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Virginia Code Commission

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VIRGINIA REGISTER INFORMATION PAGE

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

ADOPTION, AMENDMENT, AND REPEAL OF REGULATIONS

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

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

July 2016 through July 2017

Volume: Issue	Material Submitted By Noon*	Will Be Published On
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
33:17	March 29, 2017	April 17, 2017
33:18	April 12, 2017	May 1, 2017
33:19	April 26, 2017	May 15, 2017
33:20	May 10, 2017	May 29, 2017
33:21	May 24, 2017	June 12, 2017
33:22	June 7, 2017	June 26, 2017
33:23	June 21, 2017	July 10, 2017

*Filing deadlines are Wednesdays unless otherwise specified.

PETITIONS FOR RULEMAKING

TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF DENTISTRY

Initial Agency Notice

<u>Title of Regulation:</u> 18VAC60-21. Regulations Governing the Practice of Dentistry.

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

Name of Petitioner: Deborah R. Blanchard, DDS.

<u>Nature of Petitioner's Request:</u> The request is to eliminate the requirement for posting of a copy of a dentist's registration issued by the Drug Enforcement Administration to avoid opportunity for individuals to use the number for illegal purposes.

Agency Plan for Disposition of Request: The petition will be published on July 11, 2016, in the Virginia Register of Regulations and posted on the Virginia Regulatory Town Hall at www.townhall.virginia.gov to receive public comment ending August 10, 2016. The request to amend regulations and any comments for or against the petition will be considered by the board at its meeting scheduled for September 16, 2016.

Public Comment Deadline: August 10, 2016.

<u>Agency Contact</u>: Sandra Reen, Executive Director, Department of Health Professions, 9960 Mayland Drive, Suite 300, Richmond, VA 23233, telephone (804) 367-4437, email sandra.reen@dhp.virginia.gov.

VA.R. Doc. No. R16-28; Filed June 16, 2016, 2:03 p.m.

Volume 32, Issue 23

NOTICES OF INTENDED REGULATORY ACTION

TITLE 9. ENVIRONMENT

STATE WATER CONTROL BOARD

Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the State Water Control Board intends to consider amending **9VAC25-890**, **General VPDES Permit for Discharges of Stormwater from Small Municipal Separate Storm Sewer Systems**. The purpose of the proposed action is to amend and reissue the existing general permit, which expires on June 30, 2018. The general permit governs local governments, state agencies, and federal agencies that discharge stormwater from municipally owned separate storm sewer systems located within "urbanized areas" as designated by the U.S. Census Bureau.

In addition, pursuant to Executive Order 17 (2014) and § 2.2-4007.1 of the Code of Virginia, the agency is conducting a periodic review and small business impact review of this regulation to determine whether this regulation should be terminated, amended, or retained in its current form. Public comment is sought on the review of any issue relating to this regulation, including whether the regulation (i) is necessary for the protection of public health, safety, and welfare or for the economical performance of important governmental functions; (ii) minimizes the economic impact on small businesses in a manner consistent with the stated objectives of applicable law; (iii) is designed to achieve its intended objective in the most efficient, cost-effective manner; (iv) is clearly written and easily understandable; and (v) overlaps, duplicates, or conflicts with federal or state law or regulation. Additional consideration will be given to the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation since the last review.

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

Statutory Authority: § 62.1-44.15:28 of the Code of Virginia.

Public Comment Deadline: August 10, 2016.

<u>Agency Contact:</u> Jaime Bauer, Department of Environmental Quality, 629 East Main Street, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4416, FAX (804) 698-5106, or email jaime.bauer@deq.virginia.gov.

VA.R. Doc. No. R16-4777; Filed June 22, 2016, 7:47 a.m.

TITLE 12. HEALTH

DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

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 Medical Assistance Services intends to consider amending 12VAC30-60, Standards Established and Methods Used to Assure High Quality Care. The purpose of the proposed action is to implement Chapter 413 of the 2014 Acts of Assembly, Item 301 QQQQ of Chapter 3 of the 2015 Acts of Assembly, and Item 306 PPP of Chapter 780 of the 2016 Acts of Assembly and to improve the preadmission screening process for individuals who will be eligible for long-term services and supports. The regulatory action may include (i) adding requirements for accepting screening requests, managing the screening process, and submitting findings from screenings completed by community and hospital preadmission screening (PAS) teams and contractors performing screenings; (ii) use of the electronic preadmission screening (ePAS) system; (iii) contracting with public or private entities to perform screenings that have not been completed within 30 days of an individual's request; (iv) contracting out community based screenings for children; (v) clarifying requirements of community and hospital PAS teams and screenings performed by these teams; and (vi) adding a definitions section.

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

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

Public Comment Deadline: August 10, 2016.

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

VA.R. Doc. No. R16-4355; Filed June 21, 2016, 10:25 a.m.

TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF NURSING

Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the Board of Nursing intends to consider amending **18VAC90-50**, **Regulations Governing the Certification of Massage Therapists**, as a result of the

Notices of Intended Regulatory Action

periodic review of regulations conducted by the board. The purpose of the proposed action is to clarify certain sections, offer additional options for completion of continuing education, require an attestation of compliance with laws and ethics for initial certification, and add provisions to the standards of conduct that may subject a regulant to disciplinary action. The Board of Nursing will initiate a separate regulatory action to amend the regulation in accordance with Chapter 324 of the 2016 Acts of Assembly, which requires that massage therapists be licensed, rather than certified.

This Notice of Intended Regulatory Action serves as the report of the findings of the regulatory review pursuant to § 2.2-4007.1 of the Code of Virginia.

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

Statutory Authority: §§ 54.1 2400 and 54.1-3005 of the Code of Virginia.

Public Comment Deadline: August 10, 2016.

<u>Agency Contact:</u> Jay P. Douglas, R.N., Executive Director, Board of Nursing, 9960 Mayland Drive, Suite 300, Richmond, VA 23233-1463, telephone (804) 367-4515, FAX (804) 527-4455, or email jay.douglas@dhp.virginia.gov.

VA.R. Doc. No. R16-4739; Filed June 18, 2016, 11:19 a.m.

BOARD OF PHARMACY

Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the Board of Pharmacy intends to consider amending 18VAC110-20, Regulations (i) Governing the Practice of Pharmacy, and 18VAC110-50, Regulations Governing Wholesale **Distributors.** Manufacturers, and Warehousers and (ii) adopting 18VAC110-16, Regulations Governing the Delegation of Informal Fact-Finding Proceedings to an Agency Subordinate, and 18VAC110-25, Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians. The purpose of the proposed action is to (i) reduce the size and complexity of 18VAC110-20 by moving some of the provisions of that chapter into new chapters and (ii) amend 18VAC110-20 and 18VAC110-50 to clarify certain requirements, incorporate provisions currently found in guidance documents, and update and streamline requirements where possible. Provisions relating to the licensure of pharmacists and registration of pharmacy technicians and certain general provisions will be moved from 18VAC110-20 to new chapter 18VAC110-25. Additionally, 18VAC110-20-15, relating to criteria for delegation of informal fact-finding proceedings to an agency subordinate, will be moved into new chapter 18VAC110-16 because it applies to all types of licensees, registrants, and permit holders regulated by the board.

The regulatory action being considered is in response to a periodic review of the regulations, and this Notice of Intended Regulatory Action serves as the report of the findings of the regulatory review pursuant to § 2.2-4007.1 of the Code of Virginia.

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

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

Public Comment Deadline: August 10, 2016.

<u>Agency Contact:</u> 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.

VA.R. Doc. No. R16-4673; Filed June 18, 2016, 11:20 a.m.

REGULATIONS

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

Symbol Key

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

TITLE 2. AGRICULTURE

BOARD OF AGRICULTURE AND CONSUMER SERVICES

Fast-Track Regulation

<u>Title of Regulation:</u> 2VAC5-160. Rules and Regulations Governing the Transportation of Horses (repealing 2VAC5-160-10 through 2VAC5-160-90).

Statutory Authority: § 3.2-6501 of the Code of Virginia.

<u>Public Hearing Information:</u> No public hearings are scheduled.

Public Comment Deadline: August 10, 2016.

Effective Date: August 25, 2016.

<u>Agency Contact:</u> Dr. Carolynn Bissett, Program Manager, Office of Veterinary Services, Department of Agriculture and Consumer Services, P.O. Box 1163, Richmond, VA 23218, telephone (804) 786-2483, FAX (804) 371-2380, TTY (800) 828-1120, or email carolynn.bissett@vdacs.virginia.gov.

<u>Basis:</u> Section 3.2-109 of the Code of Virginia establishes the board as a policy board with the authority to adopt regulations in accordance with the provisions of Title 3.2 of the Code of Virginia.

Section 3.2-6501 of the Code of Virginia authorizes the board to adopt regulations and guidelines consistent with the objectives and intent of the Virginia Comprehensive Animal Care Law (Chapter 65 of Title 3.2 of the Code) concerning the care and transportation of animals.

<u>Purpose:</u> The proposed regulatory action will repeal this regulation that has not been utilized or applied since it was adopted over 25 years ago. The agency cannot foresee a circumstance where the regulation would be needed in the future as there are no longer any operating horse slaughter plants in the United States. If horse slaughter plants were to reopen in the United States, or if Virginia horses are transported outside of the United States for slaughter, the humane care of horses is covered under the Virginia Comprehensive Animal Care Law. Additionally, federal regulations pertaining to the commercial transportation of equines for slaughter can be found in 9 CFR Part 88.

<u>Rationale for Using Fast-Track Rulemaking Process:</u> The regulation has not been utilized or applied since it was adopted over 25 years ago, and the agency cannot foresee a circumstance where the regulation would be needed in the future as other state animal care laws and federal laws pertaining to this topic exist. There is no longer a need for this regulation. The agency is not aware of any stakeholders

suggesting that the regulation be retained or that the regulation is of any benefit to them.

<u>Substance</u>: The proposed regulatory action will repeal this regulation that has not been utilized or applied since it was adopted over 25 years ago. The agency cannot foresee a circumstance where the regulation would be needed in the future as there are no longer any operating horse slaughter plants in the United States.

<u>Issues:</u> The primary advantage to the public is the repeal of an outdated regulation that specifies actions that have never been taken. The agency and the Commonwealth will no longer be in a position of having an outdated regulation that is not enforced. This action to eliminate an outdated, unnecessary regulation is part of good governance. There are no disadvantages to the public or the Commonwealth associated with repealing the regulation.

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

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. The Board of Agriculture and Consumer Services (Board) proposes to repeal this regulation.

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

Estimated Economic Impact. The existing regulation provides the rules regarding the transportation of loads of more than six horses being transported to a commercial slaughter facility in a vehicle. The regulation does not address the transportation of horses under other circumstances.

The regulation has not been utilized or applied since it was adopted over 25 years ago; also, the Department of Agriculture and Consumer Services cannot foresee a circumstance where the regulation would be needed in the future, as there are no longer any operating horse slaughter plants in the U.S. If horse slaughter plants were to reopen in the U.S., or if Virginia horses are transported outside of the U.S. for slaughter, the humane care of horses is covered under the Virginia Comprehensive Animal Care Law.¹ Additionally, federal regulations pertaining to the commercial transportation of equines for slaughter can be found in 9 CFR, Part 88.

The repeal of this regulation will have no impact beyond potentially reducing the likelihood that readers may be misled into believing that the transport of horses to operating horse slaughter plants is currently done in Virginia. To the extent that the repeal of the regulation reduces the likelihood of such confusion, the proposed repeal would be beneficial.

Businesses and Entities Affected. Since there are no operating horse slaughter plants in the U.S. and this regulation has not been utilized or applied since it was adopted over 25 years ago, its repeal will not significantly affect any businesses or entities.

Localities Particularly Affected. The proposed repeal of the regulation does not disproportionately affect particular localities.

Projected Impact on Employment. The proposed repeal of the regulation does not affect employment.

