.g., on a trailer), have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee.

(2) That are only moved inside a facility, have a physical control that forms a tangible barrier to secure the material from unauthorized movement or removal when the device is not under direct control and constant surveillance by the licensee.

e. For devices in or on a vehicle or trailer, licensees shall also utilize a method to disable the vehicle or trailer when not under direct control and constant surveillance by the licensee.

5. The licensee shall retain documentation required by this section for three years after these increased controls are no longer effective.

a. The licensee shall retain documentation regarding the trustworthiness and reliability of individual employees for three years after the individual's employment ends.

b. Each time the licensee revises the list of approved persons required in subdivision 1 d of this subsection or the documented program required by subdivision B 2 of this section, the licensee shall retain the previous documentation for three years after the revision.

e. The licensee shall retain documentation on each radioactive material carrier for three years after the licensee discontinues use of that particular carrier.

d. The licensee shall retain documentation on shipment coordination, notifications, and investigations for three years after the shipment or investigation is completed.

e. After the licensee is terminated or amended to reduce possession limits below the quantities of concern, the licensee shall retain all documentation required by this section for three years.

6. Detailed information generated by the licensee that describes the physical protection of radioactive material quantities of concern is sensitive information and shall be protected from unauthorized disclosure.

a. The licensee shall control access to its physical protection information to those persons who have an established need to know the information and are considered to be trustworthy and reliable.

b. The licensee shall develop, maintain and implement policies and procedures for controlling access to, and for

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proper handling and protection against unauthorized disclosure of, its physical protection information for radioactive material covered by this section. The policies and procedures shall include the following:

- (1) General performance requirement that each person who produces, receives, or acquires the licensee's sensitive information, protect the information from unauthorized disclosure;
- (2) Protection of sensitive information during use, storage, and transit;
- (3) Preparation, identification or marking, and transmission;
- (4) Access controls;
- (5) Destruction of documents;
- (6) Use of automatic data processing systems; and
- (7) Removal from the licensee's sensitive information category.

C. Fingerprinting.

1. Licensees who possess radionuclides in quantities greater than those listed in subsection A of this section shall establish and maintain a fingerprinting program that meets the following:

- a. Each licensee subject to these provisions shall fingerprint each individual who is seeking unescorted access to risk significant radioactive materials equal to or greater than the quantities listed in subsection A of this section. The licensee shall review and use the information received from the Federal Bureau of Investigation (FBI) identification and criminal history records check and ensure that the provisions in this subsection are satisfied;
- b. The licensee shall notify each affected individual that the fingerprints will be used to secure a review of his criminal history record and inform the individual of the procedures for revising the record or including an explanation in the record as specified in subdivision 3 of this subsection;
- c. Fingerprints for unescorted access need not be taken if an employed individual (e.g., a licensee employee, contractor, manufacturer, or supplier) is relieved from the fingerprinting requirement by 10 CFR 73.61, or any person who has been favorably decided by a U.S. government program involving fingerprinting and an FBI identification and criminal history records check (e.g., National Agency Check, Transportation Worker Identification Credentials in accordance with 49 CFR Part 1572, Bureau of Alcohol Tobacco Firearms and Explosives background checks and clearances in accordance with 27 CFR Part 555, Health and Human Services security risk assessments for possession and use of select agents and toxins in accordance with 42 CFR Part 73, Hazardous Material security threat assessment

for hazardous material endorsement to commercial drivers license in accordance with 49 CFR Part 1572, Customs and Border Patrol's Free and Secure Trade Program (Note 1: within the last five calendar years, or any person who has an active federal security clearance provided in the latter two cases that they make available the appropriate documentation; Note 2: Written confirmation from the agency/employer that granted the federal security clearance or reviewed the FBI criminal history records results based upon a fingerprint identification check must be provided. The licensee must retain this documentation for a period of three years from the date the individual no longer requires unescorted access to certain radioactive material associated with the licensee's activities.));

d. All fingerprints obtained by the licensee pursuant to this section must be submitted to the NRC (Office of Administration, Security Processing Unit, Mail Stop TWB-05 B32M, US NRC, Washington, DC 20555-0012) for transmission to the FBI. Additionally, the licensee shall submit a certification of the trustworthiness and reliability of the Trustworthy & Reliability (T & R) Official as determined in accordance with subdivision 5 of this subsection. (See the NRC's website at www.nrc.gov for more information on submitting fingerprints, including pricing and address changes). The licensee shall review the information received from the FBI and consider it, in conjunction with the trustworthiness and reliability requirements of subdivision B 1 of this section, in making a determination whether to grant unescorted access to certain radioactive materials;

e. The licensee shall use any information obtained as part of a criminal history records check solely for the purpose of determining an individual's suitability for unescorted access to risk significant radioactive materials equal to or greater than the quantities listed in subsection A of this section; and

f. The licensee shall document the basis for its determination whether to grant or continue to allow unescorted access to risk significant radioactive materials equal to or greater than those listed in subsection A of this section.

2. Prohibitions. A licensee shall not base a final determination to deny an individual unescorted access to certain radioactive material solely on the basis of information received from the FBI involving: an arrest more than one year old for which there is no information of the disposition of the case, or an arrest that resulted in dismissal of the charge or an acquittal. A licensee shall not use information received from a criminal history check obtained pursuant to this section in a manner that would infringe upon the rights of any individual under the First Amendment to the Constitution of the United States, nor

shall the licensee use the information in any way that would discriminate among individuals on the basis of race, religion, national origin, sex, or age.

3. ~~Right to correct and complete information. Prior to any final adverse determination, the licensee shall make available to the individual the contents of any criminal records obtained from the FBI for the purpose of assuring correct and complete information. Written confirmation by the individual of receipt of this notification must be maintained by the licensee for a period of one year from the date of the notification. If, after reviewing the record, an individual believes that it is incorrect or incomplete in any respect and wishes to change, correct, or update the alleged deficiency, or to explain any matter in the record, the individual may initiate challenge procedures. These procedures include either direct application by the individual challenging the record to the agency (i.e., law enforcement agency) that contributed the questioned information, or direct challenge as to the accuracy or completeness of any entry on the criminal history record to the Assistant Director, Federal Bureau of Investigation Identification Division, Washington, DC 20537-9700. In the latter case, the FBI forwards the challenge to the agency that submitted the data and requests that agency to verify or correct the challenged entry. Upon receipt of an official communication directly from the agency that contributed the original information, the FBI Identification Division makes any changes necessary in accordance with the information supplied by that agency.~~

~~The licensee must provide at least 10 days for an individual to initiate an action challenging the results of an FBI identification and criminal history records check after the record is made available for his review. The licensee may make a final unescorted access to certain radioactive material determination based upon the criminal history record only upon receipt of the FBI's ultimate confirmation or correction of the record. Upon a final adverse determination on unescorted access to certain radioactive material, the licensee shall provide the individual its documented basis for denial. Unescorted access to certain radioactive material shall not be granted to an individual during the review process.~~

4. ~~Protection of information:~~

~~a. Each licensee who obtains a criminal history record on an individual pursuant to this section shall establish and maintain a system of files and procedures for protecting the record and the personal information from unauthorized disclosure.~~

~~b. The licensee may not disclose the record or personal information collected and maintained to persons other than the subject individual, his representative, or to those who have a need to access the information in performing assigned duties in the process of determining unescorted access to certain radioactive material. No individual~~

~~authorized to have access to the information may re-disseminate the information to any other individual who does not have a need to know.~~

~~e. The personal information obtained on an individual from a criminal history record check may be transferred to another licensee if the licensee holding the criminal history record check receives the individual's written request to re-disseminate the information contained in his file, and the gaining licensee verifies information such as the individual's name, date of birth, social security number, sex, and other applicable physical characteristics for identification purposes.~~

~~d. The licensee shall make criminal history records obtained under this section available for examination by an authorized representative of VDH to determine compliance with the regulations.~~

~~e. The licensee shall retain all fingerprints and criminal history records from the FBI, or a copy if the individual's file has been transferred, for three years after termination of employment or determination of unescorted access to certain radioactive material (whether unescorted access was approved or denied). After the required three year period, these documents shall be destroyed by a method that will prevent reconstruction of the information in whole or in part.~~

5. ~~Trustworthy & Reliability Official:~~

~~a. The licensee shall provide under oath or affirmation, a certification to the agency that the T & R Official (an individual with the responsibility to determine the trustworthiness and reliability of another individual requiring unescorted access to the radioactive materials identified in subsection A of this section) is deemed trustworthy and reliable by the licensee as required in subdivision 5 b below.~~

~~b. The T & R Official, if he does not require unescorted access, must be deemed trustworthy and reliable by the licensee in accordance with the requirements of subdivision B 1 of this section before making a determination regarding the trustworthiness and reliability of another individual. If the T & R Official requires unescorted access, the licensee must consider the results of fingerprinting and the review of an FBI identification and criminal history records check as a component in approving a T & R Official.~~

~~6. The licensee shall notify the agency at (804) 864 6168 and the NRC HQ Operations Center at (301) 816 5100 within 24 hours if the results from an FBI identification and criminal history records check indicate that an individual is identified on the FBI's Terrorist Screening Data Base.~~

~~7. Prior to requesting fingerprints from any individual, the licensee shall provide a copy of 12VAC5 481 451 to that individual.~~

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B. Background investigations and access authorization program.

1. Personnel access authorization requirements for Category 1 or Category 2 quantities of radioactive material.

a. Each licensee that possesses an aggregated quantity of radioactive material that equals or exceeds the Category 2 threshold shall establish, implement, and maintain its access authorization program in accordance with the requirements in this subsection. An applicant for a new license and each licensee that would become newly subject to the requirements in this subsection upon an amendment request of its license shall implement the requirements of this subsection, as appropriate, before taking possession of an aggregated quantity of radioactive material that equals or exceeds the Category 2 threshold. Any licensee that has not previously implemented the increased control requirements of this section shall implement the provisions of this subsection before aggregating radioactive material to a quantity that equals or exceeds the Category 2 threshold.

b. Licensees shall subject the following individuals to an access authorization program:

(1) Any individual whose assigned duties require unescorted access to Category 1 or Category 2 quantities of radioactive material; and

(2) Reviewing officials.

c. Licensees shall approve for unescorted access to Category 1 or Category 2 quantities of radioactive material only those individuals whose assigned job duties require unescorted access to Category 1 or Category 2 quantities of radioactive material.

d. Licensees need not subject the categories of individuals listed in subdivision 5 a of this subsection to the investigation elements of the access authorization program.

2. Access authorization program requirements.

a. Granting unescorted access authorization.

(1) Licensees shall implement the requirements of this subsection for granting initial or reinstated unescorted access authorization.

(2) Individuals who have been determined to be trustworthy and reliable shall also complete the security training required by subdivision C 2 c of this section before being allowed unescorted access to Category 1 or Category 2 quantities of radioactive material.

b. Reviewing officials.

(1) Reviewing officials are the only individuals who may make trustworthiness and reliability determinations that allow individuals to have unescorted access to Category 1 or Category 2 quantities of radioactive materials possessed by the licensee.

(2) Each licensee shall name one or more individuals to be reviewing officials. After completing the background investigation on the reviewing official, the licensee shall provide under oath or affirmation a certification that the reviewing official is deemed trustworthy and reliable by the licensee. The fingerprints of the named reviewing official shall be taken by a law-enforcement agency, a federal or state agency that provides fingerprinting services to the public, or a commercial fingerprinting service authorized by a state to take fingerprints. The licensee shall recertify that the reviewing official is deemed trustworthy and reliable every 10 years in accordance with subdivision 3 c of this subsection.

(3) Reviewing officials shall be permitted to have unescorted access to Category 1 or Category 2 quantities of radioactive material.

(4) Reviewing officials cannot approve other individuals to act as reviewing officials.

(5) A reviewing official does not need to undergo a new background investigation before being named by the licensee as the reviewing official if:

(a) The individual has undergone a background investigation that included fingerprinting and an FBI criminal history records check and has been determined to be trustworthy and reliable by the licensee; or

(b) The individual is subject to a category listed in subdivision 5 a of this subsection.

c. Informed consent.

(1) Licensees may not initiate a background investigation without the informed and signed consent of the subject individual. This consent shall include authorization to share personal information with other individuals or organizations as necessary to complete the background investigation. Before a final adverse determination, the licensee shall provide the individual with an opportunity to correct any inaccurate or incomplete information that is developed during the background investigation. Licensees do not need to obtain signed consent from those individuals who meet the requirements of subdivision 3 b of this subsection. A signed consent shall be obtained prior to any reinvestigation.

(2) The subject individual may withdraw his consent at any time. Licensees shall inform the individual that:

(a) If an individual withdraws his consent, the licensee may not initiate elements of the background investigation that were not in progress at the time the individual withdrew his consent; and

(b) The withdrawal of consent for the background investigation is sufficient cause of denial or termination of unescorted access authorization.

d. Any individual who is applying for unescorted access authorization shall disclose the personal history information that is required by the licensee's access

authorization program for the reviewing official to make a determination of the individual's trustworthiness and reliability. Refusal to provide, or the falsification of, any personal history information required by this subsection is sufficient cause for denial or termination of unescorted access.

e. Determination basis.

(1) The reviewing official shall determine whether to permit, deny, unfavorably terminate, maintain, or administratively withdraw an individual's unescorted access authorization based on an evaluation of all the information collected to meet the requirements of this subsection.

(2) The reviewing official may not permit any individual to have unescorted access until the reviewing official has evaluated all the information collected to meet the requirements of this subsection and determined that the individual is trustworthy and reliable. The reviewing official may deny unescorted access to any individual based on information obtained at any time during the background investigation.

(3) The licensee shall document the basis for concluding whether or not there is reasonable assurance that an individual is trustworthy and reliable.

(4) The reviewing official may terminate or administratively withdraw an individual's unescorted access authorization based on information obtained after the background investigation has been completed and the individual granted unescorted access information.

(5) Licensees shall maintain a list of persons currently approved for unescorted access authorization. When a licensee determines that a person no longer requires unescorted access or meets the access authorization requirement, the licensee shall remove the person from the approved list as soon as possible, but no later than seven working days, and take prompt measures to ensure that the individual is unable to have unescorted access to the material.

f. Licensees shall develop, implement, and maintain written procedures for implementing the access authorization program. The procedures shall include the provisions for the notification of individuals who are denied unescorted access. The procedures shall include provisions for the review, at the request of the affected individual, of a denial or termination of unescorted access authorization. The procedures shall contain a provision to ensure that the individual is informed of the grounds for the denial or termination of unescorted access authorization and allow the individual an opportunity to provide additional relevant information.

g. Right to correct and complete information.

(1) Prior to any final adverse determination, licensees shall provide each individual subject to this subsection

with the right to complete, correct, and explain information obtained as a result of the licensee's background investigation. Confirmation of receipt by the individual of this notification shall be maintained by the licensee for a period of one year from the date of the notification.

(2) If, after reviewing his criminal history record, an individual believes that it is incorrect or incomplete in any respect and wishes to change, correct, update, or explain anything in the record, the individual may initiate challenge procedures. These procedures include direct application by the individual challenging the record to the law-enforcement agency that contributed the questioned information or a direct challenge as to the accuracy or completeness of any entry on the criminal history record to the Federal Bureau of Investigation, Criminal Justice Information Services (CJIS) Division, ATTN: SCU, Mod. D-2, 1000 Custer Hollow Road, Clarksburg, WV 26306 as set forth in 28 CFR 16.30 through 28 CFR 16.34. In the latter case, the Federal Bureau of Investigation (FBI) will forward the challenge to the agency that submitted the data and will request that the agency verify or correct the challenged entry. Upon receipt of an official communication directly from the agency that contributed the original information, the FBI Identification Division will make any change necessary in accordance with the information supplied by that agency. Licensees shall provide at least 10 days for an individual to initiate action to challenge the results of an FBI criminal history records check after the record being made available for his review. The licensee may make a final adverse determination based upon the criminal history records only after receipt of the FBI's confirmation or correction of the record.

h. Records.