Effects on the Use and Value of Private Property. The proposed repeal of the regulation does not affect the use and value of private property.

Real Estate Development Costs. The proposed repeal of the regulation does not affect real estate development costs.

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 proposed repeal of the regulation does not affect small businesses.

Alternative Method that Minimizes Adverse Impact. The proposed repeal of the regulation does not affect small businesses.

Adverse Impacts:

Businesses. The proposed repeal of the regulation will not adversely affect businesses.

Localities. The proposed repeal of the regulation will not adversely affect localities.

Other Entities. The proposed repeal of the regulation will not adversely affect other entities.

¹http://law.lis.virginia.gov/vacode/title3.2/chapter65/

<u>Agency's Response to Economic Impact Analysis:</u> The agency concurs with the analysis of the Department of Planning and Budget.

Summary:

The regulatory action repeals the chapter, which has not been utilized or applied since it was adopted over 25 years ago. The agency cannot foresee a circumstance where the regulation would be needed in the future as other state animal care laws and federal laws pertaining to this topic exist. Therefore, the regulation is repealed.

VA.R. Doc. No. R16-4645; Filed June 21, 2016, 11:27 a.m.

Fast-Track Regulation

<u>Title of Regulation:</u> 2VAC5-501. Regulations Governing the Cooling, Storing, Sampling and Transporting of Milk (amending 2VAC5-501-10, 2VAC5-501-50 through 2VAC5-501-90; repealing 2VAC5-501-110).

Statutory Authority: §§ 3.2-5206, 3.2-5223, and 3.2-5224 of the Code of Virginia.

<u>Public Hearing Information:</u> No public hearings are scheduled.

Public Comment Deadline: August 10, 2016.

Effective Date: August 25, 2016.

<u>Agency Contact:</u> Robert Trimmer, Program Supervisor, Department of Agriculture and Consumer Services, P.O. Box 1163, Richmond, VA 23218, telephone (804) 786-1452, FAX (804) 371-7792, TTY (800) 828-1120, or email robert.trimmer@vdacs.virginia.gov.

<u>Basis</u>: Section 3.2-109 of the Code of Virginia establishes the Board of Agriculture and Consumer Services as a policy board and authorizes the board to adopt regulations in accordance with the provisions of Title 3.2 of the Code of Virginia.

Section 3.2-5206 of the Code of Virginia authorizes the board to establish definitions and standards of quality and identity and to adopt and enforce regulations dealing with the issuance of permits, production, importation, processing, grading, labeling, and sanitary standards for milk, milk products, market milk, market milk products, and those products manufactured or sold in semblance to or as substitutes for milk, milk products, market milk, or market milk products.

This section also authorizes the board to adopt (i) any regulation or part thereof under federal law that pertains to milk or milk products, amending the federal regulation as necessary for intrastate application and (ii) any model ordinance or regulation issued under federal law including the Pasteurized Milk Ordinance (PMO) and the U.S. Department of Agriculture's Milk for Manufacturing Purposes.

<u>Purpose:</u> The amendments bring the regulation in line with current federal standards as established by the 2013 revision of the PMO. In addition to providing for consistency with current federal standards and existing Virginia regulations, these amendments provide for sufficient flexibility regarding milk storage times for the dairy industry while continuing to protect the public's health, safety, and welfare by ensuring the safety and wholesomeness of all milk shipped from Virginia dairy farms.

Surrounding states have already updated their regulations to be consistent with the less stringent requirements established in the revised PMO governing the storage and transportation of milk. The changes facilitate interstate sales of Virginia milk producers by providing a level playing field with surrounding states in regards to the storage and transportation of milk. The regulatory modifications should effect a cost savings to producers associated with the transportation of

milk from farms to processing facilities with no adverse effects on the health and safety of consumers.

Rationale for Using Fast-Track Rulemaking Process: The amendments are noncontroversial changes requested by the dairy industry and bring the regulation in line with current federal standards and regulations adopted by surrounding states. The amendments are less stringent than the requirements currently in place, and producers are not required to exercise the 72-hour storage option. The additional 20 hours of storage provided for in the amendments does not affect the safety of the milk supply and reduces producer costs associated with the transportation of milk. The amendment aids producers during extreme weather events that disrupt normal transportation by increasing the permissible storage time and reducing the need to seek emergency variances during such weather events.

Substance: The substantive changes are as follows:

1. The addition of 20 hours of milk storage time in a farm bulk tank, allowing for the sale of milk no older than 72 hours from completion of the first milking. The current regulation allows 52 hours of storage time in a farm bulk tank.

2. Allows for a 24, 48, or 168 hour (seven day) rotation of recording charts based on the frequency of milk pick up. These changes align the regulations with existing federal regulation and regulations of surrounding states.

The removal of 2VAC5-501-110 from the chapter since this section is no longer relevant and is unnecessary for the enforcement of 2VAC5-501.

<u>Issues:</u> The primary advantage to the public is that the regulation allows for the safe storage and cooling of milk produced on dairy farms in Virginia and sold in intrastate and interstate commerce. This ensures that the public is afforded the opportunity to consume a safe product and further ensures that the dairy industry is afforded additional flexibility regarding the storage of milk.

The primary advantage to the agency and Commonwealth is that the regulation ensures that the Commonwealth can adequately protect the public. The requirements also aid the continued intrastate and interstate sale of milk on a more competitive basis, which ultimately benefits Virginia's economy.

This regulatory action poses no disadvantages to the public or the Commonwealth.

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

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. The Department of Agriculture and Consumer Services (DACS) proposes to increase the permissible storage time of milk in a farm bulk tank from 52 hours to 72 hours and to allow the use of chart recorders supporting a 72-hour pick up schedule.

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

Estimated Economic Impact. In most farms once milk is obtained from the cow it is stored in a tank to be picked up by a hauler at certain frequencies to be delivered to the processing plant. Under the current regulations, producers can store milk in a farm tank up to 52 hours. However, the permissible storage time in surrounding states as well as the standard established in the federal Pasteurized Milk Ordinance is 72 hours. The proposed regulation will allow storage of milk in Virginia farms up to 72 hours.

An increase in storage time would allow producers to reduce the frequency of pick-ups from the farm; albeit lower frequency pick-ups may require a larger tank and a new chart recorder. According to DACS, haulers usually charge \$65 to \$100 per pick-up; the cost of a storage tank is about \$100 per gallon of capacity; and a recorder that can support a 72-hour rotation schedule costs about \$1,800. The proposed regulation allows but does not require storage of milk up to 72 hours. Thus, producers that anticipate savings from less frequent pick-ups will be allowed to do so under the proposed regulation. The proposed change may also reduce the need to seek emergency variances during extreme weather events. Given the federal ordinance and the permissible storage times from neighboring states, the proposed increase in the storage time is not expected to affect the safety of milk supply or pose any health risks.

In addition, consistency with dairy industry standards in surrounding states would promote competition. Virginia farmers will now be able to reduce their transportation costs to the levels comparable to those of producers in other states which may promote production. Since Virginia's current storage times are more restrictive than the other states, there may also be an increase in the quantity of milk imported to the Commonwealth further promoting competition.

The remaining proposed changes are clarifying in nature and are not expected to create any significant economic effects other than improving the clarity of the regulation.

Businesses and Entities Affected. There are 639 estimated Grade "A" milk producers in Virginia. Some of these producers may already have the storage tank capacity and a chart recorder to accommodate a 72-hour pick-up schedule. There are 281 licensed haulers that drive the trucks and pick up milk and 17 companies in and out of state that hire them. There are approximately five dairy equipment dealers in Virginia that represent or distribute for a number of dairy equipment manufacturers.¹

Localities Particularly Affected. The proposed changes apply statewide.

Projected Impact on Employment. The proposed changes will allow the dairy industry to reduce transportation costs and improve competition. An increase in competition may lead to more production and an increased demand for labor. In addition, demand for storage tanks and chart recorders may increase. On the other hand, less frequent milk pick up times has the potential to reduce the demand for transportation services offered by milk haulers.

Effects on the Use and Value of Private Property. The proposed changes may have a positive impact on asset values of some producers of milk, manufacturers, distributors, and installers of storage tanks and chart recorders, and may have a negative impact on asset values of some milk haulers and businesses that hire them.

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. Most of the producers of milk, milk haulers, distributors and installers of tanks and recorders are considered small businesses. The potential effects on them are the same as those discussed above.

Alternative Method that Minimizes Adverse Impact. There is no known alternative to minimize the potential adverse impact on milk haulers and businesses that hire them while achieving the intended policy goals.

Adverse Impacts:

Businesses. The proposed amendments are not anticipated to have an adverse impact on non-small businesses.

Localities. The proposed amendments will not adversely affect localities.

Other Entities. The proposed amendments will not adversely affect other entities.

¹ Data source: Department of Agriculture and Consumer Services

<u>Agency's Response to Economic Impact Analysis:</u> The agency concurs with the analysis of the Department of Planning and Budget.

Summary:

The amendments (i) add 20 hours of milk storage time in a farm bulk tank, allowing for the sale of milk no older than 72 hours from completion of the first milking; (ii) allow the use of a 24-hour, 48-hour, or 168-hour (seven-day) chart recorder based upon the frequency of milk pickup from producers; and (iii) update certain standards incorporated by reference. 2VAC5-501-110 is repealed as it is no longer necessary for the enforcement of the chapter.

2VAC5-501-10. Definitions.

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

"Bulk milk hauler" means any person who holds a permit issued by the Virginia Department of Agriculture and Consumer Services to collect official milk samples and transport: (i) raw milk from a dairy farm to a milk plant, receiving station, or transfer station; or (ii) raw milk products from one milk plant, receiving station, or transfer station to another milk plant, receiving station, or transfer station.

"Bulk milk pickup tanker" means a vehicle, including the truck, tank, and those appurtenances necessary for its use, used by a bulk milk hauler or bulk milk sampler to transport bulk raw milk for pasteurization from a dairy farm to a milk plant, receiving station, or transfer station.

"Bulk milk pickup tanker commingled milk" means the commingled raw milk from two or more dairy farms which that has not been removed from the bulk milk pickup tanker.

"Bulk milk sampler" means any person who holds a permit issued by the Virginia Department of Agriculture and Consumer Services to collect, store, or transport official milk samples.

"Cancel" means to permanently nullify, void, or delete a permit issued by the Virginia Department of Agriculture and Consumer Services.

"Contract hauler" or "subcontract hauler" means any person who contracts; (i) to transport raw milk from a dairy farm to a milk plant, receiving station, or transfer station; or (ii) to transport raw milk or milk products between a milk plant, receiving station, or transfer station and another milk plant, receiving station, or transfer station.

"Dairy farm" means any place or premises (i) where any cow, goat, sheep, water buffalo, or other mammal (except humans) is kept, or (ii) from which any cow, goat, sheep, water buffalo, or other mammal (except humans) milk, dairy product, or milk product is sold or offered for sale for human consumption.

"Dairy plant sampler" means any employee of: (i) a milk plant who is responsible for collecting official milk samples in the Commonwealth of Virginia; (ii) the Virginia Department of Agriculture and Consumer Services who is responsible for collecting raw milk or pasteurized milk product samples at a milk plant; or (iii) the Virginia Department of Health who is responsible for collecting raw milk or pasteurized milk product samples at a milk plant and who holds a permit issued by the Virginia Department of Agriculture and Consumer Services for the collection of official milk samples for regulatory purposes.

"Dairy product" means butter, natural or processed cheese, dry whole milk, nonfat dry milk, dry buttermilk, dry whey, evaporated whole or skim milk, condensed whole milk, and condensed plain or sweetened skim milk.

"Deny" means the Virginia Department of Agriculture and Consumer Services will not issue a permit to the applicant.

"Farm bulk cooling or holding tank" means any tank installed on a dairy farm for the purpose of cooling or storing raw milk.

"Milk" means the whole, fresh, clean lacteal secretion obtained by the complete milking of one or more healthy cows, goats, sheep, water buffalo, or other mammal (except humans) intended for human consumption excluding that obtained before and after birthing for such a period as may be necessary to render the milk practically colostrum-free.

"Milk plant" means any place, premises, or establishment where milk, milk products, or dairy products are collected, handled, processed, stored, pasteurized, aseptically processed, bottled, packaged, or prepared for distribution.

"Milk producer" means any person who operates a dairy farm and provides, sells, or offers any milk for human consumption.

"Milk product" means: (i) acidified lowfat milk, acidified milk, acidified milk product, acidified skim milk, acidified sour cream, acidified sour half-and-half, aseptically processed milk, aseptically processed milk product, buttermilk, coffee cream, concentrated milk, concentrated milk product, cottage cheese, cottage cheese dry curd, cream, cultured half-andhalf, cultured milk, cultured lowfat milk, cultured skim milk, cultured sour cream, dry curd cottage cheese, eggnog, eggnog-flavored milk, flavored milk, flavored milk product, fortified milk, fortified milk product, frozen milk concentrate, goat milk, half-and-half, heavy cream, lactose-reduced lowfat milk, lactose-reduced milk, lactose-reduced skim milk, light cream, light whipping cream, lowfat cottage cheese, lowfat milk, lowfat yogurt, low-sodium lowfat milk, low-sodium milk. low-sodium skim milk. milk. nonfat milk. nonfat yogurt, recombined milk, recombined milk product, reconstituted milk, reconstituted milk product, sheep milk, skim milk, sour cream, sour half-and-half, table cream, vitamin D milk, vitamin D milk product, whipped cream, whipped light cream, whipping cream, or yogurt; (ii) any of the following foods: milk, lowfat milk, or skim milk with added safe and suitable microbial organisms; or (iii) any food made with a food specified in clause (i) of this definition by the addition or subtraction of milkfat or addition of safe and suitable optional ingredients for protein, vitamin, or mineral fortification. Milk products also include those dairy foods made by modifying the federally standardized products listed above in this definition in accordance with 21 CFR 130.10 -Requirements for foods named by use of a nutrient content claim and a standardized term.

"Milk tank truck" means the term used to describe both a bulk milk pickup tanker and a milk transport tank.

"Milk tank truck cleaning facility" means any place, premise, or establishment, separate from a milk plant, receiving station, or transfer station where a bulk milk pickup tanker or milk transport tank is cleaned and sanitized. "Milk transport tank" means a vehicle, including the truck and tank, used by a bulk milk hauler to transport bulk shipments of milk, milk product, or dairy product from a milk plant, receiving station, or transfer station to another milk plant, receiving station, or transfer station.

"Official laboratory" means a facility where biological, chemical, or physical testing is performed that is operated or approved by the state regulatory authority.

"Official milk sample" means each sample of milk, milk product, or dairy product that is collected for compliance with requirements of this chapter by a person who holds a permit to collect milk, milk product, or dairy product samples issued by the state regulatory authority.

"Other mammals" means any mammal except humans, cows, goats, sheep, or water buffalo.

"Pay purpose laboratory" means a laboratory that conducts tests for the purpose of determining the composition of milk, milk product, cream, or dairy product as a basis for payment in buying or selling any milk, milk product, cream, or dairy product.

"Permit" means the written document issued by the Virginia Department of Agriculture and Consumer Services to a person qualified to (i) be a bulk milk hauler, bulk milk sampler, contract hauler, subcontract hauler, dairy plant sampler, or pay purpose tester, or to (ii) operate a pay purpose laboratory, bulk milk pickup tanker, or milk transport tank.

"Person" means any individual, plant operator, partnership, corporation, company, firm, trustee, institution, or association.

"Raw" means unpasteurized.

"Receiving station" means any place, premises, or establishment where any milk, milk product, or dairy product is received, collected, handled, stored or cooled, and prepared for further transporting.

"Revoke" means to permanently annul, repeal, rescind, countermand, or abrogate the opportunity for any person or persons to hold a permit issued by the Virginia Department of Agriculture and Consumer Services.

"State regulatory authority" means the Virginia Department of Agriculture and Consumer Services, the agency having jurisdiction and control over the matters embraced within this chapter.

"Summarily suspend" means the immediate suspension of a permit issued by the state regulatory authority without the permit holder being granted the opportunity to contest the action prior to the effective date and time of the suspension.

"Suspend" means to temporarily nullify, void, debar, or cease for a period of time a permit issued by the Virginia Department of Agriculture and Consumer Services.

"Transfer station" means any place, premises, or establishment where milk, dairy products, or milk products are transferred directly from one <u>milk</u> transport milk tank to another, or from one or more bulk milk pickup tankers to one or more <u>milk</u> transport milk tanks.

"Transport-commingled milk" means any raw milk, milk product, or dairy product that has been removed from one or more bulk milk pickup tankers or any silo, vat, or container in a milk plant and loaded into a milk transport tank.

"Transport tank operator" means any person who hauls transport-commingled milk.

"3-A Sanitary Standards" means the standards for dairy equipment and accepted practices formulated by the 3-A Sanitary Standards Committees representing the International Association for Food Protection, the U.S. U.S. Public Health Service, and the Dairy Industry Committee and published by the International Association for Food Protection.

2VAC5-501-50. Cooling temperature and storage standards for milk stored on a dairy farm.

A. Each person who that operates a dairy farm shall cool his raw milk to 40° F or cooler, but not frozen, within two hours after milking and the temperature at any time thereafter shall not be warmer than 50° F. Raw milk that is warmer than a temperature of 50° F two hours after the first milking or at any time thereafter shall be deemed a public health hazard and shall not be utilized in any milk, milk product, or dairy product, offered for sale, or sold.

B. No person who that operates a dairy farm and holds a grade "A" dairy farm permit shall sell or offer to sell any milk as grade "A" milk if the age of the milk is older than $\frac{52}{72}$ hours after the completion of the first milking.

C. No person who that operates a dairy farm and holds a permit to produce milk for manufacturing purposes shall sell, offer to sell, or process any milk for manufacturing purposes if the age of the milk is older than 76 hours after the completion of the first milking. Raw milk for manufacturing purposes older than 76 hours shall be deemed to be a public health hazard.

2VAC5-501-60. Construction and operation of farm bulk milk cooling or holding tanks, recording thermometers, interval timing devices, and other required milkhouse or milkroom facilities.

A. Each person who <u>that</u> operates a dairy farm and installs one or more farm bulk cooling or holding tanks in <u>his the</u> milkhouse shall provide the following facilities:

1. A milk hose port opening no larger than eight inches in diameter through a wall in the milkhouse closest to the area the bulk milk pickup tanker will be parked to receive the milk from each farm bulk cooling or holding tank;. The hose port shall be:

a. Provided with a self-closing door that shall open to the outside; and

b. Of sufficient height above the milkhouse floor and the outside apron to prevent flooding or draining of the milkhouse;

2. The hose port shall be provided with a self closing door which shall open to the outside;

3. The hose port shall be of sufficient height above the milkhouse floor and the outside apron to prevent flooding or draining of the milkhouse;

4. <u>2.</u> An outside apron constructed of concrete or other equally impervious material shall be provided on the outside of the milkhouse directly beneath the hose port to protect the milk-conducting equipment from contamination;, and:

a. If constructed of concrete, each outside apron shall be a minimum of four inches thick and measure a minimum of two feet by two feet horizontally; or

b. If constructed of a material other than concrete, each outside apron shall measure a minimum of two feet by two feet horizontally;

5. Each outside apron shall be a minimum of four inches thick if constructed of concrete and measure a minimum of two feet by two feet horizontally;

6. Each outside apron constructed of a material other than concrete shall measure a minimum of two feet by two feet horizontally;

7. 3. A 220-volt grounded weatherproof electrical outlet installed on the outside of the milkroom or milkhouse near the hoseport for the bulk milk hauler's use to power the milk pump on the bulk milk pickup tanker; and

8. <u>4.</u> A switch to control the electrical power to the 220volt grounded weatherproof electrical outlet located on the inside of the milkroom or milkhouse near the outlet to the farm bulk cooling or holding tank.

B. Each person who that operates a dairy farm and installs one or more farm bulk cooling or holding tanks in his the milkhouse or milkroom shall comply with the following requirements:

1. Each farm bulk cooling or holding tank shall comply with all the requirements contained in:

a. 3-A Sanitary Standards for Farm Milk Cooling and Holding Tanks, Document No. 13-09 (Nov. 1993) <u>13-11</u> (July 2012); or

b. 3-A Sanitary Standards for Farm Milk Storage Tanks, Document No. 30-01 (Sept. 1984);

2. Each farm bulk cooling or holding tank shall be equipped with an indicating thermometer accurate to plus or minus 2.0°F and capable of registering the temperature of the milk in the tank before it reaches 10% of the tank's volume;

3. Each farm bulk cooling or holding tank shall be installed to comply with the following minimum clearance distances around, above, and below each farm bulk cooling or holding tank:

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a. Three feet measured horizontally between a wash vat and the outermost portion of any farm bulk cooling or holding tank;

b. Three feet measured horizontally in a 180-degree arch from the front of the tank where the outlet valve is located;

c. Two feet measured horizontally from the sides and rear of any farm bulk cooling or holding tank to any wall, shelves, water heater, hand-basin, or other object;

d. Eighteen inches measured horizontally from the outermost portion of any farm bulk cooling or holding tank to any floor drain and the floor drain shall not be located underneath the tank;

e. Three feet measured vertically from the top of the manhole cover of any farm bulk cooling or holding tank to the ceiling;

f. Eight inches measured vertically from the floor underneath the bottom of any round farm bulk cooling or holding tank that measures greater than 72 inches in diameter;

g. Four inches measured vertically from the floor underneath the bottom of any round farm bulk cooling or holding tank that measures equal to or less than 72 inches in diameter; and

h. Six inches measured vertically from the floor underneath the bottom of any flat bottom farm bulk cooling or holding tank;

4. Farm bulk cooling or holding tanks installed through a milkroom wall shall meet the following minimum requirements:

a. The area between the farm bulk cooling or holding tank and the wall shall be tightly sealed;

b. All vents and openings on the farm bulk cooling or holding tank located outside the milkroom shall be protected from dust, insects, moisture, and other debris which might enter the tank; and

c. All agitators located outside the milkroom shall be equipped with a tightly fitting seal between the bottom of the agitator motor and the top of the farm bulk cooling or holding tank;

5. Each person who that operates a dairy farm shall ensure that each farm bulk cooling or holding tank is installed with a foundation of sufficient strength to support the tank when it is full;

6. Each person who that operates a dairy farm shall obtain prior approval from the state regulatory authority for each farm bulk cooling or holding tank and its installation before it is installed on the person's dairy farm; and

7. Each person who that operates a dairy farm shall ensure each farm bulk cooling or holding tank on his the farm is installed, gauged, and a volume chart prepared in compliance with § 3.2 5260 regulations adopted pursuant to § 3.2-5206 of the Code of Virginia. Each farm bulk cooling or holding tank and any gauge rod, surface gauge, gauge, or gauge tube and calibration chart associated with it shall be identified by serial number in a prominent manner.