(1) The licensee shall retain documentation regarding the trustworthiness and reliability of individual employees for three years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material.

(2) The licensee shall retain a copy of the current access authorization program procedures as a record for three years after the procedure is no longer needed. If any portion of the procedure is superseded, the licensee shall retain the superseded material for three years after the record is superseded.

(3) The licensee shall retain the list of individuals approved for unescorted access authorization for three years after the list is superseded or replaced.

3. Background investigations.

a. Before allowing an individual unescorted access to Category 1 or Category 2 quantities of radioactive material or to the devices containing the material, licensees shall complete a background investigation of

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the individual seeking unescorted access authorization. The scope of the investigation shall encompass at least the seven years preceding the date of the background investigation or since the individual's 18th birthday, whichever is shorter. The background investigation shall include at a minimum:

(1) Fingerprinting and an FBI identification and criminal history records check in accordance with subdivision 4 of this subsection;

(2) Verification of true identity of the individual who is applying for unescorted access authorization. A licensee shall review official identification documents (e.g., driver's license; passport; government identification; certificate of birth issued by the state, province, or country of birth) and compare the documents to personal information data provided by the individual to identify any discrepancy in the information. Licensees shall document the type, expiration, and identification number of the identification document or maintain a photocopy of identifying documents on file in accordance with subdivision 6 of this subsection. Licensees shall certify in writing that the identification was properly reviewed and shall maintain the certification and all related documents for review upon inspection;

(3) Verification of employment history, including military history. Licensees shall verify the individual's employment with each previous employer for the most recent seven years before the date of application;

(4) Verification that the individual participated in the education process during the claimed period;

(5) Completion of reference checks to determine the character and reputation of the individual who has applied for unescorted access authorization. Unless other references are not available, reference checks may not be conducted with any person who is known to be a close member of the individual's family, including but not limited to, the individual's spouse, parents, siblings, or children, or any individual who resides in the individual's permanent household. Reference checks under this subsection shall be limited to whether the individual has been and continues to be trustworthy and reliable;

(6) To the extent possible, obtain independent information to corroborate the information provided by the individual (e.g., seek references not supplied by the individual); and

(7) If a previous employer, educational institution, or any other entity with which the individual claims to have been engaged fails to provide the information or indicates an inability or unwillingness to provide information within a timeframe deemed appropriate by the licensee but at least after 10 business days of the request or if the licensee is unable to reach the entity, the licensee shall document the refusal, unwillingness, or inability in the

record of investigation and attempt to obtain the information from an alternate source.

b. Individuals who have been determined to be trustworthy and reliable for unescorted access to Category 1 or Category 2 quantities of radioactive material in accordance with 12VAC5-481-451, "Increased controls and fingerprinting," as effective on October 3, 2008, can continue to have unescorted access to Category 1 and Category 2 quantities of radioactive material without further investigation. These individuals shall be subject to the reinvestigation requirement of subdivision 3 c of this subsection.

c. Licensees shall conduct a reinvestigation every 10 years for any individual with unescorted access to Category 1 or Category 2 quantities of radioactive material. The reinvestigation shall consist of fingerprinting and an FBI identification and criminal history records check in accordance with subdivision 4 of this subsection. The reinvestigations shall be completed within 10 years of the date on which these elements were last completed.

4. Requirements for criminal history records checks of individuals granted unescorted access to Category 1 or Category 2 quantities of radioactive material.

a. General performance objective and requirements.

(1) Except for those individuals listed in subdivision 5 a of this subsection and those individuals grandfathered under subdivision 3 b of this subsection, each licensee subject to the provisions of this section shall fingerprint each individual who is to be permitted unescorted access to Category 1 or Category 2 quantities of radioactive material. The licensee shall submit all collected fingerprints to the NRC for transmission to the FBI. The licensee shall use the information received from the FBI as part of the required background investigation to determine whether to grant or deny further unescorted access to Category 1 or Category 2 quantities of radioactive materials for that individual.

(2) The licensee shall notify each affected individual that his fingerprints will be used to secure a review of his criminal history record and shall inform him of the procedures for revising the record or adding explanations to the record.

(3) Fingerprinting is not required if a licensee is reinstating an individual's unescorted access authorization to Category 1 or Category 2 quantities of radioactive material if:

(a) The individual returns to the same facility that granted unescorted access authorization within 365 days of the termination of his unescorted access authorization; and

(b) The previous access was terminated under favorable conditions.

(4) Fingerprints do not need to be taken if an individual who is an employee of a licensee, contractor, manufacturer, or supplier has been granted unescorted access to Category 1 or Category 2 quantities of radioactive material, access to safeguards information, or safeguards information-modified handling by another licensee based upon a background investigation conducted under this subsection, regulations or Fingerprint Orders from another agreement state, or 10 CFR Part 73. An existing criminal history records check file may be transferred to the licensee asked to grant unescorted access in accordance with the provisions of subdivision 6 c of this subsection.

(5) Licensees shall use the information obtained as part of a criminal history records check solely for the purpose of determining an individual's suitability for unescorted access authorization to Category 1 or Category 2 quantities of radioactive materials, access to safeguards information, or safeguards information-modified handling.

b. Prohibitions.

(1) Licensees may not base a final determination to deny an individual unescorted access authorization to Category 1 or Category 2 quantities of radioactive material solely on the basis of information received from the FBI involving:

(a) An arrest more than one year old for which there is no information of the disposition of the case; or

(b) An arrest that resulted in dismissal of the charge or an acquittal.

(2) Licensees may not use information received from a criminal history records check obtained under this subsection in a manner that would infringe upon the rights of any individual under the First Amendment to the Constitution of the United States, nor shall licensees use the information in any way that would discriminate among individuals on the basis of race, religion, national origin, gender, or age.

c. Procedures for processing of fingerprint checks.

(1) For the purpose of complying with this subsection, licensees shall submit to the U.S. Nuclear Regulatory Commission, Director, Division of Facilities and Security, 11545 Rockville Pike, ATTN: Criminal History Program/Mail Stop T-03B46M, Rockville, MD, 20852-2738, one completed, legible standard fingerprint card (form FD-258, ORIMDNRCOOZ), electronic fingerprint scan, or, where practicable, other fingerprint record for each individual requiring unescorted access to Category 1 or Category 2 quantities of radioactive material. Copies of these forms may be obtained by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling (630) 829-9565, or by email to

forms.resource@nrc.gov. Guidance on submitting electronic fingerprints can be found at <http://www.nrc.gov/site-help/e-submittals.html>.

(2) Fees for processing of fingerprint cards are due upon application. Licensees shall submit payment with the application for the processing of fingerprints through corporate check, certified check, cashier's check, money order, or electronic payment, made payable to the "U.S. NRC." (For guidance on making electronic payments, contact the Security Branch, Division of Facilities and Security at (301) 492-3531.) Combined payment for multiple applications is acceptable. The NRC publishes the amount of the fingerprint check application fee on the NRC public website. To find the current fee amount, go to the Electronic Submittals page at <http://www.nrc.gov/site-help/e-submittals.html> and see the link for the Criminal History Program under Electronic Submission Systems.

(3) The NRC will forward to the submitting licensee all data received from the FBI as a result of the licensee's application for a criminal history records check.

5. Relief.

a. Fingerprinting, identification and criminal history records checks, and other elements of the background investigation required by this subsection are not required for the following individuals prior to granting unescorted access to Category 1 or Category 2 quantities of radioactive material:

(1) An employee of the NRC or of the executive branch of the U.S. government who has undergone fingerprinting for a prior U.S. government criminal history records check;

(2) A member of Congress;

(3) An employee of a member of Congress or congressional committee who has undergone fingerprinting for a prior U.S. government criminal history records check;

(4) The governor of a state or his designated state employee representative;

(5) Federal, state, or local law-enforcement personnel;

(6) State radiation control program directors and state homeland security advisors or their designated employee representatives;

(7) Representatives of the International Atomic Energy Agency (IAEA) engaged in activities associated with the U.S./IAEA Safeguards Agreement who have been certified by the NRC;

(8) Emergency response personnel who are responding to an emergency;

(9) Commercial vehicle drivers for road shipments of Category 2 quantities of radioactive material;

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(10) Package handlers at transportation facilities such as freight terminals and railroad yards;

(11) Any individual who has an active federal security clearance and provides the appropriate documentation. Written confirmation from the agency or employer that granted the federal security clearance or reviewed the criminal history records check shall be provided to the licensee. The licensee shall retain this documentation for a period of three years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material; and

(12) Any individual employed by a service provider licensee for whom the service provider licensee has conducted the background investigation for the individual and approved the individual for unescorted access to Category 1 or Category 2 quantities of radioactive material. Written verification from the service provider shall be provided to the licensee. The licensee shall retain the documentation for a period of three years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material.

b. Fingerprinting and identification and criminal history records checks required by this subsection are not required for an individual who has had a favorably adjudicated U.S. Government criminal history records check within the last five years, under a comparable U.S. Government program involving fingerprinting and an FBI identification and criminal history records check, and the individual provides the appropriate documentation. Written confirmation from the agency or employer that reviewed the criminal history records check shall be provided to the licensee. The licensee shall retain this documentation for a period of three years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material. These programs include, but are not limited to:

(1) National Agency Check;

(2) Transportation Worker Identification Credentials (TWIC) under 49 CFR Part 1572;

(3) Bureau of Alcohol, Tobacco, Firearms, and Explosives background check and clearances under 27 CFR Part 555;

(4) Health and Human Services security risk assessments for possession and use of select agents and toxins under 42 CFR Part 73;

(5) Hazardous material security threat assessment for hazardous material endorsement to commercial driver's license under 49 CFR Part 1572; and

(6) Customs and Border Protection's Free and Secure Trade (FAST) Program.

6. Protection of information.

a. Each licensee that obtains background information on an individual under this subsection shall establish and maintain a system of files and written procedures for protection of the record and the personal information from unauthorized disclosure.

b. The licensee may not disclose the record or personal information collected and maintained to persons other than the subject individual, his representative, or to those who have a need to have access to the information in performing assigned duties in the process of granting or denying unescorted access to Category 1 or Category 2 quantities of radioactive material. No individual authorized to have access to the information may disseminate the information to any other individual who does not have a need to know.

c. The personal information obtained on an individual from a background investigation may be provided to another licensee:

(1) Upon the individual's written request to the licensee holding the data to disseminate the information contained in that individual's file; and

(2) The recipient licensee verifies information such as name, date of birth, social security number, gender, and other applicable physical characteristics.

d. The licensee shall make background investigation records obtained under this subsection available for examination by an authorized representative of the agency to determine compliance with the regulations and laws.

e. The licensee shall retain all fingerprint and criminal history records (including data indicating no record) received from the FBI, or a copy of these records if the individual's file has been transferred, on an individual for three years from the date the individual no longer requires unescorted access to Category 1 or Category 2 quantities of radioactive material.

7. Access authorization program review.

a. Each licensee shall be responsible for the continuing effectiveness of the access authorization program. Each licensee shall ensure that access authorization programs are reviewed to confirm compliance with the requirements of this subsection and that comprehensive actions are taken to correct any noncompliance that is identified. The review program shall evaluate all program performance objectives and requirements. The review shall be performed at least annually.

b. The results of the reviews, along with all recommendations, shall be documented. Each review report shall identify conditions that are adverse to the proper performance of the access authorization program; the cause of the conditions and, when appropriate, recommend corrective actions; and corrective actions taken. The licensee shall review the findings and take

additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

c. Review records shall be maintained for three years.

C. Physical protection requirements during use.

1. Security program.

a. Each licensee that possesses an aggregated Category 1 or Category 2 quantity of radioactive material shall establish, implement, and maintain a security program in accordance with the requirements of this subsection. An applicant for a new license and each licensee that would become newly subject to the requirements of this subsection upon an amendment request for modification of its license shall implement the requirements of this subsection, as appropriate, before taking possession of an aggregated Category 1 or Category 2 quantity of radioactive material. Any licensee that has not previously implemented the requirements of this subsection shall provide written notification to the agency at least 90 days before aggregating radioactive material to a quantity that equals or exceeds the Category 2 threshold.

b. Each licensee shall establish, implement, and maintain a security program that is designed to monitor and, without delay, detect, assess, and respond to an actual or attempted unauthorized access to Category 1 or Category 2 quantities of radioactive material.

c. Each licensee's security program shall include the program features, as appropriate, described in subdivisions 2 through 8 of this subsection.

2. General security program requirements.

a. Security plan.

(1) Each licensee identified in subdivision 1 a of this subsection shall develop a written security plan specific to its facilities and operations. The purpose of the security plan is to establish the licensee's overall security strategy to ensure the integrated and effective functioning of the security program required by this subsection. The security plan shall, at a minimum, (i) describe the measures and strategies used to implement the requirements of this subsection and (ii) identify the security resources, equipment, and technology used to satisfy the requirements of this subsection.

(2) The security plan shall be reviewed and approved by the individual with overall responsibility for the security program.

(3) A licensee shall revise its security plan as necessary to ensure the effective implementation of agency requirements. The licensee shall ensure that (i) the revision has been reviewed and approved by the individual with overall responsibility for the security program and (ii) the affected individuals are instructed on the revised plan before the changes are implemented.

(4) The licensee shall retain a copy of the current security plan as a record for three years after the security plan is no longer required. If any portion of the plan is superseded, the licensee shall retain the superseded material for three years after the record is superseded.

b. Implementing procedures.

(1) The licensee shall develop and maintain written procedures that document how the requirements of this subsection and the security plan will be met.

(2) The implementing procedures and revisions to these procedures shall be approved in writing by the individual with overall responsibility for the security program.

(3) The licensee shall retain a copy of the current procedure as a record for three years after the procedure is no longer needed. Superseded portions of the procedure shall be retained for three years after the record is superseded.

c. Training.

(1) Each licensee shall conduct training to ensure that those individuals implementing the security program possess and maintain the knowledge, skills, and abilities to carry out their assigned duties and responsibilities effectively. The training shall include at a minimum, instruction on:

(a) The licensee's security program and procedures to secure Category 1 or Category 2 quantities of radioactive material, and the purpose and function of the security measures employed;

(b) The responsibility to report promptly to the licensee any condition that causes or may cause a violation of agency requirements;

(c) The responsibility of the licensee to report promptly to the local law-enforcement agency and the agency any actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material; and

(d) The appropriate response to security alarms.

(2) In determining those individuals who shall be trained on the security program, the licensee shall consider each individual's assigned activities during authorized use and response to potential situations involving actual or attempted theft, diversion, or sabotage of Category 1 or Category 2 quantities of radioactive material. The extent of the training shall be commensurate with the individual's potential involvement in the security of Category 1 or Category 2 quantities of radioactive material.

(3) Refresher training shall be provided at a frequency not to exceed 12 months and when significant changes have been made to the security program. This training shall include (i) review of the training requirements of this subsection and changes made to the security program

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since the last training; (ii) reports on all relevant security issues, problems, and lessons learned; (iii) relevant results of agency inspections; and (iv) relevant results of the licensee's program review and testing and maintenance.

(4) The licensee shall maintain records of the initial and refresher training for three years from the date of the training. The training records shall include dates of the training, topics covered, a list of licensee personnel in attendance, and related information.

d. Protection of information.

(1) Licensees authorized to possess Category 1 or Category 2 quantities of radioactive material shall limit access to and prevent the unauthorized disclosure of their security plan, implementing procedures, and the list of individuals who have been approved for unescorted access.

(2) Efforts to limit access shall include the development, implementation, and maintenance of written policies and procedures for controlling access to and for proper handling and protection against unauthorized disclosure of the security plan and implementing procedures.

(3) Before granting an individual access to the security plan or implementing procedures, licensees shall:

(a) Evaluate an individual's need to know the security plan or implementing procedures; and

(b) If the individual has not been authorized for unescorted access to Category 1 or Category 2 quantities of radioactive material, the licensee shall complete a background investigation to determine the individual's trustworthiness and reliability. A trustworthiness and reliability determination shall be conducted by the reviewing official and shall include the background investigation elements contained in subdivisions B 3 a (2) through (7) of this section.

(4) Licensees need not subject any individual to background investigation elements for protection of information if that individual is included in the categories of individuals listed in subdivisions B 5 a (1) through (12) of this section or is a security service provider employee, provided written verification that the employee has been determined to be trustworthy and reliable, by the required background investigation in subdivisions B 3 a (2) through (7) of this subsection, has been provided by the security service provider.

(5) The licensee shall document the basis for concluding that an individual is trustworthy and reliable and should be granted access to the security plan or implementing procedures.

(6) Licensees shall maintain a list of persons currently approved for access to the security plan or implementing procedures. When a licensee determines that a person no longer needs access to the security plan or implementing

procedures or no longer meets the access authorization requirements for access to the information, the licensee shall remove the person from the approved list as soon as possible, but no later than seven working days after the determination, and take prompt measures to ensure that the individual is unable to obtain the security plan or implementing procedures.

(7) When not in use, the licensee shall store its security plan and implementing procedures in a manner to prevent unauthorized access. Information stored in nonremovable electronic form shall be password protected.

(8) The licensee shall retain as a record a copy of the information protection procedures and the list of individuals approved for access to the security plan or implementing procedures for three years after the document has been superseded.

3. Local law-enforcement agency (LLEA) coordination.

a. A licensee subject to this subsection shall coordinate, to the extent practicable, with an LLEA for responding to threats to the licensee's facility, including any necessary armed response. The information provided to the LLEA shall include:

(1) A description of the facilities and the Category 1 and Category 2 quantities of radioactive materials along with a description of the licensee's security measures that have been implemented to comply with this subsection; and

(2) A notification that the licensee will request a timely armed response by the LLEA to any actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantities of material.

b. The licensee shall notify the agency within three business days if:

(1) The LLEA has not responded to the request for coordination within 60 days of the coordination request; or

(2) The LLEA notifies the licensee that the LLEA does not plan to participate in coordination activities.

c. The licensee shall document its efforts to coordinate with the LLEA. The documentation shall be kept for three years.

d. The licensee shall coordinate with the LLEA at least every 12 months, or when changes to the facility design or operation adversely affect the potential vulnerability of the licensee's material to theft, sabotage, or diversion.

4. Security zones.

a. Licensees shall ensure that all aggregated Category 1 or Category 2 quantities of radioactive material are used or stored within licensee-established security zones. Security zones may be permanent or temporary.

b. Temporary security zones shall be established as necessary to meet the licensee's transitory or intermittent

business activities, such as periods of maintenance, source delivery, and source replacement.

c. Security zones shall, at a minimum, allow unescorted access only to approved individuals by:

(1) Isolation of Category 1 and Category 2 quantities of radioactive materials by the use of continuous physical barriers that allow access to the security zone only through established access control points. A physical barrier is a natural or man-made structure or formation sufficient for the isolation of the Category 1 or Category 2 quantities of radioactive material within a security zone;

(2) Direct control of the security zone by approved individuals at all times; or

(3) A combination of continuous physical barriers and direct control.

d. For Category 1 quantities of radioactive material during periods of maintenance, source receipt, preparation for shipment, installation, or source removal or exchange, the licensee shall, at a minimum, provide sufficient individuals approved for unescorted access to maintain continuous surveillance of sources in temporary security zones and in any security zone in which physical barriers or intrusion detection systems have been disabled to allow such activities.

e. Individuals not approved for unescorted access to Category 1 or Category 2 quantities of radioactive material shall be escorted by an approved individual when in a security zone.

5. Monitoring, detection, and assessment.

a. Monitoring and detection.

(1) Licensees shall establish and maintain the capability to continuously monitor and detect without delay all unauthorized entries into its security zones. Licensees shall provide the means to maintain continuous monitoring and detection capability in the event of a loss of the primary power source, or provide for an alarm and response in the event of a loss of this capability to continuously monitor and detect unauthorized entries.

(2) Monitoring and detection shall be performed by:

(a) A monitored intrusion detection system that is linked to an onsite or offsite central monitoring facility;

(b) Electronic devices for intrusion detection alarms that will alert nearby facility personnel;

(c) A monitored video surveillance system;

(d) Direct visual surveillance by approved individuals located within the security zone; or

(e) Direct visual surveillance by a licensee designed individual located outside the security zone.

(3) A licensee subject to this subsection shall also have a means to detect unauthorized removal of the radioactive

material from the security zone. This detection capability shall provide:

(a) For Category 1 quantities of radioactive material, immediate detection of any attempted unauthorized removal of the radioactive material from the security zone. Such immediate detection capability shall be provided by electronic sensors linked to an alarm, continuous monitored video surveillance, or direct visual surveillance; and

(b) For Category 2 quantities of radioactive material, weekly verification through physical checks, tamper indicating devices, use, or other means to ensure that the radioactive material is present.

b. Licensees shall immediately assess each actual or attempted unauthorized entry into the security zone to determine whether the unauthorized access was an actual or attempted theft, sabotage, or diversion.

c. For personnel and automated or electronic systems supporting the licensee's monitoring, detection, and assessments system, licensees shall:

(1) Maintain continuous capability for personnel communication and electronic data transmission and processing among site security systems; and

(2) Provide an alternate communication capability for personnel, and an alternative data transmission and processing capability, in the event of a loss of the primary means of communication or data transmission and processing. Alternative communications and data transmissions systems may not be subject to the same failure modes as the primary systems.

d. Licensees shall immediately respond to any actual or attempted unauthorized access to the security zones, or actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material at licensee facilities or temporary job sites. For any unauthorized access involving an actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material, the licensee's response shall include requesting, without delay, an armed response from the LLEA.

6. Maintenance and testing.

a. Each licensee subject to this subsection shall implement a maintenance and testing program to ensure that intrusion alarms, associated communication systems, and other physical components of the systems used to secure or detect unauthorized access to radioactive material are maintained in operable condition and are capable of performing their intended function when needed. The equipment relied on to meet the security requirements of this subsection shall be inspected and tested for operability and performance at the manufacturer's suggested frequency. If there is no frequency suggested by the manufacturer or the

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frequency specified is greater than three months, the testing shall be performed at least quarterly, not to exceed three months.

b. The licensee shall maintain records on the maintenance and testing activities for three years.

7. Requirements for mobile devices. Each licensee that possesses mobile devices containing Category 1 or Category 2 quantities of radioactive material shall:

a. Have two independent physical controls that form tangible barriers to secure the material from unauthorized removal when the device is not under direct control and constant surveillance by the licensee; and

b. For devices in or on a vehicle or trailer, unless the health and safety requirements for a site prohibit the disabling of the vehicle, the licensee shall utilize a method to disable the vehicle or trailer when not under direct control and constant surveillance by the licensee. Licensees shall not rely on the removal of an ignition key to meet this requirement.

8. Security program review.

a. Each licensee shall be responsible for the continuing effectiveness of the security program. Each licensee shall ensure that the security program is reviewed to confirm compliance with the requirements of this subsection and that comprehensive actions are taken to correct any noncompliance that is identified. The review shall include the radioactive material security program content and implementation. The review shall be conducted at least annually, not to exceed 12 months.

b. The results of the review, along with all recommendations, shall be documented. Each review report shall identify conditions that are adverse to the proper performance of the security program, the cause of the condition, corrective actions taken, and, when appropriate, recommend corrective actions. The licensee shall review the findings and take any additional corrective actions necessary to preclude repetition of the condition, including reassessment of the deficient areas where indicated.

c. The licensee shall maintain the review documentation for three years.

9. Reporting of events.

a. The licensee shall immediately notify the LLEA after determining that an unauthorized entry resulted in an actual or attempted theft, sabotage, or diversion of Category 1 or Category 2 quantity of radioactive material. As soon as possible after initiating a response, but not at the expense of causing delay or interfering with the LLEA response to the event, the licensee shall notify the agency by telephone at 804-864-8150 during normal business hours and 804-624-2400 after hours. In no case shall the notification to the agency be later than four

hours after the discovery of any attempted or actual theft, sabotage, or diversion.

b. The licensee shall assess any suspicious activity related to possible theft, sabotage, or diversion of Category 1 or Category 2 quantities of radioactive material and notify the LLEA as appropriate. As soon as possible but not later than four hours after notifying the LLEA, the licensee shall notify the agency by telephone 804-864-8150 during normal business hours and 804-624-2400 after hours.

c. The initial telephonic notification shall be followed within a period of 30 days by a written report submitted to the agency. The report shall include sufficient information for agency analysis and evaluation, including identification of any necessary corrective actions to prevent future instances.

D. Physical protection in transit.

1. Additional requirements for transfer of Category 1 and Category 2 quantities of radioactive material. A licensee transferring a Category 1 or Category 2 quantity of radioactive material to a licensee of the agency, the NRC, or another agreement state shall meet the license verification provisions listed in this subdivision instead of those listed in 12VAC5-481-570.

a. Any licensee transferring Category 1 quantities of radioactive material to a licensee of the agency, the NRC, or another agreement state, prior to conducting such transfer, shall verify with the NRC's license verification system or the license issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred and that the licensee is authorized to receive radioactive material at the location requested for delivery. If the verification is conducted by contacting the license-issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

b. Any licensee transferring Category 2 quantities of radioactive material to a licensee of the agency, the NRC, or another agreement state, prior to conducting such transfer, shall verify with the NRC's license verification system or the license-issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred. If the verification is conducted by contacting the license-issuing authority, the transferor shall document the verification. For transfers within the same organization, the licensee does not need to verify the transfer.

c. In an emergency where the licensee cannot reach the license-issuing authority and the license verification system is nonfunctional, the licensee may accept a written certification by the transferee that it is authorized

by license to receive the type, form, and quantity of radioactive material to be transferred. The certification shall include the license number, current revision number, issuing agency, expiration date, and for a Category 1 shipment, the authorized address. The licensee shall keep a copy of the certification. The certification shall be confirmed by use of the NRC's license verification system or by contacting the license-issuing authority by the end of the next business day.

d. The transferor shall keep a copy of the verification documentation as a record for three years.

2. Applicability of physical protection of Category 1 and Category 2 quantities of radioactive material during transit.

a. For shipments of category 1 quantities of radioactive material, each shipping licensee shall comply with the requirements for physical protection contained in subdivisions 3 a, 3 e, 4, 5 a (1), 5 b (1), 5 c, 6 a, 6 c, 6 e, 6 g, and 6 h of this subsection.

b. For shipments of Category 2 quantities of radioactive material, each shipping licensee shall comply with the requirements for physical protection contained in subdivisions 3 b through 3 e, 5 a (2), 5 a (3), 5 b (2), 5 c, 6 b, 6 d, 6 f, 6 g, and 6 h of this subsection.

c. The shipping licensee shall be responsible for meeting the requirements of this subsection unless the receiving licensee has agreed in writing to arrange for the in-transit physical protection required under this subsection.

3. Preplanning and coordination of shipment of Category 1 or Category 2 quantities of radioactive material.

a. Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a Category 1 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall:

(1) Preplan and coordinate shipment arrival and departure times with the receiving licensee;

(2) Preplan and coordinate shipment information with the governor or the governor's designee of any state through which the shipment will pass to discuss the state's intention to provide law-enforcement escorts and identify safe havens; and

(3) Document the preplanning and coordination activities.

b. Each licensee that plans to transport, or deliver to a carrier for transport, licensed material that is a Category 2 quantity of radioactive material outside the confines of the licensee's facility or other place of use or storage shall coordinate the shipment no-later-than arrival time and the expected shipment arrival with the receiving licensee. The licensee shall document the coordination activities.

c. Each licensee that receives a shipment of a Category 2 quantity of radioactive material shall confirm receipt of the shipment with the originator. If the shipment has not arrived by the no-later-than arrival time, the receiving licensee shall notify the originator.

d. Each licensee that transports or plans to transport a shipment of a Category 2 quantity of radioactive material and determines that the shipment will arrive after the no-later-than arrival time provided pursuant to subdivision 3 b of this subsection, shall promptly notify the receiving licensee of the new no-later-than arrival time.

e. The licensee shall retain a copy of the documentation for preplanning and coordination and any revision thereof as a record for three years.

4. As specified in subdivision 3 of this subsection, each licensee shall provide advance notification to the agency and the governor of a state, or the governor's designee, of the shipment of licensed material in a Category 1 quantity, through or across the boundary of the state, before the transport or delivery to a carrier for transport of the licensed material outside the confines of the licensee's facility or other place of use or storage.

a. Procedures for submitting advance notification:

(1) The notification shall be made to the agency and to the office of each appropriate governor or governor's designee. The contact information, including telephone and mailing addresses, of governors and governor's designees is available on the NRC website at <http://nrc-stp.ornl.gov/special/designee.pdf>. The notification to the agency shall be in accordance with 12VAC5-481-150.

(2) A notification delivered by mail shall be postmarked at least seven days before transport of the shipment commences at the shipping facility.

(3) A notification delivered by any means other than mail shall reach the agency at least four days before the transport of the shipment commences and shall reach the office of the governor or the governor's designee at least four days before transport of a shipment within or through the state.

b. Each advance notification of shipment of Category 1 quantities of radioactive material shall contain the following information, if available at the time of the notification:

(1) The name, address, and telephone number of the shipper, carrier, and receiver of the Category 1 radioactive material;

(2) The license numbers of the shipper and receiver;

(3) A description of the radioactive material contained in the shipment, including the radionuclides and quantity;

(4) The point of origin of the shipment and the estimated time and date that shipment will commence;

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(5) The estimated time and date that the shipment is expected to enter each state along the route;

(6) The estimated time and date of arrival for the shipment at the destination; and

(7) A point of contact, with a telephone number, for current shipment information.

c. Revision notice.

(1) The licensee shall provide any information not previously available at the time of the initial notification, as soon as the information becomes available but not later than commencement of the shipment, to the agency and the governor of the state or the governor's designee.

(2) A licensee shall promptly notify the agency and governor of the state or the governor's designee of any changes to the information provided in accordance with this subdivision.

d. Each licensee who cancels a shipment for which advance notification has been sent shall send a cancellation notice to the agency and the governor of each state or to the governor's designee previously notified. The licensee shall send the cancellation notice before the shipment would have commenced or as soon thereafter as possible. The licensee shall state in the notice that it is a cancellation and identify the advance notification that is being canceled.

e. The licensee shall retain a copy of the advance notification and any revision and cancellation notices as a record for three years.

5. Requirements for physical protection of Category 1 and Category 2 quantities of radioactive material during shipment.

a. Shipments by road.