C. Each person who that holds a grade "A" dairy farm permit and installs a farm bulk cooling or holding tank shall comply with the following:

1. Each farm bulk cooling or holding tank shall be equipped with a recording thermometer;

2. Each recording thermometer shall be installed to comply with the following:

a. Each recording thermometer shall be installed in the milkhouse;

b. No recording thermometer may be installed on or attached to a farm bulk cooling or holding tank;

c. Each recording thermometer shall be installed: (i) on an inside wall of the milkhouse; (ii) on an outside wall of the milkhouse or milkroom if installed with one inch of rigid insulation between the back of the recording thermometer and the surface of the outside wall; or (iii) on metal brackets from the ceiling or floor; and

d. Each recording thermometer sensor shall be installed on the farm bulk cooling or holding tank to record the temperature of the milk in the tank before the milk reaches 10% of the tank's volume;

3. Standards for recording thermometers. Each recording thermometer installed on a farm bulk cooling or holding tank shall comply with the following minimum requirements:

a. The case for each recording thermometer shall be moisture proof under milkhouse conditions;

b. The case for each recording thermometer shall be UL rated NEMA 4X enclosure or equivalent as provided in ANSI/NEMA 250, Enclosures for Electrical Equipment (1000 Volts Maximum) dated August 30, 2001 December 29, 2014;

c. The case for each recording thermometer shall be equipped with a corrosion-resistant latching mechanism that keeps the recording thermometer tightly closed;

d. The recorder chart for each recording thermometer shall not exceed a maximum chart rotation time of 48 168 hours (seven days). Recorder charts for farm bulk cooling or holding tanks that are picked up every other day shall have a chart rotation time of 48 hours. Recorder charts for farm bulk cooling or holding tanks that are picked up every day may have a chart rotation time of 24 or 48 hours;

e. The recorder chart for each recording thermometer shall be marked with water resistant ink;

f. The scale on the recording chart shall cover a minimum of 30° F to 180° F, with the scale reversed to

show cold temperatures at the outside of the chart for best resolution;

g. Each division on the recording chart shall represent a maximum of 1.0° F between 30° F and 60° F, with two degree divisions between 60° F and 180° F;

h. Spacing of divisions on the recorder chart shall be a minimum of 0.040 inches per 2.0° F, with the ink line easily distinguishable from the printed line;

i. The recording thermometer speed of response or sensing of temperature shall be a maximum of 20 seconds;

j. The recording thermometer shall be accurate to plus or minus 2.0° F;

k. The sensor for each recording thermometer shall be; (i) a resistance temperature detector (RTD) type sensor; (ii) constructed of stainless steel type 304 or type 316 on all exterior surfaces; (iii) hermetically sealed; (iv) accurate to 0.3° C; and (v) continuous run wire;

1. Each recording thermometer and sensor shall be calibrated and supplied as a package;

m. No capillary system containing any toxic gas or liquid shall be allowed to come into direct contact with any milk or milk product;

n. Other recording devices may be accepted by the state regulatory authority if they comply with the requirements of subdivisions 3 a through m of this subsection;

o. If a strip chart style recorder is used, it shall move not less than one inch per hour, and may be continuous for a maximum of 30 days; and

p. Recording thermometers may be manually wound or electrically operated;

4. Recording thermometer operation: Each recording thermometer installed on a farm bulk cooling or holding tank shall comply with the following minimum operating requirements:

a. Each recording thermometer shall be provided with a means to seal the calibration and zeroing mechanism to provide evidence of unauthorized adjustment or tampering;

b. Each recording thermometer shall be provided with a pin in the hub to prevent the recording chart from being rotated; and

c. Each recording thermometer shall be properly grounded and short circuit protected;

5. Each person who that operates a dairy farm and installs a recording thermometer on his the farm bulk cooling or holding tank shall maintain a minimum of a 30-day supply of unused recorder charts designed for the specific recording thermometer he installed and shall maintain a minimum of the past 60 days of used charts for purposes of inspection; and

6. Each person who that operates a dairy farm and installs a recording thermometer on his the farm bulk cooling or holding tank shall provide a moisture proof storage container in the milkhouse or milkroom for purpose of storing a supply of new charts and a minimum of 60 days of used charts.

D. No person may remove from the dairy farm any recorder chart that has been used once and removed from the recorder within the past 60 days unless he has obtained permission from the state regulatory authority. All recorder charts removed from any dairy farm by any person other than a representative of the state regulatory authority shall be returned to the dairy farm within ten <u>10</u> days. All recorder charts shall be available to the state regulatory authority.

E. Handling of recording charts. Each bulk milk hauler shall comply with the following requirements when picking up milk from a dairy farm if the farm bulk cooling or holding tank is equipped with a recording thermometer:

1. Each milk hauler, in making a milk pickup, shall properly agitate the milk and remove the chart from the recorder;

2. Each milk hauler shall record the following information on each chart removed from the recorder:

a. The date and time of pickup; and

b. The signature of the milk hauler;

3. Each milk hauler shall store the used chart in the storage container supplied by the dairy farmer;

4. Each milk hauler shall obtain a new chart from the supply provided by the dairy farmer and record the following information in the chart:

a. The date; and

b. The patron number of the dairy farmer;

5. If a recorder chart is used for more than one pickup, each milk hauler shall identify each lot of milk on the chart with the date, time of pickup, and his signature; <u>and</u>

6. Before removing any milk from the farm tank, each milk hauler shall check the recorder chart. If the recorder chart indicates that the milk temperature has varied in a manner that would preclude acceptance, he shall immediately notify his superior and the dairy farmer. If the milk is rejected, each milk hauler shall record this information on the chart. If the milk is picked up, each milk hauler shall sign the chart and record the date and time of pickup<u>+</u>.

F. <u>Maintenance of recording thermometers</u>. Each person who <u>that</u> operates a dairy farm and holds a grade "A" dairy farm permit shall be responsible for maintaining each of <u>his</u> <u>the</u> recording thermometers in good repair and adjustment to include calibrating the recording thermometer to read accurately within plus or minus 2.0°F of the actual milk temperature in the farm bulk cooling or holding tank.

G. Sealing of recording thermometers: Each recording thermometer installed on a farm bulk cooling or holding tank

shall be inspected and may be sealed by the state regulatory authority after it has been shown to be properly installed and calibrated.

H. Each person who that holds a grade "A" dairy farm permit and installs a farm bulk cooling or holding tank shall:

1. Install on each farm bulk cooling or holding tank an interval timing device that automatically agitates the milk in the farm bulk tank for not less than five minutes every hour during the entire time milk is being cooled or stored in the tank;

2. Not install a manual switch capable of turning off the interval timing device on any farm bulk milk cooling or holding tank while any milk is being cooled or stored; and

3. Maintain in good repair and operating condition each interval timing device installed on his the farm bulk cooling or holding tank.

2VAC5-501-70. Measuring, sampling, and testing.

A. Quantity measurements. Each person who determines the quantity of milk in any lot of milk being picked up on any dairy farm in Virginia shall comply with one of the following:

1. If the milk is being picked up from a farm bulk cooling or holding tank, the person shall use only a measuring rod, gauge, or gauge tube accurately calibrated to the individual farm bulk cooling or holding tank and the accompanying calibration chart with a serial number that matches the serial number for the specific farm bulk cooling or holding tank for which it was prepared;

2. If the milk being picked up is not stored in a farm bulk cooling or holding tank, the person shall determine the quantity of milk at the point of delivery to the milk plant processing the milk by commingling all of the milk in a vessel equipped with a gauge rod, surface gauge, gauge, or gauge tube and a volume chart that has been prepared in compliance with § 3.2-5620 of the Code of Virginia;

3. If the milk being picked up is not stored in a farm bulk cooling or holding tank and the basis for payment for the milk will be based solely on the volume of milk in gallons, the person shall determine the quantity of milk by adding the volume in gallons of each separate full container and the volume in gallons of any milk in containers that are not full; or

4. If the milk being picked up is not stored in a farm bulk cooling or holding tank and the basis for payment for the milk will be based solely on the pounds of milk delivered, the person shall determine the quantity of milk in pounds by weighing each of the containers of milk on a commercial scale before and after they have been emptied and subtracting the weight of the empty containers from the total weight of the containers and the milk, the difference being the weight in pounds of milk.

B. Each person who desires to convert a volumetric measurement of milk to weight in pounds of milk shall multiply the volume of milk in gallons by 8.60.

C. Each person who that operates a dairy farm and transports any milk in cans or other containers from his the dairy farm to a milk plant and intends to determine the basis for payment of his the milk based solely on its volume in gallons or solely on its weight in pounds, shall ensure the cans or other containers comply with the following:

1. Each container shall be provided with a visual means to measure the volume of milk in the container in divisions of one or more whole gallons up to the total capacity of the container;

2. Each container shall be equipped with a tightly fitting lid that prevents any milk from leaking out around the closure;

3. Each container shall be manufactured from stainless steel, food grade plastic, or tinned metal;

4. No container shall be manufactured from glass or other easily breakable material;

5. Each container shall be smooth and easily cleanable; and

6. Each container shall be equipped with an opening large enough to allow the container to be washed by hand if it is intended to be washed by hand or washed by mechanical means if it is intended to be washed by mechanical means.

D. Each person who that operates a pay purpose laboratory shall:

1. Provide a separate room of sufficient size in which pay purpose testing shall be conducted;

2. Provide lighting of at least 20 foot-candles when measured at work bench levels and at all other work areas used to conduct testing;

3. Provide adequate ventilation sufficient to prevent condensation from forming and to prevent noxious or hazardous chemical fumes from collecting in the laboratory;

4. Provide heating and cooling equipment sufficient to maintain a constant room temperature of 70°F plus or minus 2.0°F in his laboratory at all times;

5. Provide a separate permanently installed hand-washing facility with hot and cold running water under pressure supplied through a mix valve, soap, and single service paper towels;

6. Provide only potable water under pressure in his the laboratory;

7. Provide walls that are constructed of impervious material with a light-colored material and that are easily cleanable;

8. Provide floors made of concrete or other equally impervious material that are easily cleanable;

9. Provide toilet facilities for his employees;

10. Use only methods and equipment approved by the state regulatory authority to test milk for protein, solids, solids not fat, and fat;

11. Construct the facility to <u>insure ensure</u> that the laboratory environment has a stable electrical supply, <u>stable</u> water supply, stable heating and cooling, and stable ventilation to allow a constantly controllable environment for pay purpose testing procedures and pay purpose equipment; and

12. Dispose of all liquid, solid, and gaseous wastes in a manner that complies with state and federal requirements for waste disposal.

E. Sampling. Each bulk milk hauler shall:

1. Collect at least two representative samples from each bulk milk cooling or holding tank each time that milk is picked up from the dairy farm for use as official milk samples;

2. Collect a minimum of four ounces of milk for each official milk sample collected;

3. Maintain custody of all official milk samples collected or transfer custody of all official milk samples collected to another permitted bulk milk hauler, bulk milk sampler, or at the discretion of the state regulatory agency, lock all official milk samples in a suitable container in which they may be transported or stored;

4. <u>Pickup</u> <u>Pick up</u> all of the milk in each farm bulk cooling or holding tank each time that milk is picked up from the farm bulk cooling or holding tank; and

5. Pick up only milk that is 45°F or cooler, but not frozen.

F. Butterfat testing. Each person who desires to determine the butterfat content of milk as a basis for payment shall: 1. Select <u>either select</u> from each dairy farm supplying them with milk a minimum of four milk samples taken at irregular intervals each month and utilize only laboratory butterfat test results from milk samples that have been tested within 48 hours of collection for pay purposes; or:

2. <u>1.</u> Collect a representative sample from each shipment of each producer supplying them with milk for a maximum of 16 days, if composite milk samples are used to determine butterfat content;

3. <u>2.</u> Store composite milk samples only in an approved milk laboratory that will perform the butterfat test;

4. <u>3.</u> Preserve all composite milk samples with an appropriate preservative designed to prevent the spoilage of milk and that will not affect the butterfat test; and

5. <u>4.</u> Test each composite milk sample within three days following the end of the number of days used to create the composite milk sample.

2VAC5-501-80. Farm bulk milk pickup tanker and milk transport tank requirements.