(1) Each licensee who transports or delivers to a carrier for transport in a single shipment a Category 1 quantity of radioactive material shall:

(a) Ensure that movement control centers are established that maintain position information from a remote location. These control centers shall monitor shipments 24 hours a day, seven days a week and have the ability to communicate immediately, in an emergency, with the appropriate law-enforcement agencies;

(b) Ensure that redundant communications are established that allow the transport to contact the escort vehicle, when an escort vehicle is used, and movement control center at all times. Redundant communications may not be subject to the same interference factors as the primary communication;

(c) Ensure that shipments are continuously and actively monitored by a telemetric position monitoring system or an alternative tracking system reporting to a movement control center. A movement control center shall provide positive confirmation of the location, status, and control

over the shipment. The movement control center shall be prepared to promptly implement preplanned procedures in response to deviations from the authorized route or a notification of actual, attempted, or suspicious activities related to the theft, loss, or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route;

(d) Provide an individual to accompany the driver for those highway shipments with a driving time period greater than the maximum number of allowable hours of service in a 24-hour duty day as established by the U.S. Department of Transportation Federal Motor Carrier Safety Administration. The accompanying individual may be another driver; and

(e) Develop written normal and contingency procedures to address (i) notifications to the communication center and law-enforcement agencies; (ii) communication protocols that shall include a strategy for the use of authentication codes and duress codes and provisions for refueling and other stops, detours, and locations where communication is expected to be temporarily lost; (iii) loss of communication; and (iv) responses to an actual or attempted theft or diversion of a shipment.

(f) Each licensee who makes arrangements for the shipment of Category 1 quantities of radioactive material shall ensure that drivers, accompanying personnel, and movement control center personnel have access to the normal and contingency procedures.

(2) Each licensee that transports Category 2 quantities of radioactive material shall maintain constant control and surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance.

(3) Each licensee who delivers to a carrier for transport in a single shipment a Category 2 quantity of radioactive material shall:

(a) Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and surveillance, the package tracking system shall allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control;

(b) Use carriers that maintain constant control and surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

(c) Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

b. Shipments by rail.

(1) Each licensee who transports, or delivers to a carrier for transport, in a single shipment a Category 1 quantity of radioactive material shall:

(a) Ensure that rail shipments are monitored by a telemetric position monitoring system or an alternative tracking system reporting to the licensee, third-party, or railroad communications center. The communications center shall provide positive confirmation of the location of the shipment and its status. The communications center shall implement preplanned procedures in response to deviations from the authorized route or to a notification of actual, attempted, or suspicious activities related to the theft or diversion of a shipment. These procedures will include, but not be limited to, the identification of and contact information for the appropriate LLEA along the shipment route; and

(b) Ensure that periodic reports to the communications center are made at preset intervals.

(2) Each licensee who transports, or delivers to a carrier for transport, in a single shipment a Category 2 quantity of radioactive material shall:

(a) Use carriers that have established package tracking systems. An established package tracking system is a documented, proven, and reliable system routinely used to transport objects of value. In order for a package tracking system to maintain constant control and surveillance, the package tracking system shall allow the shipper or transporter to identify when and where the package was last and when it should arrive at the next point of control;

(b) Use carriers that maintain constant control and surveillance during transit and have the capability for immediate communication to summon appropriate response or assistance; and

(c) Use carriers that have established tracking systems that require an authorized signature prior to releasing the package for delivery or return.

c. Each licensee who makes arrangements for the shipment of Category 1 quantities of radioactive material shall immediately conduct an investigation upon discovery that a Category 1 shipment is lost or missing. Each licensee who makes arrangements for the shipment of Category 2 quantities of radioactive material shall immediately conduct an investigation, in coordination with the receiving licensee, of any shipment that has not arrived by the designated no-later-than arrival time.

6. Reporting of events.

a. The shipping licensee shall notify the appropriate LLEA and the agency within one hour of its determination that a shipment of Category 1 quantities of radioactive material is lost or missing. The appropriate LLEA would be the law-enforcement agency in the area

of the shipment's last confirmed location. During the investigation required by this subsection, the shipping licensee will provide agreed upon updates to the agency on the status of the investigation.

b. The shipping licensee shall notify the agency within four hours of its determination that a shipment of Category 2 quantities of radioactive material is lost or missing. If, after 24 hours of its determination that the shipment is lost or missing, the radioactive material has not been located and secure, the licensee shall immediately notify the agency.

c. The shipping licensee shall notify the designated LLEA along the shipment route as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment or suspicious activities related to the theft or diversion of a shipment of a Category 1 quantity of radioactive material. As soon as possible after notifying the LLEA, the licensee shall notify the agency upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment, of Category 1 radioactive material.

d. The shipping licensee shall notify the agency as soon as possible upon discovery of any actual or attempted theft or diversion of a shipment, or any suspicious activity related to the shipment, of a Category 2 quantity of radioactive material.

e. The shipping licensee shall notify the agency and the LLEA as soon as possible upon recovery of any lost or missing Category 1 quantities of radioactive material.

f. The shipping licensee shall notify the agency as soon as possible upon recovery of any lost or missing Category 2 quantities of radioactive material.

g. The initial telephonic notification required by subdivisions 6 a through 6 d of this subsection shall be followed within a period of 30 days by a written report submitted to the agency. The report shall include the following information:

(1) A description of the licensed material involved, including kind, quantity, and chemical and physical form;

(2) A description of the circumstances under which the loss or theft occurred;

(3) A statement of disposition, or probable disposition, of the licensed material involved;

(4) Actions that have been taken, or will be taken, to recover the material; and

(5) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.

h. Subsequent to filing the written report, the licensee shall also report any additional substantive information

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on the loss or theft within 30 days after the licensee learns of such information.

E. Records.

1. Each record required by this section shall be legible throughout the retention period specified. The record may be the original or a reproduced copy or a microform, provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications shall include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

2. Licensees shall maintain the records that are required by this section for the period specified. If a retention period is not otherwise specified, these records shall be retained until the agency terminates the facility's license. All records related to this section may be destroyed upon agency termination of the facility license.

VA.R. Doc. No. R16-4629; Filed January 21, 2016, 11:20 a.m.

health carrier's closed formulary, including that the requirements pertaining to such requests apply only to health plans in the individual and small group markets; (ii) describe the requirements for the exception request process, which enhances and further clarifies the process identified in subdivisions B 2 and B 3 of § 38.2-3407.9:01 of the Code of Virginia and is in accordance with 45 CFR 156.122(c); (iii) differentiate the period of time that a standard exception request must be reviewed and acted upon from the time in which a coverage determination must be made; and (iv) provide further clarification to an existing provision in the urgent care appeals section.

AT RICHMOND, JANUARY 13, 2016

COMMONWEALTH OF VIRGINIA, ex rel.

STATE CORPORATION COMMISSION

CASE NO. INS-2015-00184

Ex Parte: In the matter of Amending Rules
Governing Internal Appeal and External Review

ORDER ADOPTING REVISIONS TO RULES

On November 9, 2015, the State Corporation Commission ("Commission") issued an Order to Take Notice ("Order") to consider revisions to the Rules Governing Internal Appeal and External Review set forth in Chapter 216 of Title 14 of the Virginia Administrative Code ("Rules").¹

These amendments were proposed by the Bureau of Insurance ("Bureau") to define an "exception request" for an enrollee to obtain a prescription drug that is not on a health carrier's closed formulary and to describe the requirements for the exception request process that will enhance and further clarify the process identified in § 38.2-3407.9:01 B 2 and 3 of the Code of Virginia. The amendments also provide further clarification to the urgent care appeals section.

The Order required that on or before December 18, 2015, any person requesting a hearing on the amendments to the Rules shall have filed such request for a hearing with the Clerk of the Commission ("Clerk"). No request for a hearing was filed with the Clerk.

The Order also required any interested persons to file with the Clerk their comments in support of or in opposition to the amendments to the Rules on or before December 18, 2015. Comments were timely filed by the Virginia Association of Health Plans ("VAHP"). These comments sought to clarify the proposed definition of "exception request" in Rule 14 VAC 5-216-20, and to differentiate the period of time that a standard exception request must be reviewed and acted upon from the time in which a coverage determination must be made in Rule 14 VAC 5-216-65 A 1. The Bureau filed a Response to Comments with the Clerk on January 5, 2016, and recommends that the amendments to Rules 14 VAC 5-216-20 and 14 VAC 5-216-65 A 1 that were suggested by the VAHP be made, as attached.

NOW THE COMMISSION, having considered the proposed amendments, the filed comments, and the Bureau's

TITLE 14. INSURANCE

STATE CORPORATION COMMISSION

Final Regulation

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

Title of Regulation: 14VAC5-216. Rules Governing Internal Appeal and External Review (amending 14VAC5-216-10, 14VAC5-216-20, 14VAC5-216-40, 14VAC5-216-50; adding 14VAC5-216-65).

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

Effective Date: February 1, 2016.

Agency Contact: Tom Bridenstine, Manager, Life and Health Division, Bureau of Insurance, State Corporation Commission, P.O. Box 1157, Richmond, VA 23218, telephone (804) 371-9746, FAX (804) 371-9944, or email tom.bridenstine@scc.virginia.gov.

Summary:

The amendments (i) define an "exception request" for an enrollee to obtain a prescription drug that is not on a

Response to Comments and recommendation, is of the opinion that the attached amendments to the Rules should be adopted.

Accordingly, IT IS ORDERED THAT:

(1) The amendments to the Rules Governing Internal Appeal and External Review at Chapter 216 of Title 14 of the Virginia Administrative Code, which amend the Rules at 14 VAC 5-216-10, 14 VAC 5-216-20, 14 VAC 5-216-40, and 14 VAC 5-216-50 and establish a new section at 14 VAC 5-216-65, and which are attached hereto and made a part hereof, are hereby ADOPTED, to be effective February 1, 2016.

(2) The Bureau forthwith shall give notice of the adoption of the amendments to the Rules by sending, by e-mail or U.S. mail, a copy of this Order, together with a copy of the adopted Rules, to all insurers, health maintenance organizations and health services plans licensed in Virginia to sell accident and sickness insurance, and to all interested persons.

(3) The Commission's Division of Information Resources forthwith shall cause a copy of this Order, together with the final amended Rules, to be forwarded to the Virginia Registrar of Regulations for appropriate publication in the Virginia Register of Regulations.

(4) The Commission's Division of Information Resources shall make available this Order and the attached amendments to the Rules on the Commission's website: <http://www.scc.virginia.gov/case>.

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

(6) This case is dismissed, and the papers herein shall be placed in the file for ended causes.

AN ATTESTED COPY hereof shall be sent by the Clerk of the Commission to the Commission's Office of General Counsel and the Bureau in care of Deputy Commissioner Althelia P. Battle.

¹The Rules can be found at: <http://law.lis.virginia.gov/admincode/title14/agency5/chapter216>.

Part I
General

14VAC5-216-10. Scope and purpose.

A. This chapter shall apply to all health carriers, except that the provisions of this chapter shall not apply to a policy or certificate that provides coverage only for a specified disease, specified accident or accident-only coverage; credit; disability income; hospital indemnity; long-term care; dental, vision care, or any other limited supplemental benefit or to a Medicare supplement policy of insurance; coverage under a plan through Medicare, Medicaid, or the federal employees health benefits program; self-insured plans except that a self-insured employee welfare benefit plan may elect to use the

state external review process; any coverage issued under Chapter 55 of Title 10 of the U.S. Code (TRICARE), and any coverage issued as supplemental to that coverage; any coverage issued as supplemental to liability insurance, workers' compensation or similar insurance; and automobile medical payment insurance or any insurance under which benefits are payable with or without regard to fault, whether written on a group or individual basis.

B. The purpose of this chapter is to set forth rules to carry out the provisions of Chapter 35.1 (§ 38.2-3556 et seq.) of Title 38.2 of the Code of Virginia as well as federal law to provide a health carrier with guidelines to assist with establishing a procedure for an internal appeals process under which there will be a full and fair review of any adverse benefit determination. This chapter also sets forth requirements for the external review process.

C. This chapter shall apply to any adverse benefit determination made on or after July 1, 2011, by any health carrier for a grandfathered or non-grandfathered health benefit plan, as defined by the PPACA.

D. This chapter also sets forth requirements for an exception request for plan years beginning on or after January 1, 2016.

14VAC5-216-20. Definitions.

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

"Adverse benefit determination" in the context of the internal appeals process means (i) a determination by a health carrier or its designee utilization review entity that, based on the information provided, a request for, a benefit under the health carrier's health benefit plan upon application of any utilization review technique does not meet the health carrier's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness or is determined to be experimental or investigational and the requested benefit is therefore denied, reduced, or terminated or payment is not provided or made, in whole or in part, for the requested benefit; (ii) the denial, reduction, or termination of, or failure to provide or make payment in whole or in part for, a benefit based on a determination by a health carrier or its designee utilization review entity of a covered person's eligibility to participate in the health carrier's health benefit plan; (iii) any review determination that denies, reduces, or terminates or fails to provide or make payment, in whole or in part, for a benefit; (iv) a rescission of coverage determination as defined in § 38.2-3438 of the Code of Virginia; or (v) any decision to deny individual coverage in an initial eligibility determination.

"Adverse determination" in the context of external review means a determination by a health carrier or its designee utilization review entity that an admission, availability of care, continued stay, or other health care service that is a covered benefit has been reviewed and, based upon the information provided, does not meet the health carrier's

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requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness or is determined to be experimental or investigational and the requested service or payment for the service is therefore denied, reduced, or terminated.

"Authorized representative" means (i) a person to whom a covered person has given express written consent to represent the covered person; (ii) a person authorized by law to provide substituted consent for a covered person; (iii) a family member of a covered person or the covered person's treating health care professional when the covered person is unable to provide consent; (iv) a health care professional when the covered person's health benefit plan requires that a request for a benefit under the plan be initiated by the health care professional; or (v) in the case of an urgent care internal appeal, a health care professional with knowledge of the covered person's medical condition.

"Clinical peer reviewer" means a practicing health care professional who holds a nonrestricted license in a state, district, or territory of the United States and in the same or similar specialty as typically manages the medical condition, procedure, or treatment under appeal.

"Commission" means the State Corporation Commission.

"Concurrent review" means utilization review conducted during a patient's stay or course of treatment in a facility, the office of a health care professional, or other inpatient or outpatient health care setting.

"Covered person" means a policyholder, subscriber, enrollee, or other individual participating in a health benefit plan. For purposes of this chapter with respect to the administration of appeals, references to a covered person include a covered person's authorized representative, if any.

"Emergency services" means those health care services that are rendered after the sudden onset of a medical condition that manifests itself by symptoms of sufficient severity, including severe pain, that the absence of immediate medical attention could reasonably be expected by a prudent layperson who possesses an average knowledge of health and medicine to result in (i) serious jeopardy to the mental or physical health of the individual, (ii) danger of serious impairment of the individual's bodily functions, (iii) serious dysfunction of any of the individual's bodily organs, or (iv) in the case of a pregnant woman, serious jeopardy to the health of the fetus.

"Exception request" means a process that allows a covered person, authorized representative, or prescribing physician (or other prescriber, as appropriate) to request and gain access to clinically appropriate drugs not otherwise covered by a health benefit plan [in the individual and small group market because of formulary restrictions].

"Final adverse determination" means an adverse determination involving a covered benefit that has been upheld by a health carrier, or its designee utilization review

entity, at the completion of the health carrier's internal appeal process.

"Group health plan" means an employee welfare benefit plan (as defined in the Employee Retirement Income Security Act of 1974 (29 USC § 1002(1)), to the extent that the plan provides medical care and including items and services paid for as medical care to employees or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise.

"Health benefit plan" means a policy, contract, certificate, or agreement offered or issued by a health carrier to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services. "Health benefit plan" does not include accident only, credit, or disability insurance; coverage of Medicare services or federal employee health plans pursuant to contracts with the United States government; Medicare supplement or long-term care insurance; Medicaid coverage; dental only or vision only insurance; specified disease insurance; hospital indemnity coverage; limited benefit health coverage; coverage issued as a supplement to liability insurance; insurance arising out of a workers' compensation or similar law; automobile medical payment insurance; medical expense and loss of income benefits; or insurance under which benefits are payable with or without regard to fault and that is statutorily required to be contained in any liability insurance policy or equivalent self-insurance.

"Health care professional" means a physician or other health care practitioner licensed, accredited, or certified to perform specified health care services consistent with the laws of the Commonwealth.

"Health carrier" means an entity, subject to the insurance laws and regulations of the Commonwealth or subject to the jurisdiction of the commission, that contracts or offers to contract to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services, including an accident and sickness insurance company, a health maintenance organization, a nonprofit hospital and health service corporation, or a nonstock corporation offering or administering a health services plan, a hospital services plan, or a medical or surgical services plan, or any other entity providing a plan of health insurance, health benefits, or health care services except as excluded under § 38.2-3557 of the Code of Virginia.

"Independent review organization" means an entity that conducts independent external reviews of adverse determinations and final adverse determinations, as well as alleged violations of 14VAC5-216-30 through 14VAC5-216-70 pertaining to internal appeal.

"PPACA" means the Patient Protection and Affordable Care Act (P.L. 111-148), as amended by the Health Care and Education Reconciliation Act of 2010 (P.L. 111-152).

"Pre-service claim" means a claim for a benefit under a health benefit plan that requires approval of the benefit in

whole or in part, in advance of obtaining the service or treatment.

"Post-service claim" means a claim for a benefit under a health benefit plan that is not a pre-service claim, or the service or treatment has been provided to the covered person.

"Self-insured plan" means an "employee welfare benefit plan" that has the meaning set forth in the Employee Retirement Income Security Act of 1974, 29 USC § 1002(1).

"Urgent care appeal" means an appeal for medical care or treatment with respect to which the application of the time periods for making non-urgent care determinations (i) could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function; or (ii) in the opinion of the treating health care professional with knowledge of the covered person's medical condition, would subject the covered person to severe pain that cannot be adequately managed without the care or treatment that is the subject of the appeal. An urgent care appeal shall not be available for any post-service claim or retrospective adverse benefit determination.

"Utilization review" means a set of formal techniques designed to monitor the use of or evaluate the clinical necessity, appropriateness, efficacy, or efficiency of health care services, procedures or settings. Techniques may include ambulatory review, prospective review, second opinion, certification, concurrent review, case management, discharge planning, or retrospective review.

14VAC5-216-40. Minimum appeal requirements.

A. Each covered person shall be entitled to a full and fair review of an adverse benefit determination. Within 180 days after the date of receipt of a notice of an adverse benefit determination, a covered person may file an appeal with the health carrier. A health carrier may designate a utilization review entity to coordinate the review. For purposes of this chapter, "health carrier" may also mean its designated utilization review entity.

B. The health carrier shall conduct the appeal in a manner to ensure the independence and impartiality of the individuals involved in reviewing the appeal. In ensuring the independence and impartiality of such individuals, the health carrier shall not make decisions regarding hiring, compensation, termination, promotion, or other similar matters based upon the likelihood that an individual will support the denial of benefits.

C. 1. In deciding an appeal of any adverse benefit determination that is based in whole or in part on a medical judgment, including determinations with regard to whether a particular treatment, drug, or other service is experimental, investigational, or not medically necessary or appropriate, the health carrier shall designate a clinical peer reviewer to review the appeal. The clinical peer reviewer shall not have been involved in any previous adverse benefit determination with respect to the claim.

2. A reviewer of any other type of adverse benefit determination shall be an appropriate person designated by the health carrier. The reviewer of the appeal shall not be the individual who made any previous adverse benefit determination of the subject appeal nor the subordinate of such individual and shall not defer to any prior adverse benefit determination.

D. A full and fair review shall also provide for:

1. The covered person to have an opportunity to submit written comments, documents, records, and other information relating to the appeal for the reviewer or reviewers to consider when reviewing the appeal.

2. Upon request to the health carrier, the covered person to have reasonable access to and free of charge copies of all documents, records, and other information relevant to the covered person's request for benefits. This information shall be provided to the covered person as soon as practicable.

3. An appeal process that takes into account all comments, documents, records, and other information submitted by the covered person relating to the appeal, without regard to whether such information was submitted or considered in the initial benefit determination.

4. The identification of medical or vocational experts whose advice was obtained on behalf of the health ~~benefit plan~~ carrier in connection with a covered person's adverse benefit determination, without regard to whether the advice was relied upon in making the benefit determination.

5. An urgent care appeal process.

6. Prior to issuing a final adverse benefit determination, the health carrier to provide free of charge to the covered person any new or additional evidence relied upon or generated by the health carrier or at the direction of the health carrier, in connection with the internal appeal sufficiently in advance of the date the determination is required to be provided to permit the covered person a reasonable opportunity to respond prior to that date.

E. A health carrier shall notify the covered person of the final benefit determination within a reasonable period of time appropriate to the medical circumstances, but not later than the timeframes established in subdivisions 1 and 2 of this subsection.

1. If an internal appeal involves a pre-service claim review request, the health carrier shall notify the covered person of its decision within 30 days after receipt of the appeal. A health carrier may provide a second level of internal appeal for group health plans only, provided that a maximum of 15 days is allowed for a benefit determination and notification from each level of the appeal.

2. If an internal appeal involves a post-service claim review request, the health carrier shall notify the covered person of its decision within 60 days after receipt of the appeal. A health carrier may provide a second level of

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internal appeal for group health plans only, provided that a maximum of 30 days is allowed for a benefit determination and notification from each level of the appeal.

14VAC5-216-50. Urgent care appeals.

A. The health carrier shall notify the covered person of its initial benefit determination as soon as possible taking into account medical exigencies, but not later than 72 hours after receipt of the request, unless the covered person fails to provide sufficient information to determine whether, or to what extent, benefits are covered or payable under the health benefit plan. In the case of such failure, the health carrier shall notify the covered person as soon as possible, but not later than 24 hours after receipt of the request, of the specific information necessary to complete the claim. The covered person shall be afforded a reasonable amount of time, taking into account the circumstances, but not less than 48 hours to provide the specified information. The health carrier shall notify the covered person of its benefit determination not later than 48 hours after the earlier of (i) its receipt of the specified information or (ii) the end of the period afforded to the covered person to provide the specified additional information.

B. The notification of an urgent care adverse benefit determination that is based on a medical necessity, appropriateness, health care setting, level of care, effectiveness, experimental or investigational service or treatment, or similar exclusion or limit, shall include a description of the health carrier's urgent care appeal process including any time limits applicable to those procedures and the availability of and procedures for an expedited external review.

C. Upon receipt of an adverse benefit determination, a covered person may submit a request for an urgent care appeal either orally or in writing to the health carrier. Any appeal request made under this section by a treating health care professional shall be handled as an urgent care appeal. If such request is made by the covered person and not the treating health care professional, an individual acting on behalf of the health carrier shall apply the judgment of a prudent layperson who possesses an average knowledge of health and medicine to determine whether the appeal meets urgent care requirements.

D. All necessary information, including the benefit determination on appeal, shall be transmitted between the health carrier and the covered person by telephone, facsimile, or the most expeditious method available.

E. The health carrier shall notify the covered person and the treating health care professional of its benefit determination as soon as possible, taking into account the medical exigencies, but not later than 72 hours after receipt of an urgent care appeal.

14VAC5-216-65. Exception request for prescription drugs.

A. For plan years beginning on or after January 1, 2016, notwithstanding any other provision of this chapter, a health carrier shall have a process in place that allows for a covered person or his prescribing physician (or other prescriber) to request and gain access to clinically appropriate drugs not otherwise covered by the health benefit plan, known as an exception request, in accordance with the requirements of 45 CFR §156.122(c).

1. A standard exception request shall be reviewed [and acted upon within one business day of receipt of the request,] and a coverage determination [shall be] provided to the covered person and prescribing physician ~~no later than [the earlier of one business day or]~~ 72 hours following receipt of the request.

2. An expedited exception request may be made when exigent circumstances exist. Exigent circumstances exist when the covered person is suffering from a health condition that may seriously jeopardize the covered person's life, health, or ability to regain maximum function or when the covered person is undergoing a current course of treatment using a nonformulary drug. An expedited exception request shall be reviewed and a coverage determination provided to the covered person and prescribing physician no later than 24 hours following receipt of the request.

3. If a health carrier denies coverage as a result of a standard exception request or an expedited exception request, the covered person or prescribing physician may submit an external exception request to the health carrier, requiring that the original exception request and subsequent denial be reviewed by an independent review organization. Such request shall be reviewed and a coverage determination provided to the covered person and prescribing physician no later than 72 hours following receipt of the request if the original request was a standard exception request, or 24 hours following receipt of the request if the original request was an expedited exception request.

B. The health carrier shall provide the nonformulary drug or drugs for the duration of the prescription (including refills) if coverage is granted under a standard exception request, or for the duration of the exigency if coverage is granted under an expedited exception request, including those granted through an external exception request. Coverage for each drug approved by an exception request shall be applied as if the drug was part of the prescription formulary.

C. A health carrier shall contract with at least one accredited independent review organization to conduct reviews in accordance with the requirements of subdivision A 3 of this section.

VA.R. Doc. No. R16-4534; Filed January 13, 2016, 7:11 p.m.

TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF PHARMACY

Fast-Track Regulation

Titles of Regulations: **18VAC110-20. Regulations Governing the Practice of Pharmacy (amending 18VAC110-20-10; adding 18VAC110-20-211).**

18VAC110-50. Regulations Governing Wholesale Distributors, Manufacturers, and Warehousemen (amending 18VAC110-50-10; adding 18VAC110-50-51).

Statutory Authority: §§ 54.1-2400 and 54.1-3307 of the Code of Virginia.

Public Hearing Information: No public hearings are scheduled.

Public Comment Deadline: March 9, 2016.

Effective Date: March 24, 2016.

Agency Contact: Caroline Juran, RPh, Executive Director, Board of Pharmacy, 9960 Mayland Drive, Suite 300, Richmond, VA 23233-1463, telephone (804) 367-4416, FAX (804) 527-4472, or email caroline.juran@dhp.virginia.gov.

Basis: Section 54.1-2400 of the Code of Virginia authorizes the Board of Pharmacy to promulgate regulations that are reasonable and necessary to administer effectively the regulatory system and establish renewal schedules.

The specific authority to regulate prescription drugs in the Commonwealth is found in Chapters 33 (§ 54.1-3300 et seq.) and 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia.

Purpose: The purpose of this regulatory action is to establish regulations that will authorize the board to inspect for and enforce standards for collection on controlled substances. If requirements for collection and destruction are not followed, there may be opportunity for diversion of donated drugs or adulteration of controlled substances when there is risk of commingling with existing stocks. Designation of authorized collection sites will facilitate the disposal of unused prescription drugs, which in turn reduces the supply of such drugs for abuse and diversion and protects public health and safety. However, the collection must be handled in a manner that protects the drugs until destruction in compliance with local, state, and federal laws.

Rationale for Using Fast-Track Process: This action was begun with a Notice of Intended Regulatory Action that was published in the Virginia Register of Regulations in Volume 31, Issue 20, on June 1, 2015, with comment until July 1, 2015. No comment was received, and no controversy is expected. The proposed regulation was unanimously recommended by the board's Regulation Committee and

adopted by the board. To facilitate the authorization for collection sites, the board is promulgating the regulation as a fast-track rulemaking action under § 2.2-4012.1 of the Code of Virginia.

Substance: The new regulations will include requirements found in the federal Drug Enforcement Administration (DEA) regulations, such as registration with the DEA as an authorized collector to serve as a site for the collection of controlled substances from an ultimate user. An ultimate user is defined as a person who has lawfully obtained and who possesses a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household. Manufacturers, wholesale distributors, reverse distributors, narcotic treatment programs, hospitals with an on-site pharmacy, and retail pharmacies may become collectors by modifying their current DEA registration to be approved as authorized collectors.

Authorized collectors may maintain collection receptacles and then must dispose of collected drugs in accordance with DEA rules for destruction. Authorized collectors may conduct a mail-back program, but are not authorized to conduct take-back events. Registered collection sites may accept Schedule II through VI drugs in a single collection receptacle but may not accept illicit drugs (Schedule I, heroin, etc.). Authorized hospitals with on-site pharmacies may maintain collection receptacles at long-term care facilities at which drugs may be disposed on behalf of an ultimate user who resides or has resided at the facility.

Drugs so collected by the authorized collector must be destroyed in a manner that makes the drugs nonretrievable, meaning they cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue.

Issues: The advantage to the public is assurance that a facility that serves as an authorized collector is not commingling donated drugs intended for disposal with drug stocks and that the board has some oversight authority. There are no disadvantages. If a facility meets the DEA requirements for an authorized collector, it will be able to comply with board regulations.

The advantage to the Commonwealth is facilitation of authorized collector sites for disposal of unused medications to take those drugs out of circulation for abuse or diversion.

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. The proposed regulation will require that entities registered by the federal Drug Enforcement Administration (DEA) to collect and destroy unused drugs from consumers provide certain information to the Virginia Board of Pharmacy to help enforce compliance.

Result of Analysis. The benefits likely exceed the costs for all proposed changes.

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Estimated Economic Impact. In 2014, the DEA promulgated federal regulations to allow entities authorized to possess controlled substances to collect previously prescribed but unused drugs from a consumer (ultimate user) for appropriate disposal in a safe and effective manner consistent with controls against diversion. Authorized entities include pharmacies, manufacturers, wholesale distributors, reverse distributors, and narcotic treatment programs. Participation in the federal collection and disposal program is voluntary. Entities may choose to establish disposal programs for various reasons, including for profit, to build goodwill in the community, to attract customers, to advertise businesses, and to preserve the environment.¹ These costs and benefits are not discussed here because they cannot be attributed to this proposed state regulation. The proposed regulation merely requires that if an authorized Virginia entity participates in the DEA program it provide notification to the Virginia Board of Pharmacy (Board) of its name, address, license number, and the intended methods of collection. No additional fee is required from participants who hold a valid state controlled substances registration. However, if a narcotic treatment program without an in-house pharmacy wants to become an authorized collector, it will need a registration at a one-time cost of \$90. Without the required information, the Board would not have essential information to enforce compliance and would completely rely on DEA. The Board states that DEA typically relies on state boards to conduct inspections and to regulate the safety and integrity of prescription drugs. Thus, the proposed regulation will likely enhance compliance with federal and state rules and reduce opportunities for diversion of donated drugs or adulteration of controlled substances if there is risk of co-mingling with existing stocks. In addition, the Board will be able to list names of collectors on its website to inform the public of where to take their unwanted drugs for destruction and promote collection efforts.

Businesses and Entities Affected. Currently, there are 1836 licensed pharmacies, 71 restricted manufacturers and 122 wholesale distributors. It is estimated that a very small number of those will choose to become authorized collectors.²

Localities Particularly Affected. The proposed changes apply throughout the Commonwealth.

Projected Impact on Employment. The proposed amendments are unlikely to significantly affect employment.

Effects on the Use and Value of Private Property. No significant impact on the use and value of private property is expected.

Real Estate Development Costs. No impact on real estate development costs is expected.

Small Businesses:

Definition. Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as "a business entity, including its affiliates, that (i) is independently owned and operated and

(ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million."