A. Each contract hauler or subcontract hauler shall:

1. Use only a farm bulk milk pickup tanker or a milk transport tank that complies with all the requirements contained in 3-A Sanitary Standards for Stainless Steel Automotive Transportation Tanks for Bulk Delivery and Farm Pick-Up Service, Number 05-15 (effective November 24, 2002), (3-A Sanitary Standards, Incorporated) and that are maintained in good repair;

2. Ensure that all appurtenances of each farm bulk milk pickup tanker or each milk transport tank including any hoses, pumps, and fittings comply with all applicable <u>the</u> <u>requirements contained in</u> 3-A Sanitary Standards <u>for</u> <u>Stainless Steel Automotive Transportation Tanks for Bulk</u> <u>Delivery and Farm Pick-Up Service, Number 05-15</u> (effective as of November 20, 2001) <u>24, 2002)</u>, (3-A Sanitary Standards, Incorporated) for construction and are maintained in good repair;

3. Provide sample racks for holding all milk samples collected in the sample cooler;

4. Provide a sample dipper or other sampling device of sanitary design that is maintained clean and in good repair;

5. Provide milk sample storage coolers that have sufficient insulation to maintain proper milk temperatures under all conditions throughout the year;

6. Provide only sterile sample bags, tubes, or bottles, properly stored to prevent contamination;

7. Provide a calibrated pocket thermometer certified as accurate within plus or minus 2.0°F to each bulk milk hauler in his employ and ensure the pocket thermometer is recertified a minimum of each six months thereafter;

8. Provide a United States U.S. Environmental Protection Agency approved and registered sanitizer for the sample dipper container;

9. Provide a suitable sanitizer test kit to each bulk milk hauler in his employ for use in checking the strength of sanitizing solutions;

10. Ensure that each appurtenance requiring flexibility for the milk transfer system to operate properly is free draining, supported to maintain a uniform slope and alignment, and easily disassembled and accessible for inspection without the use of tools;

11. Ensure that each farm bulk milk pickup tanker or a milk transport tank and their appurtenances are cleaned and sanitized prior to being used the first time, after each use thereafter, and each time 72 hours has elapsed since the last cleaning and sanitizing treatment;

12. Ensure that multiple milk pickups from dairy farms occur during a 24-hour period without washing and sanitizing the farm bulk milk pickup tanker only if a maximum of two hours elapses between the time of the last delivery and start of the next milk pickup;

13. <u>Pickup Pick up</u> any milk in a farm bulk milk pickup tanker or milk transport tank only if there exists a wash and sanitize record for the farm bulk milk pickup tanker or milk transport tank documenting that the tank has been washed and sanitized within the past 72 hours;

14. Install and use clamps on each milk pickup hose that are easily dismantled by hand without the use of tools;

15. Identify and maintain each farm bulk milk pickup tanker or milk transport tank with the identification numbers and letters assigned to each farm bulk milk pickup tanker or milk transport tank by the state regulatory agency. The identification shall be affixed to the left rear bulkhead of the tanker;

16. Provide a suitable enclosure in the rear milk hose or sample compartment of each farm bulk milk pickup tanker for storing inspection sheets capable of protecting the inspection sheets from excessive moisture, dust, soil, or light that might damage or render the inspection sheets illegible and so they will be available to any state or federal regulatory agent wherever the farm bulk milk pickup tanker might deliver;

17. Provide a suitable enclosure located within three feet of the tank outlet valve or located on top of one of the rear wheel fenders for each milk transport tank for storing inspection sheets capable of protecting the inspection sheets from excessive moisture, dust, soil, or light that might damage or render the inspection sheets illegible and so they will be available to any state or federal regulatory agent wherever the milk transport tank might deliver;

18. Completely empty the farm bulk cooling or holding tank each time that milk is picked up;

19. Store the three most recent inspection reports for each farm bulk milk pickup tanker or transport tank in the protected enclosure provided on each farm bulk milk pickup tanker or transport tank at all times; and

20. Provide a means to lock or seal each opening into a bulk milk pickup tanker or milk transport tank for security purposes.

B. When picking up and transporting any milk in a bulk milk pickup tanker each bulk milk hauler shall:

1. Practice good hygiene, maintain a neat and clean appearance, and abstain from using tobacco products in any milkhouse;

2. Conduct all pickup and handling practices to prevent contamination of any milk contact surface;

3. Pass the milk transfer hose through the hose port and remove the cap from the transfer milk hose and set it where it will not become contaminated and then attach the transfer milk hose to the tank outlet valve;

4. Wash his hands thoroughly and dry his hands with a clean single-service towel or electric forced air hand dryer immediately prior to measuring or sampling the milk in the tank;

5. Examine the milk in the tank by sight and smell for any off odor or any other abnormalities that would render the milk unacceptable and reject the milk if necessary;

6. Record the milk producer's name, milk producer's identification number, the date and time of pickup, the temperature of the milk, the measuring rod reading, the poundage, the name of the purchasing organization, and the signature of the bulk milk hauler on the producer's weight ticket;

7. Check the temperature of the milk in each farm bulk cooling or holding tank at least once a month with an accurately calibrated pocket thermometer after it has been properly sanitized;

8. Turn off the milk tank agitator if it is running when they arrive <u>he arrives</u> at the milkhouse or milkroom and allow the surface of the milk to become quiescent;

9. Carefully insert the measuring rod, after it has been wiped dry with a single-service towel, into the tank and then read the measurement. Each bulk milk hauler shall repeat this procedure until two identical measurements are obtained and then shall record the measurement on the weight ticket;

10. Agitate the milk in each tank holding two-thousand 2,000 gallons or less of milk a minimum of five minutes before collecting any milk sample;

11. Agitate the milk in each tank holding more than two thousand 2,000 gallons of milk a minimum of ten <u>10</u> minutes before collecting any milk sample;

12. While the tank is being agitated, bring the sample container, dipper, dipper container, and sanitizing agent, or single service sampling tubes into the milkhouse aseptically;

13. While the tank is being agitated, remove the cap from the tank outlet valve and examine for milk deposits or foreign matter and then sanitize if necessary;

14. Remove the sample dipper or sampling device from the sanitizing solution and rinse it in the milk from the tank at least twice before collecting any official milk sample;

15. Collect two representative samples from each tank after the milk has been properly agitated, transferring the milk from the sample dipper to the sample container away from the tank opening to avoid spilling any milk back into the tank, and filling the sample containers only three quarters 3/4 full;

16. Rinse the sample dipper with water until it is free of visible milk and replace it in its carrying container;

17. Close the cover or lid of the bulk tank;

18. Identify each milk sample with the producer's patron or member number and the date of collection;

19. Collect at the first pickup for each load of milk two temperature samples and identify the temperature samples with the date, time, temperature of the milk, producer number, and name of the bulk milk hauler;

20. Place each milk sample collected immediately on ice in the sample storage cooler;

21. After collection of milk samples, open the outlet valve and start the pump to transfer the milk from the farm tank to the bulk milk pickup tanker;

22. Turn off the agitator once the level of milk in the tank has reached the level where over-agitation will occur;

23. Disconnect and cap the transfer hose after removing it from the outlet valve of the tank;

24. Observe the walls and bottom of the tank for foreign matter and extraneous material and record any objectionable observations on the weight ticket;

25. Rinse the entire inside of the tank with warm water while the tank outlet valve is open;

26. Use only sample containers and single-service sampling tubes that comply with all the requirements contained in Standard Methods for the Examination of Dairy Products, 16th 17th Edition, 1992 2004;

27. Cool and store all official milk samples to a temperature of 40° F or cooler, but not frozen;

28. Provide sufficient ice and water or other coolant in the sample storage cooler to maintain all milk samples at proper temperature;

29. Discard any milk that remains in the external transfer system that exceeds 45°F including any milk in pumps, hoses, and air elimination equipment or metering systems;

30. Protect samples from contamination and shall not bury the tops of sample containers in ice or bury sample containers above the milk level in the sample containers;

31. Keep all producer milk samples that represent the commingled milk on the load with the load of milk until the load of milk has been received by a milk plant, receiving station, or transfer station or if rejected by a milk plant, receiving station, or transfer station until the milk samples are collected for official laboratory testing to determine the disposition of the load of milk; and

32. Deliver each bulk milk pickup tanker of commingled milk to a milk plant, receiving station, or transfer station within 24 hours after the last milk pickup on the route for the bulk milk pickup tanker.

C. When sampling any milk from a bulk milk pickup tanker or transport tanker the dairy plant sampler shall:

1. Practice good hygiene, maintain a neat and clean appearance, and abstain from using tobacco products in the receiving area;

2. Conduct all sampling and handling practices to prevent contamination of any milk contact surface;

3. Wash his hands thoroughly and dry his hands with a clean single-service towel or acceptable air dryer immediately prior to sampling the milk in the tank;

4. Examine the milk in the tank by sight and smell for any off odor or any other abnormalities that would classify the milk as unacceptable and reject the milk if necessary;

5. Agitate for a period of time needed to blend the milk in each compartment to a homogenous state using odor-free, pressurized, filtered air or electrically driven stirring or recirculating equipment that has been properly sanitized before sampling or receiving;

6. Check the temperature of the milk in each compartment with a properly sanitized thermometer that has been checked against a standardized thermometer at least once every six months and certified accurate;

7. Reject any milk that has a temperature above 45°F;

8. Bring the sample container, properly constructed sample dipper, and sanitizing solution to the tanker aseptically after the milk is properly agitated;

9. Remove the sample dipper or sampling device from the sanitizing solution and rinse it in the milk from the tank at least twice before collecting any official milk sample;

10. Collect at least one representative sample from each compartment of the tanker, transferring the milk from the sample dipper to the sample container away from the tank opening to avoid spilling any milk back into the tank, and filling the sample container only three quarters full;

11. Rinse the sample dipper with water until it is free of visible milk and replace it in its carrying container or storage container;

12. Close the cover or lid for each compartment of the bulk milk tanker;

13. Identify each milk sample with the tanker number, compartment if the tanker is equipped with more than one compartment, and the date of collection;

14. Place each milk sample collected immediately on ice in a sample storage cooler or deliver it to the laboratory for immediate analysis;

15. Attach the milk transfer hose to the outlet valve of the milk tank truck and open the outlet valve of the milk tank truck before starting the pump to transfer the milk from the bulk milk pickup tanker to the milk plant storage facility or silo only after the collection of official milk samples;

16. Turn off the agitator once the level of milk in the tank has reached the level where over-agitation will occur;

17. Disconnect and cap the transfer hose after removing it from the outlet valve of the tank;

18. Observe the walls and bottom of the tank for foreign matter and extraneous material and record any objectionable observations on the plant receiving log;

19. Rinse the entire inside of the tanker with warm water after the tanker has been emptied and the external transfer system has been disconnected while the tanker outlet valve is open;

20. Use only sample containers and single-service sampling tubes that comply with all the requirements contained in Standard Methods for the Examination of Dairy Products, 16th 17th Edition, 1992 2004;

21. Cool and store all official milk samples to a temperature of 40° F or cooler, but not frozen;

22. Provide sufficient ice and water or other coolant in the sample storage cooler to maintain all milk samples at proper temperature;

23. Protect samples from contamination and not bury tops of sample containers in ice or bury samples above the milk level in the sample containers;

24. Promptly deliver samples and sample data to the laboratory; and

25. Discard any milk that remains in the external transfer system that exceeds 45°F including any milk in pumps, hoses, air elimination equipment, or metering systems.

D. Wash and sanitize records. Each bulk milk hauler shall:

1. Ensure each bulk milk pickup tanker or milk transport tank is properly cleaned and sanitized after unloading;

2. Ensure a cleaning and sanitizing tag is affixed to the outlet valve of the bulk milk pickup tanker or milk transport tank after it is washed;

3. Ensure when the bulk milk pickup tanker or milk transport tank is next washed, the previous cleaning and sanitizing tag is removed and stored at the location where the bulk milk pickup tanker or milk transport tank was washed; and

4. Ensure the following information is recorded on the wash and sanitize tag before it is attached to the outlet valve of the bulk milk pickup tanker or milk transport tank:

a. Identification number of the bulk milk pickup tanker or milk transport tank;

b. Date and time of day the bulk milk pickup tanker or milk transport tank was cleaned and sanitized;

c. Location where the bulk milk pickup tanker or milk transport tank was cleaned and sanitized; and

d. The signature of the person who cleaned and sanitized the bulk milk pickup tanker or milk transport tank.