Costs and Other Effects. The participation in collection of unused drugs is voluntary. Consequently, the proposed regulation does not impose significant costs or other effects on small businesses.

Alternative Method that Minimizes Adverse Impact. No significant adverse impact on small businesses is expected.

Adverse Impacts:

Businesses: The proposed regulation does not have a significant impact on non-small businesses.

Localities: The proposed regulation will not adversely affect localities.

Other Entities: The proposed regulation will not adversely affect other entities.

¹The participation in the DEA collection and disposal program has certain costs and benefits associated with it.

²In a somewhat similar but essentially different program that collects donated drugs, there are only 15 voluntary participants in Virginia.

Agency's Response to Economic Impact Analysis: The Board of Pharmacy generally concurs with the analysis of the Department of Planning and Budget on proposed amended regulations for 18VAC110-20, Regulations Governing the Practice of Pharmacy. The board does not believe any entity would choose to become a collection site for unused drugs with profit as a motivation, since costs for destruction will likely be borne by the entity. Pharmacies and other authorized entities are more likely to provide the collection option as a service to the community in an effort to take unused drugs out of circulation for possible abuse.

Summary:

The amendments (i) establish standards for collection sites similar to those required by the Drug Enforcement Administration (DEA) to register as an "authorized collector" in Virginia, (ii) require notification to the board prior to establishing a collection site, and (iii) authorize the board to inspect for and enforce standards for collection. As of October 2014, DEA regulations allow entities authorized to possess controlled substances, such as pharmacies and wholesale distributors, to collect unused drugs to deliver for appropriate disposal in a safe and effective manner consistent with effective controls against diversion.

Part I

General Provisions

18VAC110-20-10. Definitions.

In addition to words and terms defined in §§ 54.1-3300 and 54.1-3401 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"ACPE" means the Accreditation Council for Pharmacy Education.

"Acquisition" of an existing entity permitted, registered or licensed by the board means (i) the purchase or transfer of all or substantially all of the assets of the entity or of any corporation that owns or controls the entity; (ii) the creation of a partnership by a sole proprietor or change in partnership composition; (iii) the acquiring of 50% or more of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market; or (iv) the merger of a corporation owning the entity, or of the parent corporation of a wholly owned subsidiary owning the entity, with another business or corporation.

"Actively reports" means reporting all dispensing errors and analyses of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error.

"Alternate delivery site" means a location authorized in 18VAC110-20-275 to receive dispensed prescriptions on behalf of and for further delivery or administration to a patient.

"Analysis" means a review of the findings collected and documented on each dispensing error, assessment of the cause and any factors contributing to the dispensing error, and any recommendation for remedial action to improve pharmacy systems and workflow processes to prevent or reduce future errors.

"Authorized collector" means a narcotic treatment program, hospital, or clinic with an on-site pharmacy, or pharmacy that is authorized by the U.S. Drug Enforcement Administration to receive drugs from an ultimate user, a person lawfully entitled to dispose of an ultimate user decedent's property, or a long-term care facility on behalf of an ultimate user who resides or has resided at that facility for the purpose of destruction.

"Beyond-use date" means the date beyond which the integrity of a compounded, repackaged, or dispensed drug can no longer be assured and as such is deemed to be adulterated or misbranded as defined in §§ 54.1-3461 and 54.1-3462 of the Code of Virginia.

"Board" means the Virginia Board of Pharmacy.

"CE" means continuing education as required for renewal of licensure by the Board of Pharmacy.

"CEU" means a continuing education unit awarded for credit as the equivalent of 10 contact hours.

"Chart order" means a lawful order for a drug or device entered on the chart or in a medical record of a patient by a prescriber or his designated agent.

"Compliance packaging" means packaging for dispensed drugs that is comprised of a series of containers for solid oral

dosage forms and designed to assist the user in administering or self-administering the drugs in accordance with directions for use.

"Contact hour" means the amount of credit awarded for 60 minutes of participation in and successful completion of a continuing education program.

"Correctional facility" means any prison, penitentiary, penal facility, jail, detention unit, or other facility in which persons are incarcerated by government officials.

"DEA" means the ~~United States~~ U.S. Drug Enforcement Administration.

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

1. Variation from the prescriber's prescription drug order, including but not limited to:
 - a. Incorrect drug;
 - b. Incorrect drug strength;
 - c. Incorrect dosage form;
 - d. Incorrect patient; or
 - e. Inadequate or incorrect packaging, labeling, or directions.
 2. Failure to exercise professional judgment in identifying and managing:
 - a. Known therapeutic duplication;
 - b. Known drug-disease contraindications;
 - c. Known drug-drug interactions;
 - d. Incorrect drug dosage or duration of drug treatment;
 - e. Known drug-allergy interactions;
 - f. A clinically significant, avoidable delay in therapy; or
 - g. Any other significant, actual, or potential problem with a patient's drug therapy.
 3. Delivery of a drug to the incorrect patient.
 4. Variation in bulk repackaging or filling of automated devices, including but not limited to:
 - a. Incorrect drug;
 - b. Incorrect drug strength;
 - c. Incorrect dosage form; or
 - d. Inadequate or incorrect packaging or labeling.
- "Drug donation site" means a permitted pharmacy that specifically registers with the board for the purpose of receiving or redispensing eligible donated prescription drugs pursuant to § 54.1-3411.1 of the Code of Virginia.
- "Electronic prescription" means a written prescription that is generated on an electronic application in accordance with 21 CFR Part 1300 and is transmitted to a pharmacy as an electronic data file.
- "EMS" means emergency medical services.

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"Expiration date" means that date placed on a drug package by the manufacturer or repacker beyond which the product may not be dispensed or used.

"Facsimile (FAX) prescription" means a written prescription or order which is transmitted by an electronic device over telephone lines which sends the exact image to the receiver (pharmacy) in a hard copy form.

"FDA" means the ~~United States~~ U.S. Food and Drug Administration.

"Floor stock" means a supply of drugs that have been distributed for the purpose of general administration by a prescriber or other authorized person pursuant to a valid order of a prescriber.

"Foreign school of pharmacy" means a school outside the United States and its territories offering a course of study in basic sciences, pharmacology, and pharmacy of at least four years in duration resulting in a degree that qualifies a person to practice pharmacy in that country.

"Forgery" means a prescription that was falsely created, falsely signed, or altered.

"FPGEC certificate" means the certificate given by the Foreign Pharmacy Equivalency Committee of NABP that certifies that the holder of such certificate has passed the Foreign Pharmacy Equivalency Examination and a credential review of foreign training to establish educational equivalency to board approved schools of pharmacy, and has passed approved examinations establishing proficiency in English.

"Generic drug name" means the nonproprietary name listed in the United States Pharmacopeia-National Formulary (USP-NF) or in the United States Adopted Names (USAN) and the USP Dictionary of Drug Names.

"Hospital" or "nursing home" means those facilities as defined in Title 32.1 of the Code of Virginia or as defined in regulations by the Virginia Department of Health.

"Inactive license" means a license that is registered with the Commonwealth but does not entitle the licensee to practice, the holder of which is not required to submit documentation of CE necessary to hold an active license.

"Long-term care facility" means a nursing home, retirement care, mental care, or other facility or institution that provides extended health care to resident patients.

"NABP" means the National Association of Boards of Pharmacy.

"Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

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

"On-hold prescription" means a valid prescription that is received and maintained at the pharmacy for initial dispensing on a future date.

"Patient safety organization" means an organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (Pub. L. 109-41) and is credentialed by the Agency for Healthcare Research and Quality.

"Permitted physician" means a physician who is licensed pursuant to § 54.1-3304 of the Code of Virginia to dispense drugs to persons to whom or for whom pharmacy services are not reasonably available.

"Perpetual inventory" means an ongoing system for recording quantities of drugs received, dispensed, or otherwise distributed by a pharmacy.

"Personal supervision" means the pharmacist must be physically present and render direct, personal control over the entire service being rendered or act being performed. Neither prior nor future instructions shall be sufficient nor; shall supervision rendered by telephone, written instructions, or by any mechanical or electronic methods be sufficient.

"Pharmacy closing" means that the permitted pharmacy ceases pharmacy services or fails to provide for continuity of pharmacy services or lawful access to patient prescription records or other required patient records for the purpose of continued pharmacy services to patients.

"Pharmacy technician trainee" means a person who is currently enrolled in an approved pharmacy technician training program and is performing duties restricted to pharmacy technicians for the purpose of obtaining practical experience in accordance with § 54.1-3321 D of the Code of Virginia.

"PIC" means the pharmacist-in-charge of a permitted pharmacy.

"Practice location" means any location in which a prescriber evaluates or treats a patient.

"Prescription department" means any contiguous or noncontiguous areas used for the compounding, dispensing and storage of all Schedule II through VI drugs and devices and any Schedule I investigational drugs.

"PTCB" means the Pharmacy Technician Certification Board, co-founded by the American Pharmaceutical Association and the American Society of Health System Pharmacists, as the national organization for voluntary examination and certification of pharmacy technicians.

"Quality assurance plan" means a plan approved by the board for ongoing monitoring, measuring, evaluating, and, if necessary, improving the performance of a pharmacy function or system.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance, but does not include drugs such as carbon-containing compounds or potassium-containing salts that include trace

quantities of naturally occurring radionuclides. The term also includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

"Repackaged drug" means any drug removed from the manufacturer's original package and placed in different packaging.

"Robotic pharmacy system" means a mechanical system controlled by a computer that performs operations or activities relative to the storage, packaging, labeling, dispensing, or distribution of medications, and collects, controls, and maintains all transaction information.

"Safety closure container" means a container that meets the requirements of the federal Poison Prevention Packaging Act of 1970 (15 USC §§ 1471-1476), that is, in testing such containers, that 85% of a test group of 200 children of ages 41-52 months are unable to open the container in a five-minute period and that 80% fail in another five minutes after a demonstration of how to open it and that 90% of a test group of 100 adults must be able to open and close the container.

"Satellite pharmacy" means a pharmacy that is noncontiguous to the centrally permitted pharmacy of a hospital but at the location designated on the pharmacy permit.

"Special packaging" means packaging that is designed or constructed to be significantly difficult for children younger than five years of age to open to obtain a toxic or harmful amount of the drug contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging that all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

"Special use permit" means a permit issued to conduct a pharmacy of a special scope of service that varies in any way from the provisions of any board regulation.

"Storage temperature" means those specific directions stated in some monographs with respect to the temperatures at which pharmaceutical articles shall be stored, where it is considered that storage at a lower or higher temperature may produce undesirable results. The conditions are defined by the following terms:

1. "Cold" means any temperature not exceeding 8°C (46°F). A refrigerator is a cold place in which temperature is maintained thermostatically between 2° and 8°C (36° and 46°F). A freezer is a cold place in which the temperature is maintained thermostatically between -20° and -10°C (-4° and 14°F).
2. "Room temperature" means the temperature prevailing in a working area.
3. "Controlled room temperature" means a temperature maintained thermostatically that encompasses the usual and customary working environment of 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature

calculated to be not more than 25°C; and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses.

4. "Warm" means any temperature between 30° and 40°C (86° and 104°F).

5. "Excessive heat" means any temperature above 40°C (104°F).

6. "Protection from freezing" means where, in addition to the risk of breakage of the container, freezing subjects a product to loss of strength or potency, or to the destructive alteration of its characteristics, the container label bears an appropriate instruction to protect the product from freezing.

7. "Cool" means any temperature between 8° and 15°C (46° and 59°F).

"Terminally ill" means a patient with a terminal condition as defined in § 54.1-2982 of the Code of Virginia.

"Ultimate user" means a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household.

"Unit dose container" means a container that is a single-unit container, as defined in United States Pharmacopeia-National Formulary, for articles intended for administration by other than the parenteral route as a single dose, direct from the container.

"Unit dose package" means a container that contains a particular dose ordered for a patient.

"Unit dose system" means a system in which multiple drugs in unit dose packaging are dispensed in a single container, such as a medication drawer or bin, labeled only with patient name and location. Directions for administration are not provided by the pharmacy on the drug packaging or container but are obtained by the person administering directly from a prescriber's order or medication administration record.

"USP-NF" means the United States Pharmacopeia-National Formulary.

"Well-closed container" means a container that protects the contents from extraneous solids and from loss of the drug under the ordinary or customary conditions of handling, shipment, storage, and distribution.

18VAC110-20-211. Disposal of drugs by authorized collectors.

Any narcotic treatment program, hospital, or clinic with an on-site pharmacy, or pharmacy wishing to accept for return a previously dispensed drug for the purpose of destruction from an ultimate user, a person lawfully entitled to dispose of an ultimate user decedent's property, or a long-term care facility on behalf of an ultimate user who resides or has resided at that facility shall first be authorized by the DEA as a collector. The process used to collect and destroy drugs, along

Regulations

with any required recordkeeping, shall comply with applicable federal and state law.

1. Prior to collecting drugs, an authorized collector shall submit in writing to the board:

a. The name, address, and license number, if applicable, of the facility;

b. The intended method or methods of collection (i.e., collection receptacle or mail-back program); and

c. Signature of PIC or medical director of a narcotic treatment program.

2. If an authorized collector chooses to cease acting as a collector, the PIC or medical director shall notify the board within 30 days.

3. A narcotic treatment program that does not have an in-house pharmacy shall obtain a controlled substance registration.

Part I General Provisions

18VAC110-50-10. Definitions.

In addition to words and terms defined in §§ 54.1-3300 and 54.1-3401 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Authorized collector" means a registered manufacturer, wholesale distributor, or reverse distributor that is authorized by the U.S. Drug Enforcement Administration to receive drugs from an ultimate user, a person lawfully entitled to dispose of an ultimate user decedent's property, or a long-term care facility on behalf of an ultimate user who resides or has resided at that facility for the purpose of destruction.

"Authorized distributor of record" means a wholesale distributor with whom a manufacturer has entered into a written agreement under which such wholesale distributor is either authorized to distribute all of that manufacturer's prescription drug products, or only those products listed in the agreement, for such a period of time or number of shipments as specified in the agreement.

"Control number" means the unique identifying customer number assigned by the Virginia Department of Motor Vehicles to an individual when issuing a driver's license, learner's permit, or official identification card. This number is displayed on the driver's license or ID card in lieu of the social security number.

"DEA" means the ~~United States~~ U.S. Drug Enforcement Administration.

"Drop shipment" means the sale and distribution of a prescription drug in which a manufacturer, ~~third party~~ third-party logistics provider, or the manufacturer's exclusive distributor directly ships the prescription drug to a pharmacy, chain drug warehouse, or other person authorized to dispense or administer the prescription drug, and the pharmacy, chain drug warehouse or other authorized person is invoiced by a

wholesale distributor that took title to the prescription drug during the shipping, but did not take physical possession of the prescription drug.

"Expiration date" means that date placed on a drug package by the manufacturer or repacker beyond which the product may not be dispensed or used.

"FDA" means the ~~United States~~ U.S. Food and Drug Administration.

"Manufacturer's exclusive distributor" means a distributor licensed by the board as a wholesale distributor or registered as a nonresident wholesale distributor who contracts with a manufacturer to provide or coordinate warehousing, distribution or other services on behalf of a manufacturer for a prescription drug and who takes title to that manufacturer's prescription drug, but who does not have general responsibility to direct the sale or disposition of the prescription drug.

"Third-party logistics provider" means an entity licensed by the board as a wholesale distributor or registered as a nonresident wholesale distributor ~~who that~~ that contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer for a prescription drug, but does not take title to the prescription drug and ~~who that~~ that only sells, distributes, or otherwise disposes of the prescription drug at the direction of the manufacturer.

"Ultimate user" means a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household.

"USP-NF" means the United States Pharmacopeia-National Formulary.

18VAC110-50-51. Disposal of drugs by authorized collectors.

Any manufacturer, wholesale distributor, or reverse distributor wishing to accept for return a previously dispensed drug in Schedules II through V for the purpose of destruction from an ultimate user, or a person lawfully entitled to dispose of an ultimate user decedent's property, shall first be authorized by the DEA as a collector. The process used to collect and destroy drugs, along with any required recordkeeping, shall comply with federal and state law.

1. Prior to collecting drugs, an authorized collector shall submit in writing to the board:

a. The name, address, and license number, if applicable, of the facility;

b. The intended method or methods of collection (i.e., collection receptacle or mail-back program); and

c. Signature of the responsible party.

2. If an authorized collector chooses to cease acting as a collector, the responsible party shall notify the board within 30 days.

VA.R. Doc. No. R15-4325; Filed January 11, 2016, 2:46 p.m.

GOVERNOR

EXECUTIVE ORDER NUMBER 51 (2016)

Declaration of a State of Emergency for the Commonwealth of Virginia Due to a Severe Winter Storm Event

Importance of the Issue

On this date, January 21, 2016, I am declaring a state of emergency to exist for the Commonwealth of Virginia based on National Weather Service forecasts projecting a severe winter storm event beginning today in parts of the Commonwealth with the potential for significant snow and ice accumulations as well as high wind speeds through the weekend, which could create transportation issues and significant power outages.

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

Therefore, by virtue of the authority vested in me by § 44-146.17 of the Code of Virginia, as Governor and as Director of Emergency Management, and by virtue of the authority vested in me by Article V, Section 7 of the Constitution of Virginia and by § 44-75.1 of the Code of Virginia, as Governor and Commander-in-Chief of the armed forces of the Commonwealth, and subject always to my continuing and ultimate authority and responsibility to act in such matters, I hereby confirm, ratify, and memorialize in writing my verbal orders issued on this date, January 21, 2016, whereby I am proclaiming that a state of emergency exists, and I am directing that appropriate assistance be rendered by agencies of both state and local governments to prepare for potential impacts of the winter storm, alleviate any conditions resulting from the incident, and to implement recovery and mitigation operations and activities so as to return impacted areas to pre-event conditions in so far as possible. Pursuant to § 44-75.1(A)(3) and (A)(4) of the Code of Virginia, I am also directing that the Virginia National Guard and the Virginia Defense Force be called forth to state active duty to be prepared to assist in providing such aid. This shall include Virginia National Guard assistance to the Virginia Department of State Police to direct traffic, prevent looting, and perform such other law enforcement functions as the Superintendent of State Police, in consultation with the State Coordinator of Emergency Management, the Adjutant General, and the Secretary of Public Safety and Homeland Security, may find necessary.

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

hereby order the following protective and restoration measures:

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

B. Activation of the Virginia Emergency Operations Center (VEOC) and the Virginia Emergency Support Team (VEST) to coordinate the provision of assistance to local governments. I am directing that the VEOC and VEST coordinate state actions in support of affected localities, other mission assignments to agencies designated in the COVEOP, and others that may be identified by the State Coordinator of Emergency Management, in consultation with the Secretary of Public Safety and Homeland Security, which are needed to provide for the preservation of life, protection of property, and implementation of recovery activities.

C. The authorization to assume control over the Commonwealth's state-operated telecommunications systems, as required by the State Coordinator of Emergency Management, in coordination with the Virginia Information Technologies Agency, and with the consultation of the Secretary of Public Safety and Homeland Security, making all systems assets available for use in providing adequate communications, intelligence, and warning capabilities for the incident, pursuant to § 44-146.18 of the Code of Virginia.

D. The evacuation of areas threatened or stricken by effects of the winter storm as appropriate. Following a declaration of a local emergency pursuant to § 44-146.21 of the Code of Virginia, if a local governing body determines that evacuation is deemed necessary for the preservation of life or other emergency mitigation, response, or recovery effort, pursuant to § 44-146.17(1) of the Code of Virginia, I direct 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 VEOC, acting on behalf of the State Coordinator of Emergency Management, shall determine. Notwithstanding the foregoing, I reserve the right to direct and compel evacuation from the same and different areas and determine a different timetable both where local governing bodies have made such a determination and where local governing bodies have not made such a determination. Also, in those localities that have declared a local emergency pursuant to § 44-146.21 of the Code of Virginia, if the local governing body determines that controlling movement of persons is deemed necessary for the preservation of life, public safety, or other emergency mitigation, response, or recovery effort, pursuant to § 44-146.17(1) of the Code of Virginia, 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 VEOC, 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.

E. The 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, to provide for the evacuation and reception of injured and other persons and the exchange of medical, fire, police, National Guard personnel and equipment, public utility, reconnaissance, welfare, transportation, and communications personnel, equipment, and supplies. 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.

F. The authorization of the Departments of State Police, Transportation, and Motor Vehicles to grant temporary overweight, over width, registration, or license exemptions to all carriers transporting essential emergency relief supplies, livestock or poultry, feed or other critical supplies for livestock or poultry, heating oil, motor fuels, or propane, or providing restoration of utilities (electricity, gas, phone, water, wastewater, and cable) in and through any area of the Commonwealth in order to support the disaster response and recovery, regardless of their point of origin or destination. Such exemptions shall not be valid on posted structures for restricted weight.

All over width loads, up to a maximum of 12 feet, and over height loads up to a maximum of 14 feet must follow Virginia Department of Motor Vehicles (DMV) hauling permit and safety guidelines.

In addition to described overweight/over width transportation privileges, carriers are also exempt from registration with the Department of Motor Vehicles. This includes vehicles en route and returning to their home base. The above-cited agencies shall communicate this information to all staff responsible for permit issuance and truck legalization enforcement.

Authorization of the State Coordinator of Emergency Management to grant limited exemption of hours of service by any carrier when transporting essential emergency relief supplies, passengers, property, livestock, poultry, equipment, food, feed for livestock or poultry, fuel, construction materials, and other critical supplies to or from any portion of the Commonwealth for purpose of providing direct relief or assistance as a result of this disaster, pursuant to § 52-8.4 of the Code of Virginia and Title 49 Code of Federal Regulations, Section 390.23 and Section 395.3.

The foregoing overweight/over width transportation privileges as well as the regulatory exemption provided by § 52-8.4(A) of the Code of Virginia, and implemented in 19VAC30-20-40 (B) of the "Motor Carrier Safety Regulations," shall remain in effect for 30 days from the onset of the disaster, or until emergency relief is no longer necessary, as determined by the Secretary of Public Safety and Homeland Security in consultation with the Secretary of Transportation, whichever is earlier.

G. The discontinuance of provisions authorized in paragraph F above may be implemented and disseminated by publication of administrative notice to all affected and interested parties. I hereby delegate to the Secretary of Public Safety and Homeland Security, after consultation with other affected Cabinet Secretaries, the authority to implement this order as set forth in § 2.2-104 of the Code of Virginia.

H. The authorization of a maximum of \$1,800,000 in state sum sufficient funds for state and local governments mission assignments authorized and coordinated through the Virginia Department of Emergency Management that are allowable as defined by The Stafford Act. This funding is also available for state response and recovery operations and incident documentation. Out of this state disaster sum sufficient, \$500,000, or more if available, is authorized for the Department of Military Affairs for the state's portion of the eligible disaster related costs incurred for salaries, travel, and meals during mission assignments authorized and coordinated through the Virginia Department of Emergency Management.

I. The authorization of a maximum of \$250,000 for matching funds for the Individuals and Household Program, authorized by The Stafford Act (when presidentially authorized), to be paid from state funds.

J. The 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, 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. § 44-146.24 of the Code of Virginia also applies to the disaster activities of state agencies.

K. Designation of members and personnel of volunteer, auxiliary, and reserve groups including search and rescue (SAR), Virginia Associations of Volunteer Rescue Squads (VAVRS), Civil Air Patrol (CAP), member organizations of the Voluntary Organizations Active in Disaster (VOAD), Radio Amateur Civil Emergency Services (RACES), volunteer fire fighters, Citizen Corps Programs such as Medical Reserve Corps (MRCs), Community Emergency Response Teams (CERTs), and others 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.

L. The authorization of appropriate oversight boards, commissions, and agencies to ease building code restrictions and to permit emergency demolition, hazardous waste disposal, debris removal, emergency landfill siting, and operations and other activities necessary to address immediate health and safety needs without regard to time-consuming procedures or formalities and without regard to application or permit fees or royalties.

M. The activation of the statutory provisions in § 59.1-525 et seq., of the Code of Virginia related to price gouging. Price gouging at any time is unacceptable. Price gouging is even more reprehensible during a time of disaster after issuance of a state of emergency. I have directed all applicable executive branch agencies to take immediate action to address any verified reports of price gouging of necessary goods or services. I make the same request of the Office of the Attorney General and appropriate local officials. I further request that all appropriate executive branch agencies exercise their discretion to the extent allowed by law to address any pending deadlines or expirations affected by or attributable to this disaster event.

N. The following conditions apply to the deployment of the Virginia National Guard and the Virginia Defense Force:

1. The Adjutant General of Virginia, after consultation with the State Coordinator of Emergency Management, shall make available on state active duty such units and members of the Virginia National Guard and Virginia Defense Force and such equipment as may be necessary or desirable to assist in preparations for this incident and in alleviating the human suffering and damage to property.

2. Pursuant to § 52-6 of the Code of Virginia, I authorize the Superintendent of the Department of State Police to appoint any and all such Virginia Army and Air National Guard personnel called to state active duty as additional police officers as deemed necessary. These police officers shall have the same powers and perform the same duties as the State Police officers appointed by the Superintendent. However, they shall nevertheless remain members of the Virginia National Guard, subject to military command as members of the State Militia. Any bonds and/or insurance required by § 52-7 of the Code of Virginia shall be provided for them at the expense of the Commonwealth.

3. In all instances, members of the Virginia National Guard and Virginia Defense Force shall remain subject to military command as prescribed by § 44-78.1 of the Code of Virginia and are not subject to the civilian authorities of county or municipal governments. This shall not be deemed to prohibit working in close cooperation with members of

the Virginia Departments of State Police or Emergency Management or local law enforcement or emergency management authorities or receiving guidance from them in the performance of their duties.

4. Should service under this Executive Order result in the injury or death of any member of the Virginia National Guard, the following will be provided to the member and the member's dependents or survivors:

a. Workers' Compensation benefits provided to members of the National Guard by the Virginia Workers' Compensation Act, subject to the requirements and limitations thereof; and, in addition,

b. The same benefits, or their equivalent, for injury, disability, and/or death, as would be provided by the federal government if the member were serving on federal active duty at the time of the injury or death. Any such federal-type benefits due to a member and his or her dependents or survivors during any calendar month shall be reduced by any payments due under the Virginia Workers' Compensation Act during the same month. If and when the time period for payment of Workers' Compensation benefits has elapsed, the member and his or her dependents or survivors shall thereafter receive full federal-type benefits for as long as they would have received such benefits if the member had been serving on federal active duty at the time of injury or death. Any federal-type benefits due shall be computed on the basis of military pay grade E-5 or the member's military grade at the time of injury or death, whichever produces the greater benefit amount. Pursuant to § 44-14 of the Code of Virginia, and subject to the availability of future appropriations which may be lawfully applied to this purpose, I now approve of future expenditures out of appropriations to the Department of Military Affairs for such federal-type benefits as being manifestly for the benefit of the military service.

5. The following conditions apply to service by the Virginia Defense Force:

a. Compensation shall be at a daily rate that is equivalent of base pay only for a National Guard Unit Training Assembly, commensurate with the grade and years of service of the member, not to exceed 20 years of service;

b. Lodging and meals shall be provided by the Adjutant General or reimbursed at standard state per diem rates;

c. All privately owned equipment, including, but not limited to, vehicles, boats, and aircraft, will be reimbursed for expense of fuel. Damage or loss of said equipment will be reimbursed, minus reimbursement from personal insurance, if said equipment was

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authorized for use by the Adjutant General in accordance with § 44-54.12 of the Code of Virginia;

d. In the event of death or injury, benefits shall be provided in accordance with the Virginia Workers' Compensation Act, subject to the requirements and limitations thereof.

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 January 21, 2016, and shall remain in full force and effect until March 1, 2016, unless sooner amended or rescinded by further executive order.

Given under my hand and under the Seal of the Commonwealth of Virginia, this 21st day of January, 2016.

/s/ Terence R. McAuliffe
Governor

GENERAL NOTICES/ERRATA

DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES

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 Board of Agriculture and Consumer Services is currently reviewing each of the regulations listed below to determine whether it should be repealed, amended, or retained in its current form. The review of each regulation will be guided by the principles in Executive Order 17 (2014) and § 2.2-4007.1 of the Code of Virginia. Each regulation will be reviewed to determine 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.

2VAC5-70, Health Requirements Governing the Control of Equine Infectious Anemia in Virginia

2VAC5-160, Rules and Regulations Governing the Transportation of Horses

Contact Information: Dr. Charles Broaddus, Program Manager, Veterinary Services; P.O. Box 1163, Richmond, VA 23218, telephone (804) 786-4560, FAX (804) 371-2380, or email charles.broaddus@vdacs.virginia.gov.

2VAC5-280, Virginia Grade Standards for Slaughter and Feeder Lambs

2VAC5-290, Breeder Sheep Grade Standards

Contact Information: Michael Carpenter, Program Manager, Livestock Marketing Services, P.O. Box 1163, Richmond, VA 23218, telephone (804) 786-0577, FAX (804) 371-0247, or email mike.carpenter@vdacs.virginia.gov.

2VAC5-330, Rules and Regulations for Enforcement of the Virginia Pest Law-Virginia Gypsy Moth Quarantine

2VAC5-400, Rules and Regulations for the Enforcement of the Virginia Fertilizer Law

Contact Information: Debra Martin, Program Manager, Office of Plant Industry Service, P.O. Box 1163, Richmond, VA 23218, telephone (804) 786-3515, FAX (804) 371-7793, or email debra.martin@vdacs.virginia.gov.

2VAC5-480, Regulation Governing the Oxygenation of Gasoline

Contact Information: Joel Maddux, Program Manager, Office of Weights and Measures, P.O. Box 1163, Richmond, VA 23218, telephone (804) 786-1274, FAX (804) 786-1571, or email joel.maddux@vdacs.virginia.gov.

2VAC5-550, Rules and Regulations Pertaining to Tolerances and Prohibitions Applicable to Sausage

2VAC5-560, Rules and Regulations Pertaining to Labeling and Sale of Infant Formula

2VAC5-570, Rules and Regulations Defining Standards for Grades/Sizes of Shell Eggs

Contact Information: Ryan Davis, Program Manager, Office of Dairy and Foods, P.O. Box 1163, Richmond, VA 23218, telephone (804) 786-8910, FAX (804) 371-7792, or email ryan.davis@vdacs.virginia.gov.

The comment period begins February 8, 2016, and ends February 29, 2016.

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 the agency contacts listed above.

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.