E. Wash and sanitize records. Each person who <u>that</u> operates a milk plant, receiving station, or transfer station and each dairy plant sampler responsible for sampling and receiving milk into a milk plant, receiving station, or transfer station shall:

1. Ensure each bulk milk pickup tanker and milk transport tank is properly cleaned and sanitized after unloading;

2. Ensure a cleaning and sanitizing tag is affixed to the outlet valve of the bulk milk pickup tanker or milk transport tank after it is washed;

3. Ensure when washing a bulk milk pickup tanker or milk transport tank, the previous cleaning and sanitizing tag is removed and stored at the location where the bulk milk pickup tanker or milk transport tank is washed; and 4. Record the following information on the wash and sanitize tag before it is attached to the outlet valve of the bulk milk pickup tanker or milk transport tank:

a. Identification number of the bulk milk pickup tanker or milk transport tank;

b. Date and time of day the bulk milk pickup tanker or milk transport tank was cleaned and sanitized;

c. Location where the bulk milk pickup tanker or milk transport tank was cleaned and sanitized; and

d. The signature of the person who cleaned and sanitized the bulk milk pickup tanker or milk transport tank.

F. <u>Labeling and shipping documents</u>. Each bulk milk hauler shall ensure that each shipping document or load manifest contains the following information for each bulk milk pickup tanker or milk transport tank:

1. The shipper's name, address, and permit number;

2. The Interstate Milk Shipper Bulk Tank Unit identification number for each Bulk Tank Unit on the load of milk or the Interstate Milk Shipper listed Plant Number;

3. The milk hauler permit number if the milk hauler is not an employee of the shipper;

4. The point of origin of the shipment;

5. The bulk milk pickup tanker or milk transport tank identification number;

6. The name of the product;

7. The weight of the product;

8. The temperature of the product when loaded;

9. The date of shipment;

10. The name of the supervising regulatory agency at the point of origin of shipment;

11. A statement as to whether the contents of the load are raw, pasteurized, or in the case of cream, lowfat, or skim milk whether it has been heat-treated;

12. The seal number on inlet, outlet, wash connections and vents, if applicable; and

13. The grade of the product.

G. Protection of bulk milk and chain of custody of milk samples. Each contract hauler, subcontract hauler, bulk milk hauler, and operator of a bulk milk pickup tanker or milk transport tank shall:

1. Each contract hauler, subcontract hauler, bulk milk hauler, and operator of a bulk milk pickup tanker or milk transport tank shall ensure Ensure the proper protection of all milk and milk samples in his custody. Each contract hauler, subcontract hauler, bulk milk hauler, and operator of a bulk milk pickup tanker or milk transport tank shall seal or lock each opening into a bulk milk pickup tanker or milk transport tank including each manhole lid, vent, wash port, and door to the pump housing and sample storage box prior to leaving the bulk milk pickup tanker or milk transport tank unattended -:

2. Each contract hauler, subcontract hauler, bulk milk hauler, and operator of a bulk milk pickup tanker or milk transport tank shall inspect Inspect the condition of the seals and locks placed on each opening into the bulk milk pickup tanker or milk transport tank upon his return after an absence to determine if the seals or locks have been tampered with-:

3. Each contract hauler, subcontract hauler, bulk milk hauler, and operator of a bulk milk pickup tanker or milk transport tank shall report <u>Report</u> immediately to the state regulatory authority instances of tampering with the seals or locks-; and

4. Each contract hauler, subcontract hauler, bulk milk hauler, and operator of a bulk milk pickup tanker or milk transport tank shall hold <u>Hold</u> a valid permit issued by the state regulatory authority for the collection of milk samples prior to collecting or transporting any milk or milk samples.

H. Notwithstanding the provisions of subdivisions A 4 and A 8 of this section for each contract hauler or subcontract hauler to provide a sample dipper and approved sanitizer for the sample dipper container, the sample dipper, sample dipper container, and approved sanitizer may be provided and stored in the milkroom accessible to the contract hauler or subcontract hauler by the person operating the dairy farm where the contract hauler or subcontract hauler is picking up the milk.

2VAC5-501-90. Sanitation requirements for a milk tank truck cleaning facility.

Each person who that operates a milk tank truck cleaning facility permit shall:

1. Provide floors constructed of concrete or equally impervious material that are easily cleanable, smooth, properly sloped, and provided with trapped floor drains and kept in good repair;

2. Provide walls and ceilings with a smooth, washable, light-colored surface and kept in good repair;

3. Provide effective means to prevent the access of flies and rodents;

4. Provide solid doors or glazed windows for each opening to the outside and keep the doors and windows closed during dusty weather;

5. Provide lighting of at least 20 foot-candles measured in all work areas;

6. Provide ventilation sufficient to prevent condensation and odors;

7. Provide a toilet room fitted with tightly-fitting selfclosing doors, kept clean and in good repair, wellventilated and lighted and that does not open directly into any room in which milk or milk products are processed or milk product contact-surfaces, utensils and equipment are washed;

8. Dispose of all sewage and other wastes in a sanitary manner;

9. Provide hot and cold running water from a supply that is properly located, protected, and operated, and shall be easily accessible, adequate, and of a safe and sanitary quality;

10. Provide hand-washing facilities with hot and cold running water, soap, and individual sanitary towels or other approved hand-drying devices and keep the hand-washing facilities clean and in good repair;

11. Provide and maintain an effective insect and rodent control program and shall keep the milk tank truck cleaning facility neat and clean;

12. Provide only sanitary piping, fittings, and connections that are constructed to be smooth, impervious, corrosion-resistant, nontoxic, easily cleanable, and manufactured from material that is approved for food contact surfaces;

13. Provide and use only stainless steel piping complying with the American Iron and Steel Institute (AISI) 300 series as published in the Iron and Steel Society's Steel Products Manual for Manual: Stainless Steels, dated March 1999;

14. Provide only sanitary piping, fittings, and connections that are in good repair and constructed for ease of cleaning;

15. Provide and use only plastic, rubber, or rubber-like materials made from approved food contact-grade materials that are relatively inert, and resistant to scratching, scoring, and damage from cleaning compounds;

16. Clean and sanitize before each use the product-contact surfaces of utensils and equipment used in the transportation of any milk or food;

17. Attach a wash tag to the outlet valve of the tanker showing the date, time, place, and signature of the employee who washed the bulk milk pickup tanker or milk transport tank after the milk tank truck has been cleaned and sanitized;

18. Store and transport all clean and sanitized utensils and equipment to assure complete draining and protection from contamination before use;

19. Store all single-service containers, utensils, and materials in a sanitary manner in a clean dry place until used;

20. Store, handle, and use poisonous or toxic materials to preclude the contamination of any milk product contact-surfaces of equipment and utensils;

21. Ensure that his employees wash their hands thoroughly before commencing cleaning functions and as may be required to remove soil and contamination;

22. Allow an employee to resume work after visiting the toilet room only after that employee has thoroughly washed his hands;

23. Ensure that each of his employees employee engaged in the handling of milk product contact-surfaces, equipment, and utensils wears clean outer garments, adequate hair covering, and refrains from using any tobacco products; and

24. Keep the surroundings of the milk tank truck cleaning facility neat, clean, and free from conditions that may attract flies, insects, or rodents.

2VAC5-501-110. Regulation superseded. (Repealed.)

This chapter supersedes 2VAC5 500, Rules and Regulations Governing the Cooling, Storing, Sampling and Transporting of Milk or Milk Samples from the Farm to the Processing Plant or Laboratory, and is based upon a Notice of Intended Regulatory Action published in the Virginia Register of Regulations for June 4, 2001 at page 2704 under "Title 2. Agriculture."

<u>NOTICE</u>: The following forms used in administering the regulation were filed by the agency. The forms are not being published; however, online users of this issue of the Virginia Register of Regulations may click on the name of a form with a hyperlink to access it. The forms are also available from the agency contact or may be viewed at the Office of the Registrar of Regulations, General Assembly Building, 2nd Floor, Richmond, Virginia 23219.

FORMS (2VAC5-501)

<u>Application for a Dairy Farm Permit, ODF-DS-100 (rev. 6/2012)</u>

Dairy Farm Inspection Report, ODF-DS-102 (rev. 2/2006)

Guide for the Submission of Plans for Milking Operations, ODF-DS-104 (rev. 2/2015)

DOCUMENTS INCORPORATED BY REFERENCE (2VAC5-501)

3-A Sanitary Standards for Stainless Steel Automotive Transportation Tanks for Bulk Delivery and Farm Pick-Up Service, Number 05-15, eff. November 24, 2002, 3-A Sanitary Standards, Inc. Incorporated, 6888 Elm Street, Suite 2D, McLean, Virginia 22101, www.3-a.org

3 A Sanitary Standards, effective as of November 20, 2001, 3 A Sanitary Standards, Incorporated.

<u>3-A Sanitary Standards for Farm Milk Cooling and Holding</u> <u>Tanks, Number 13-11, eff. July 23, 2012, 3-A Sanitary</u> <u>Standards, Incorporated, 6888 Elm Street, Suite 2D, McLean,</u> <u>Virginia 22101, www.3-a.org</u>

<u>3-A Sanitary Standards for Farm Milk Storage Tanks,</u> <u>Number 30-01, eff. September 9, 1984, 3-A Sanitary</u> <u>Standards, Incorporated, 6888 Elm Street, Suite 2D, McLean,</u> <u>Virginia 22101, www.3-a.org</u> <u>UL Rated NEMA 4x Enclosure Definition as published in</u> <u>ANSI/NEMA 250, Enclosures for Electrical Equipment</u> (1000 Volts Maximum), ANSI Approval Date August 30, 2001 <u>December 29, 2014</u>, American Society of Mechanical Engineers.

<u>Standard Methods for the Examination of Dairy Products,</u> <u>16th</u> <u>17th</u> Edition, <u>1992</u> <u>2004</u>, American Public Health Association.

American Iron & Steel Institute (AISI) 300 Series as published in Steel Products Manual—: Stainless Steels, March 1999, Iron and Steel Society-, <u>186 Thorn Hill Road</u>, Warrendale, Pennsylvania 15086 www.iom3.org/iron-steelsociety

VA.R. Doc. No. R16-4567; Filed June 21, 2016, 12:44 p.m.

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TITLE 4. CONSERVATION AND NATURAL RESOURCES

BOARD OF GAME AND INLAND FISHERIES

Final Regulation

<u>REGISTRAR'S NOTICE</u>: The Board of Game and Inland Fisheries is claiming an exemption from the Administrative Process Act pursuant to § 2.2-4002 A 3 of the Code of Virginia when promulgating regulations regarding the management of wildlife.

<u>Title of Regulation:</u> 4VAC15-20. Definitions and Miscellaneous: In General (adding 4VAC15-20-230; repealing 4VAC15-20-80).

Statutory Authority: § 29.1-501 of the Code of Virginia.

Effective Date: July 1, 2016.

<u>Agency Contact:</u> Phil Smith, Regulatory Coordinator, Department of Game and Inland Fisheries, 7870 Villa Park Drive, Suite 400, Henrico, VA 23228, telephone (804) 367-8341 or email phil.smith@dgif.virginia.gov.

Summary:

The amendments (i) repeal requirements regarding execution of a certificate for a resident license by the licensee and (ii) prescribe aluminum or purple as the color of paint to be used for posting land to prohibit hunting, fishing, or trapping without the written permission of the landowner.

4VAC15-20-80. Certificate on hunting, trapping and fishing license to be executed by licensee. (Repealed.)

No state or county resident license to hunt, trap or fish in or on the lands or inland waters of this Commonwealth shall be deemed to be issued until the certificate printed on the reverse side of that license shall have been executed by the named licensee. For those licenses issued by telephone or electronic media agent pursuant to § 29.1 327 B of the Code of

Virginia, the license shall be deemed issued when the license authorization number is put on paper and the paper is signed by the designated licensee and shall remain effective only until the permanent license, for which the number was issued, is received by the licensee.

4VAC15-20-230. Color of paint prescribed for posting land.

The color of paint prescribed for posting land in accordance with § 18.2-134.1 of the Code of Virginia shall be aluminum or purple.

VA.R. Doc. No. R16-4689; Filed June 28, 2016, 4:01 p.m.

MARINE RESOURCES COMMISSION

Emergency Regulation

<u>Title of Regulation:</u> 4VAC20-1090. Pertaining to Licensing Requirements and License Fees (amending 4VAC20-1090-30).

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

Effective Dates: July 1, 2016, through July 30, 2016.

<u>Agency Contact</u>: 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:

Pursuant to § 28.2-226.2 of the Code of Virginia the amendment separates the five crab pot recreational license into two categories, one with a terrapin excluder device (\$36) and one without such device (\$46).

4VAC20-1090-30. License fees.

The following listing of license fees applies to any person who purchases a license for the purposes of harvesting for commercial purposes, or fishing for recreational purposes, during any calendar year. The fees listed below include a \$1.00 agent fee.

<u>EDITOR'S NOTE</u>: Subdivisions 1 through 10 and 12 through 16 of 4VAC20-1090-30 are not amended; therefore, the text of those subdivisions is not set out.

11. COMMERCIAL GEAR FOR RECREATIONAL USE	
Up to five crab pots <u>with a terrapin</u> <u>excluder device</u>	\$36.00
<u>Up to five crab pots without a terrapin</u> excluder device	<u>\$46.00</u>
Crab trotline (300 feet maximum)	\$10.00
One crab trap or crab pound	\$6.00
One gill net up to 300 feet in length	\$9.00
Fish dip net	\$7.00

Fish cast net	\$10.00
Up to two eel pots	\$10.00

VA.R. Doc. No. R16-4787; Filed June 29, 2016, 3:02 p.m.

Final Regulation

<u>REGISTRAR'S NOTICE:</u> Pursuant to § 28.2-106.2 of the Code of Virginia, the provisions of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia) and §§ 28.2-209 through 28.2-215 do not apply to regulations promulgated under that section.

<u>Title of Regulation:</u> 4VAC20-1320. Pertaining to Establishment of Restricted Area - Maritime Administration James River Reserve Fleet (adding 4VAC20-1320-10 through 4VAC20-1320-50).

Statutory Authority: § 28.2-106.2 of the Code of Virginia.

Effective Date: June 30, 2016.

<u>Agency Contact:</u> 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 purpose of the establishment of this regulation is to enhance the physical security of the James River Reserve Fleet as part of a comprehensive plan to protect the public, environment, and economic interests from sabotage and other subversive acts, accidents, or incidents of a similar nature. This regulation delineates an area within an undefined area already designated by the federal government under 33 CFR 162.270, Restricted areas in vicinity of Maritime Administration Reserve Fleets, and provides the Virginia Marine Police the authority to enforce Virginia law that prohibits entrance into prohibited restricted areas.

CHAPTER 1320

PERTAINING TO ESTABLISHMENT OF RESTRICTED AREA - MARITIME ADMINISTRATION JAMES RIVER RESERVE FLEET

4VAC20-1320-10. Purpose.

The purpose of this chapter is to enhance the physical security of the James River Reserve Fleet as part of a comprehensive plan to protect the public, environment, and economic interests from sabotage and other subversive acts, accidents, or incidents of a similar nature.

This regulation delineates an area within an undefined area already designated by the federal government under 33 CFR 162.270 and provides the Virginia Marine Police the authority to enforce Virginia law that prohibits entrance into prohibited restricted areas.

Volume 32, Issue 23

4VAC20-1320-20. Definitions.

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

"Restricted area" means those waters within an area beginning at latitude 37°08.4999992' N. longitude 76°38.4799994' W; thence to latitude 37°07.1885596' N, longitude76°38.4395503 W: thence to latitude 37°06.9585351' N, longitude 76°38.4331102' W; thence to latitude 37°06.4202049' N, longitude 76°38.4158624' W; latitude 37°06.1150372' longitude thence to N. 76°38.5271810' W; thence to latitude 37°06.6400002' N, 76°39.1899998' W; thence longitude to <u>latitude</u> 37°07.8999983' N, longitude 76°39.3400007' W; thence to latitude 37°08.4999986' N, longitude 76°38.6299996' W; thence to latitude 37°08.4999992' N. longitude 76°38.4799994' W, being the point of beginning.

4VAC20-1320-30. Prohibitions.

No vessel or other watercraft, except those owned or controlled by the United States government or the Virginia Marine Police, shall cruise or anchor within the restricted area as defined in 4VAC20-1320-20 any closer than 500 feet of any reserve fleet unit or units unless specific permission to do so has first been granted in each case by the Maritime Administration James River Reserve Fleet.

4VAC20-1320-40. Penalty.

<u>As set forth in § 28.2-106.2 D of the Code of Virginia, any</u> person violating any provision of this chapter shall be guilty of a Class I misdemeanor.

4VAC20-1320-50. Duration of regulation.

This regulation will remain in effect until the federal rule pertaining to this restricted area expires.

VA.R. Doc. No. R16-4794; Filed June 30, 2016, 12:13 p.m.

TITLE 8. EDUCATION

STATE BOARD OF EDUCATION

Final Regulation

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

<u>Title of Regulation:</u> 8VAC20-70. Regulations Governing Pupil Transportation (amending 8VAC20-70-460). Statutory Authority: §§ 22.1-16, 22.1-176, and 22.1-177 of the Code of Virginia.

Effective Date: August 10, 2016.

<u>Agency Contact:</u> Melissa Luchau, Director for Board Relations, Department of Education, P.O. Box 2120, 101 North 14th Street, 25th Floor, Richmond, VA 23219, telephone (804) 225-2924, FAX (804) 225-2524, or email melissa.luchau@doe.virginia.gov.

Summary:

To comport with Chapter 559 of the 2015 Acts of Assembly, the amendments permit a local school board to sell or transfer its school buses to another school division or purchase a used bus from another school division or a school bus dealer as long as the bus (i) conforms to the State Board of Education's construction and design specifications in effect at the time of manufacture, (ii) has a valid Virginia State Police inspection, and (iii) is not older than 15 model years at the time of sale, transfer, or purchase.

Part IV

General Requirements for School Buses in Virginia

8VAC20-70-460. Specifications.

It is the intent of the Board of Education to accommodate new equipment and technology that will better facilitate the safe and efficient transportation of students. When a new technology, piece of equipment, or component is desired to be applied to a school bus, it must have the approval of the Department of Education and must meet the following criteria:

1. The technology, equipment, or component shall not compromise the effectiveness or integrity of any major safety system.

2. The technology, equipment, or component shall not diminish the safety of the interior of the bus.

3. The technology, equipment, or component shall not create additional risk to students who are boarding or exiting the bus or are in or near the school bus loading zone.

4. The technology, equipment, or component shall not require undue additional activity or responsibility for the driver.

5. The technology, equipment, or component shall generally increase efficiency or safety, or both, of the bus, generally provide for a safer or more pleasant experience for the occupants and pedestrians in the vicinity of the bus, or shall generally assist the driver and make his many tasks easier to perform.

School buses and school activity buses <u>purchased new</u> must conform to the specifications relative to construction and design effective on the date of <u>the initial</u> procurement. Any variation from the specifications, in the form of additional equipment or changes in style of equipment, without prior approval of the Department of Education, is prohibited. The Department of Education shall issue specifications and standards for public school buses to reflect desired technology or safety improvements for the then current model year.

A local school board may sell or transfer any of its school buses or school activity buses to another school division or purchase a used bus from another school division or a school bus dealer as long as the school bus or school activity bus conforms to the specifications relating to construction and design in effect on the date of manufacture. The bus must also have a valid Virginia State Police inspection and may not be older than 15 model years at the time of sale, transfer, or purchase.

VA.R. Doc. No. R16-4577; Filed June 17, 2016, 2:12 p.m.

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TITLE 12. HEALTH

STATE BOARD OF HEALTH

Notice of Extension of Emergency Regulation

<u>Titles of Regulations:</u> 12VAC5-71. Regulations Governing Virginia Newborn Screening Services (amending 12VAC5-71-30, 12VAC5-71-150; adding 12VAC5-71-200 through 12VAC5-71-260).

12VAC5-191. State Plan for the Children with Special Health Care Needs Program (amending 12VAC5-191-260).

Statutory Authority: §§ 32.1-12, 32.1-65.1, and 32.1-67 of the Code of Virginia.

Expiration Date Extended Through: December 22, 2016.

The Governor has approved the State Board of Health request to extend the expiration date of the above-referenced emergency regulation for six months as provided for in § 2.2-4011 D of the Code of Virginia. Therefore, the emergency regulation will continue in effect through December 22, 2016. The emergency regulation relates to screening for critical congenital heart disease and permitting the Virginia Department of Health to collect information via the Virginia Congenital Anomalies Reporting and Education System (VaCARES) reporting system. The emergency regulation was published in 31:11 VA.R. 942-946 January 26, 2015.

<u>Agency Contact</u>: Dev Nair, Director, Division of Policy and Evaluation, Department of Health, 109 Governor Street, Richmond, VA 23219, telephone (804) 864-7662, FAX (804) 864-7647, or email dev.nair@vdh.virginia.gov.

VA.R. Doc. No. R15-4176; Filed June 17, 2016, 5:22 p.m.

DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

Final Regulation

<u>Title of Regulation:</u> 12VAC30-20. Administration of Medical Assistance Services (amending 12VAC30-20-500 through 12VAC30-20-560).

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

Effective Date: August 10, 2016.

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

Summary:

The amendments (i) address the manner in which alleged deficiencies in case summaries can be resolved and the means by which documentation can be transmitted in an informal appeal; (ii) clarify and adjust timelines and filing specifications, for example an extension of a 45-day limitation in which the hearing officer must conduct a formal hearing if agreed to by all parties and delivery using electronic means are added; and (iii) update and clarify the department's authority to take administrative action to dismiss untimely, unauthorized, or insufficient appeal requests.

<u>Summary of Public Comments and Agency's Response:</u> 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 XII Provider Appeals

12VAC30-20-500. Definitions.

The following words, <u>and terms</u> when used in this part, shall have the following meanings:

"Administrative dismissal" means a dismissal that requires only the issuance of a decision with appeal rights but does not require the submission of a case summary or any further proceeding.

"Day" means a calendar day unless otherwise stated.

"DMAS" means the Virginia Department of Medical Assistance Services or its agents or contractors.

"Hearing officer" means an individual selected by the Executive Secretary of the Supreme Court of Virginia to conduct the formal appeal in an impartial manner pursuant to §§ 2.2-4020 and 32.1-325.1 of the Code of Virginia and this part.

"Informal appeals agent" means a DMAS employee who conducts the informal appeal in an impartial manner pursuant to §§ .2-4019 and 32.1-325.1 of the Code of Virginia and this part.

"Last known address" means the provider's physical or electronic correspondence address on record in the DMAS Medicaid Management Information System as of the date DMAS transmits an item to the provider or the address of the provider's counsel of record. Nothing herein shall prevent DMAS and the provider from agreeing in writing during the course of an audit or an appeal to use an alternative location for the transmittal of an item or items related to the audit or the appeal.

"Provider" means an individual or entity that has a contract with DMAS to provide covered services and that is not operated by the Commonwealth of Virginia.

<u>"Transmit" means to send by means of the United States</u> mail, courier or other hand delivery, facsimile, electronic mail, or electronic submission.

12VAC30-20-520. Provider appeals: general provisions.

A. This part governs all DMAS informal and formal provider appeals and shall supersede supersedes any other provider appeals regulations.