COMMON INTEREST COMMUNITY BOARD

Small Business Impact Review - Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Common Interest Community Board conducted a small business impact review of **18VAC48-10, Public Participation Guidelines**, and determined that this regulation should be retained in its current form. The Common Interest Community Board is publishing its report of findings dated January 17, 2016, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

Section 2.2-4007.02 of the Code of Virginia mandates the agency to solicit the input of interested parties in the formation and development of its regulations. Therefore, the continued need for the regulation is established in statute. The regulation is necessary to protect public health, safety, and welfare by establishing public participation guidelines that promote public involvement in the development, amendment, or repeal of an agency's regulation. By soliciting the input of interested parties, the agency is better equipped to effectively regulate the occupation or profession. Since no complaints or comments were received during the public comment period, there does not appear to be a reason to amend or repeal the regulation. The regulation is clearly written and easily understandable. The regulation does not overlap, duplicate, or contravene federal or state law or regulation. The regulation was last reviewed in 2011. On December 10, 2015, the board

General Notices/Errata

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

Contact Information: Trisha Henshaw, Executive Director, Department of Professional and Occupational Regulation, 9960 Mayland Drive, Suite 400, Richmond, VA 23233, telephone (804) 367-8510, FAX (866) 490-2723, or email cic@dpor.virginia.gov.

Small Business Impact Review - Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Common Interest Community Board conducted a small business impact review of **18VAC48-40, Time-Share Regulations**, and determined that this regulation should be retained in its current form until the effective date of its replacement with 18VAC48-45. The Common Interest Community Board is publishing its report of findings dated January 17, 2016, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

Section 55-396 of the Code of Virginia authorizes the Common Interest Community Board to promulgate regulations. The continued need for the regulation is established in statute. Repeal of the regulation would remove the current public protections provided by the regulation. The Common Interest Community Board provides protection to the safety and welfare of the citizens of the Commonwealth by ensuring compliance to applicable statutes and regulations of transactions related to time-share sales in Virginia, including what is expected of the time-share developer, the unit owners' association, and the time-share instruments, as well as other aspects of the Virginia Real Estate Time-Share Act (§ 55-360 et seq. of the Code of Virginia).

No comments or complaints were received during the public comment period. The regulation is clearly written, easily understandable, and does not overlap, duplicate, or contravene federal or state law or regulation.

The most recent periodic review of the regulation occurred in 2013. On December 10, 2015, the board reviewed the regulation and, for reasons stated, determined that the regulation should not be amended or repealed but should be retained in its current form until the effective date of its replacement with 18VAC48-45.

Contact Information: Trisha Henshaw, Executive Director, Department of Professional and Occupational Regulation, 9960 Mayland Drive, Suite 400, Richmond, VA 23233, telephone (804) 367-8510, FAX (866) 490-2723, or email cic@dpor.virginia.gov.

Small Business Impact Review - Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Common Interest Community Board conducted a small business impact review of **18VAC48-50, Common Interest Community Manager Regulations**, and determined that this

regulation should be retained in its current form. The Common Interest Community Board is publishing its report of findings dated January 17, 2016, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

Section 54.1-2349 A of the Code of Virginia mandates the Common Interest Community Board to promulgate regulations. The continued need for the regulation is established in statute. Repeal of the regulation would remove the current public protections provided by the regulation.

A concern raised by the sole comment received during the public comment period is addressed in the board's prohibited acts section of regulation and compliant process. Therefore a change is not warranted.

The regulation is clearly written and easily understandable. The regulation does not overlap, duplicate, or contravene federal or state law or regulation. This is the first periodic review of the regulation since 2011. On December 10, 2015, the board reviewed the regulation and, for reasons stated, determined that the regulation should not be amended or repealed but should be retained in its current form.

Contact Information: Trisha Henshaw, Executive Director, Department of Professional and Occupational Regulation, 9960 Mayland Drive, Suite 400, Richmond, VA 23233, telephone (804) 367-8510, FAX (866) 490-2723, or email cic@dpor.virginia.gov.

Small Business Impact Review - Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Common Interest Community Board conducted a small business impact review of **18VAC48-60, Common Interest Community Board Management Information Fund Regulations**, and determined that this regulation should be retained in its current form. The Common Interest Community Board is publishing its report of findings dated January 17, 2016, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

Section 55-530 I of the Code of Virginia authorizes the Common Interest Community Board to promulgate regulations. The continued need for the regulation is established in statute. Repeal of the regulation would remove the current public protections provided by the regulation.

No comments or complaints were received during the public comment period. The regulation is clearly written, easily understandable, and does not overlap, duplicate, or contravene federal or state law or regulation.

At its December 10, 2015, meeting, the board discussed the regulation and, for the reasons stated, determined that the regulation should not be amended or repealed but should be retained in its current form.

Contact Information: Trisha Henshaw, Executive Director, Department of Professional and Occupational Regulation,

9960 Mayland Drive, Suite 400, Richmond, VA 23233, telephone (804) 367-8510, FAX (866) 490-2723, or email cic@dpor.virginia.gov.

Small Business Impact Review - Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Common Interest Community Board conducted a small business impact review of **18VAC48-70, Common Interest Community Ombudsman Regulations**, and determined that this regulation should be retained in its current form. The Common Interest Community Board is publishing its report of findings dated January 17, 2016, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

Section 55-530 I of the Code of Virginia authorizes the Common Interest Community Board to promulgate regulations. The continued need for the regulation is established in statute. Repeal of the regulation would remove the current public protections provided by the regulation.

The nature of the sole comment received during the public comment period does not appear to be regulatory in nature; however, was taken into consideration. The regulation is clearly written, easily understandable, and does not overlap, duplicate, or contravene federal or state law or regulation.

This is the first periodic review of the regulation. At its December 10, 2015, meeting, the board discussed the regulation and, for the reasons stated, determined that the regulation should not be amended or repealed but should be retained in its current form.

Contact Information: Trisha Henshaw, Executive Director, Department of Professional and Occupational Regulation, 9960 Mayland Drive, Suite 400, Richmond, VA 23233, telephone (804) 367-8510, FAX (866) 490-2723, or email cic@dpor.virginia.gov.

CRIMINAL JUSTICE SERVICES 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 Criminal Justice Services and the Criminal Justice Services Board are conducting a periodic review and small business impact review of **6VAC20-130, Regulations Governing the Privacy and Security of Criminal History Record Information Checks for Firearm Purchases**.

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 February 8, 2016, and ends March 1, 2016.

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 Barbara Peterson-Wilson, Law Enforcement Program Coordinator, Department of Criminal Justice Services, 1100 Bank Street 12th Floor, Richmond, VA 23219, telephone (804) 225-4503, FAX (804) 786-0410, or email barbara.peterson-wilson@dcjs.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.

BOARD OF PHARMACY

Public Hearing on Placing Certain Chemicals in Schedule I

Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy is giving notice of a public hearing to consider placement of chemical substances in Schedule I of the Drug Control Act. The public hearing will be conducted at 9 a.m. on March 25, 2016, at the Perimeter Center, 9960 Mayland Drive, Suite 201, Richmond, VA 23233. Public comment may also be submitted electronically or in writing prior to March 23, 2016, to Caroline Juran, Executive Director of the Board of Pharmacy, email caroline.juran@dhp.virginia.gov.

As specified in § 54.1-3443, the Virginia Department of Forensic Science (DFS) has identified six compounds for recommended inclusion by the Board of Pharmacy into Schedule I in the Code of Virginia. A brief description and chemical name for each compound is as follows:

1. N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (other name: butyryl fentanyl)

Butyryl fentanyl is a powerful synthetic opioid similar in structure to fentanyl and has been identified in DFS laboratories. Butyryl fentanyl has not been approved for medical use in the United States. DFS recommends placing butyryl fentanyl into Schedule I (subdivision 6 of § 54.1-3446 of the Code of Virginia).

General Notices/Errata

2. Flubromazolam

Flubromazolam is classified as a benzodiazepine, which is a central nervous system depressant. Flubromazolam has been identified in DFS laboratories found on blotter paper and candy. Other drugs of this type have been placed in Schedule I (subdivision 4 of § 54.1-3446 of the Code of Virginia).

3. 5-methoxy-N,N-methylisopropyltryptamine (Other name: 5-MeO-MIPT)

5-MeO-MIPT is classified as a research chemical and has been identified in DFS laboratories. 5-MeO-MIPT is similar in structure to 5-MeO-DIPT, which is currently a Schedule I compound. Drugs of this type have been placed in Schedule I (subdivision 3 of § 54.1-3446 of the Code of Virginia) in previous legislative sessions.

4. N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-[(4-fluorophenyl)methyl]-1H-indazole-3-carboxamide (Other name: ADB-FUBINACA)

ADB-FUBINACA is classified as a cannabimimetic agent and has been identified in DFS laboratories. Other drugs of this type have been placed in Schedule I (subdivision 7 b of § 54.1-3446 of the Code of Virginia) in previous legislative sessions.

5. Methyl 2-[1-[(4-fluorophenyl)methyl]-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (Other name: MDMA-FUBINACA)

MDMA-FUBINACA is classified as a cannabimimetic agent and has been identified in DFS laboratories. Other drugs of this type have been placed in Schedule I (subdivision 7 b of § 54.1-3446 of the Code of Virginia) in previous legislative sessions.

6. Methyl 2-[1-(5-fluoropentyl)-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (Other names: 5-fluoro-ADB, 5-Fluoro-MDMA-PINACA)

5-fluoro-ADB is classified as a cannabimimetic agent and has been identified in DFS laboratories. Other drugs of this type have been placed in Schedule I (subdivision 7 b of § 54.1-3446 of the Code of Virginia) in previous legislative sessions.

If approved by the Board of Pharmacy, the placement of these substances in Schedule I in the Virginia Drug Control Act shall remain in effect for a period of 18 months from the date of board action and shall then be de-scheduled unless the Drug Control Act is amended by enactment of legislation by the General Assembly.

Contact Information: Caroline Juran, RPh, Executive Director, Department of Health Professions, 9960 Mayland Drive, Suite 300, Richmond, VA 23233, telephone (804) 367-4416, FAX (804) 527-4472, or email caroline.juran@dhp.virginia.gov.

BOARD FOR WASTE MANAGEMENT FACILITY OPERATORS

Small Business Impact Review - Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Board for Waste Management Facility Operators conducted a small business impact review of **18VAC155-11, Public Participation Guidelines**, and determined that this regulation should be retained in its current form. The Board for Waste Management Facility Operators is publishing its report of findings dated January 12, 2016, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

1. There is a continued need to promote public involvement in the development, amendment, or repeal of a board's regulation. By soliciting the input of interested parties, the board is better equipped to ensure that waste management facility operators have met minimum competencies and that the regulations are not overly burdensome.
2. No public comments were received concerning the regulations.
3. The regulations are currently clear and are not a burden to the public or the licensees.
4. There is no overlap, duplication, or conflict with any federal or state law or regulation.
5. The last review of these regulations was in November 2011.

Contact Information: Eric L. Olson, Executive Director, Department of Professional and Occupational Regulation, 9960 Mayland Drive, Suite 400, Richmond, VA 23233, telephone (804) 367-8511, FAX (866) 430-1033, or email wastemgt@dpor.virginia.gov.

Small Business Impact Review - Report of Findings

Pursuant to § 2.2-4007.1 of the Code of Virginia, the Board for Waste Management Facility Operators conducted a small business impact review of **18VAC155-20, Waste Management Facility Operators Regulations**, and determined that this regulation should be retained in its current form. The Board for Waste Management Facility Operators is publishing its report of findings dated January 11, 2016, to support this decision in accordance with § 2.2-4007.1 F of the Code of Virginia.

1. There is a continued need to ensure that the operators of waste management facilities (landfills, transfer stations, composting facilities, etc.) are properly licensed in order to protect the health of all individuals that utilize the facilities, live in proximity to the facilities, or work at the facilities.
2. No public comments were received concerning the regulations.
3. The regulations were relatively correct and the board has taken action in a separate regulatory action, to clarify them

and to remove sections that were deemed to be obsolete or overly burdensome.

4. There is no overlap, duplication, or conflict with any federal or state law or regulation.

5. The regulation is currently in two review processes, one that address technological advances in the industry and one that reviewed all other factors that have changed in the industry.

Contact Information: Eric L. Olson, Executive Director, Department of Professional and Occupational Regulation, 9960 Mayland Drive, Suite 400, Richmond, VA 23233, telephone (804) 367-8511, FAX (866) 430-1033, or email wastemgt@dpor.virginia.gov.

STATE WATER CONTROL BOARD

New Living Shorelines Loan Program - Public Comment Period and Public Meeting Regarding Proposed Guidelines

On behalf of the State Water Control Board, the Department of Environmental Quality is presenting its draft guidelines for the new Living Shorelines Loan Program for public review and comment. A public meeting will be held at 10 a.m. on Tuesday, February 23, 2016, in the Department of Environmental Quality's 2nd Floor Conference Room, 629 East Main Street, Richmond, VA 23219. The public review and comment period will end on February 29, 2016.

In order to protect or improve water quality and prevent the pollution of state waters, the Virginia General Assembly amended Chapter 22 (§ 62.1-224 et seq.) of Title 62.1 of the Code of Virginia by adding § 62.1-229.5, which expands the activities of the Virginia Clean Water Facilities Revolving Fund. This addition allows the State Water Control Board to authorize low interest loans from the fund for the purpose of establishing living shorelines. Legislation authorized the board to develop guidelines for the administration of living shorelines loans. The draft guidelines are now available for public review and comment at <http://www.deq.virginia.gov/Programs/Water/CleanWaterFinancingAssistance/LivingShoreline.aspx>.

Questions and comments should be directed to the contact person below.

Contact Information: Walter Gills, Department of Environmental Quality, 629 East Main Street, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4133, or email walter.gills@deq.virginia.gov.

Proposed Consent Order for American Water Operations and Maintenance, Inc.

An enforcement action has been proposed for American Water Operations and Maintenance, Inc. for violations of the State Water Control Law and regulations at United States

Army Garrison, Fort Belvoir located in Fairfax County, Virginia. The State Water Control Board proposes to issue a consent order to resolve violations associated with an unpermitted discharge from the sanitary sewer collection system associated with Fort Belvoir. 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, FAX at (703) 583-3821, or postal mail at Department of Environmental Quality, Northern Regional Office, 13901 Crown Court, Woodbridge, VA 22193, from February 9, 2016, through March 10, 2016.

VIRGINIA CODE COMMISSION

Notice to State Agencies

Contact Information: *Mailing Address:* Virginia Code Commission, General Assembly Building, 201 North 9th Street, 2nd Floor, Richmond, VA 23219; *Telephone:* Voice (804) 786-3591; *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 <http://www.virginia.gov/connect/commonwealth-calendar>.

Cumulative Table of Virginia Administrative Code Sections Adopted, Amended, or Repealed: A table listing regulation sections that have been amended, added, or repealed in the *Virginia Register of Regulations* since the regulations were originally published or last supplemented in the print version of the Virginia Administrative Code is available at <http://register.dls.virginia.gov/documents/cumulatab.pdf>.

Filing Material for Publication in the Virginia Register of Regulations: Agencies use the Regulation Information System (RIS) to file regulations and related items for publication in the *Virginia Register of Regulations*. The Registrar's office works closely with the Department of Planning and Budget (DPB) to coordinate the system with the Virginia Regulatory Town Hall. RIS and Town Hall complement and enhance one another by sharing pertinent regulatory information.

ERRATA

VIRGINIA WORKERS' COMPENSATION COMMISSION

Title of Regulation: 16VAC30-50. Rules of the Virginia Workers' Compensation Commission.

Publication: 32:10 VA.R. 1808-1809 January 11, 2016.

General Notices/Errata

Correction to Emergency Regulation:

Page 1809, 16VAC30-50-150, table of communities and three-digit zip codes, in row "5 - Southwest," delete "244" under column titled "THREE-DIGIT ZIP CODES"

VA.R. Doc. No. R16-4565; Filed January 19, 2016, 11:44 a.m.