B. A provider may appeal any DMAS action that is subject to appeal under the Virginia Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia), including DMAS' interpretation and application of payment methodologies. A provider may not appeal the actual payment methodologies.

C. DMAS shall mail transmit all items to the last known address of the provider. It is presumed that DMAS mails transmits items on the date noted on the item. It is presumed that providers receive items mailed transmitted by United States mail to their last known address within three days after DMAS mails transmits the item by United States mail. It is presumed that providers receive items transmitted by [facsimile,] electronic mail [,] or [facsimile to their last known other] electronic [mail address of facsimile number submission] on the date transmitted. It is presumed that [the providers receive] items [are received upon transmitted by courier or other hand delivery] the date [and time] of delivery to the provider's last known address [by a courier]. These presumptions in this section shall apply unless the provider, through evidence beyond a mere denial of receipt, introduces evidence sufficient to rebut the presumption. If a provider requests a copy of an item, the transmittal date for the item remains the date originally noted on the item, and not the date that the copy of the requested item is transmitted. A provider's failure to accept delivery of an item transmitted by DMAS, or a provider's failure to open an item upon receipt, shall not result in an extension of any of the timelines established by this part.

D. Whenever DMAS or a provider is required to file a document, the document shall be considered filed when it is date stamped by the DMAS Appeals Division in Richmond, Virginia.

E. Whenever the last day specified for the filing of any document or the performance of any other act falls on a day on which DMAS is officially closed <u>for the full or partial day</u>, the time period shall be extended to the next day on which DMAS is officially open.

F. Conferences and hearings shall be conducted at DMAS' main office in Richmond, Virginia, or at such other place as agreed to upon in writing by the parties DMAS, the provider, and the informal appeals agent for informal appeals. For formal appeals, this agreement shall be between DMAS, the provider, and the hearing officer.

G. Whenever DMAS or a provider is required to attend a conference or hearing, failure by one of the parties to attend the conference or hearing shall result in dismissal of the appeal in favor of the other party.

H. DMAS shall reimburse a provider for reasonable and necessary attorneys' fees and costs associated with an informal or formal administrative appeal if the provider substantially prevails on the merits of the appeal and DMAS' position is not substantially justified, unless special circumstances would make an award unjust. In order to substantially prevail on the merits of the appeal, the provider must be successful on more than 50% of the dollar amount involved in the issues identified in the provider's notice of appeal.

I. Any document that is filed with the DMAS Appeals Division after 5 p.m. [Eastern Time shall be date stamped on the next day DMAS is officially open. Any document that is filed with the DMAS Appeals Division after 5 p.m.] Eastern Time on the due date shall be untimely.

12VAC30-20-540. Informal appeals.

A. Providers appealing a DMAS decision shall file a written notice of informal appeal with the DMAS Appeals Division within 30 days of the provider's receipt of the decision. Notice of informal appeal.

<u>1.</u> Providers appealing the termination or denial of their Medicaid agreement pursuant to § 32.1-325 [$\underline{D} \underline{E}$] of the Code of Virginia shall file a written notice of <u>informal</u> appeal with the DMAS Appeals Division within 15 days of the provider's receipt of the notice of termination or denial.

2. Providers appealing adjustments to a cost report shall file a written notice of informal appeal with the DMAS Appeals Division within 90 days of the provider's receipt of the notice of program reimbursement. The <u>written</u> notice of informal appeal shall identify the issues <u>being appealed</u>, adjustments, or items that the provider is appealing.

3. Providers appealing all other DMAS decisions shall file a written notice of informal appeal with the DMAS Appeals Division within 30 days of the provider's receipt of the decision. The written notice of informal appeal shall identify each adjustment, patient, service date, or other disputed matter that the provider is appealing.

B. Administrative dismissals.

1. Failure to <u>timely</u> file a written notice of informal appeal within 30 days of receipt of the decision or within 90 days of receipt of the notice of program reimbursement shall result in dismissal of the appeal. Failure to file a written notice of informal appeal for termination or denial of a Medicaid agreement pursuant to § 32.1 325 D of the Code of Virginia within 15 days of receipt of the notice of termination or denial shall result in dismissal of the appeal with the information required by subdivision A 2 or A 3 of this section shall result in an administrative dismissal.

2. A representative, billing company, or other third-party entity filing a written notice of appeal on behalf of a provider shall submit to DMAS, at the time of filing or upon request, a written authorization to act on the provider's behalf, signed by the provider. The authorization shall reference the specific adverse action or actions being appealed including, if applicable, each patient's name and date of service. Failure to submit a written authorization as specified in this subdivision shall result in an administrative dismissal. This requirement shall not apply to an appeal filed by a Virginia licensed attorney.

3. If a provider has not exhausted any applicable DMAS or contractor reconsideration or review process or contractor's internal appeals process that the provider is required to exhaust before filing a DMAS informal appeal, the provider's written notice of informal appeal shall be administratively dismissed.

4. If DMAS has not issued a decision with appeal rights, the provider's attempt to file a written notice of informal appeal, prior to the issuance of a decision by DMAS that has appeal rights, shall be administratively dismissed.

B. C. Written case summary.

1. DMAS shall file a written case summary with the DMAS Appeals Division within 30 days of the filing of the provider's notice of informal appeal. DMAS and shall mail transmit a complete copy of the case summary to the provider on the same day that the case summary is filed with the DMAS Appeals Division.

The case summary shall address each adjustment, patient, service date, or other disputed matter and shall state DMAS' position for each adjustment, patient, service date, or other disputed matter. The case summary shall contain the factual basis for each adjustment, patient, service date, or other disputed matter and any other information, authority, or documentation DMAS relied upon in taking its action or making its decision. 2. For each adjustment, patient, and service date or other disputed matter identified by the provider in its notice of informal appeal, the case summary shall explain the factual basis upon which DMAS relied in taking its action or making its decision and identify any authority or documentation upon which DMAS relied in taking its action or making its decision. 3. Failure to file a written case summary with the <u>DMAS</u> Appeals Division in the detail specified within 30 days of the filing of the provider's notice of informal appeal within 30 days of the filing of the written notice of informal appeal shall result in dismissal in favor of the provider on those issues not addressed in the detail specified.

4. The provider shall have 12 days following the due date of the case summary to file with the DMAS Appeals Division and transmit to the author of the case summary a written notice of all alleged deficiencies in the case summary that the provider knows, or reasonably should know, exist. Failure of the provider to timely file a written notice of deficiency with the DMAS Appeals Division shall be deemed a waiver of all deficiencies, alleged or otherwise, with the case summary.

5. Upon timely receipt of the provider's notice of deficiency, DMAS shall have 12 days to address the alleged deficiency or deficiencies. If DMAS does not address the alleged deficiency or does not address the alleged deficiency or does not address the alleged deficiency to the provider's satisfaction, the alleged deficiency or deficiencies shall become an issue to be addressed by the informal appeals agent as part of the informal appeal decision.

6. The informal appeals agent shall make a determination as to each deficiency that is alleged by the provider as set forth in this subsection. In making that determination, the informal appeals agent shall determine whether the alleged deficiency is such that it could not reasonably be determined from the case summary the factual basis and authority for the DMAS action, relating to the alleged deficiency, so as to require a dismissal in favor of the provider on the issue or issues to which the alleged deficiency pertains.

C. D. Conference.

<u>1.</u> The informal appeals agent shall conduct the conference within 90 days from the filing of the notice of informal appeal. If DMAS and, the provider, and the informal appeals agent agree, the conference may be conducted by way of written submissions. If the conference is conducted by way of written submissions, the informal appeals agent shall specify the time within which the provider may file written submissions, not to exceed 90 days from the filing of the notice of informal appeal. Only written submissions filed within the time specified by the informal appeals agent shall be considered.

D. 2. The conference may be recorded at the discretion of the informal appeals agent and solely for the convenience of the informal appeals agent. Since Because the conference is not an adversarial or evidentiary proceeding, recordings shall not be made part of the administrative record and shall not be made available to anyone other than the informal appeals agent <u>no</u> other recordings or transcriptions shall be permitted. Any recordings made for

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the convenience of the informal appeals agent shall not be released to DMAS or to the provider.

E. 3. Upon completion of the conference, the informal appeals agent shall specify the time within which the provider may file additional documentation or information, if any, not to exceed 30 days. Only documentation or information filed within the time specified by the informal appeals agent shall be considered.

F. E. Informal appeals decision. The informal appeal decision shall be issued within 180 days of receipt of the notice of informal appeal.

<u>F. Remand. Whenever an informal appeal is required</u> pursuant to a remand by court order, final agency decision, agreement of the parties, or otherwise, all time periods set forth in this section shall begin to run effective with the date that the document containing the remand is date-stamped by the DMAS Appeals Division in Richmond, Virginia.

12VAC30-20-560. Formal appeals.

A. Any A provider appealing a DMAS informal appeal decision shall file a written notice of formal appeal with the DMAS Appeals Division within 30 days of the provider's receipt of the informal appeal decision. The notice of formal appeal shall identify the issues being appealed each adjustment, patient, service date, or other disputed matter that the provider is appealing. Failure to file a written notice of formal appeal in the detail specified within 30 days of receipt of the informal appeal decision shall result in dismissal of the appeal. Pursuant to § 2.2-4019 A of the Code of Virginia, DMAS shall ascertain the fact basis for decisions through informal proceedings unless the parties consent in writing to waive such a conference or proceeding to go directly to a formal hearing, and therefore only issues that were addressed pursuant to § 2.2-4019 shall be addressed in the formal appeal, unless DMAS and the provider consent to waive the informal fact-finding process under § 2.2-4019 A of the Code of Virginia.

B. DMAS and the provider shall exchange and file with the hearing officer all documentary evidence on which DMAS or the provider relies within 21 days of the filing of the notice of formal appeal. Only documents filed within 21 days of the filing of the notice of formal appeal shall be considered. DMAS and the provider shall file any objections to the admissibility of documentary evidence within seven days of the filing of the documentary evidence. Only objections filed within seven days of the filing of the documentary evidence shall be considered. The hearing officer shall rule on any objections within seven days of the filing of the objections. Documentary evidence [, objections to documentary evidence of the objections of the filing of the objections.

1. [Objections Documentary evidence, objections] to documentary evidence, opening briefs, and reply briefs shall be filed with the DMAS Appeals Division on the date specified in this subsection. The hearing officer shall only consider those documents or pleadings that are filed within the required timeline. [DMAS and Simultaneous with filing,] the [provider filing party] shall [also] transmit [any required document a copy] to the other party and to the hearing officer [on the date of filing].

a. All documentary evidence upon which DMAS or the provider relies shall be filed within 21 days of the filing of the notice of formal appeal.

b. Any objections to the admissibility of documentary evidence shall be filed within seven days of the filing of the documentary evidence. The hearing officer shall rule on any such objections within seven days of the filing of the objections.

c. The opening brief shall be filed by DMAS and the provider within 30 days of the completion of the hearing.

d. Any reply brief from DMAS or the provider shall be filed within 10 days of the filing of the opening brief to which the reply brief responds.

2. If there has been an extension to the time for conducting the hearing pursuant to subsection C of this section, the hearing officer is authorized to alter the due dates for filing opening and reply briefs to permit the hearing officer to be in compliance with the due date for the submission of the recommended decision as required by § 32.1-325.1 B of the Code of Virginia and subsection E of this section.

C. The hearing officer shall conduct the hearing within 45 days from the filing of the notice of formal appeal, <u>unless the hearing officer</u>, <u>DMAS</u>, and the provider all mutually agree to extend the time for conducting the hearing. Notwithstanding the foregoing, the due date for the hearing officer to submit the recommended decision to the DMAS director, as required by § 32.1-325.1 B of the Code of Virginia and subsection E of this section, shall not be extended or otherwise changed.

D. Hearings shall be transcribed by a court reporter retained by DMAS.

E. Upon completion of the hearing, DMAS and the provider shall have 30 days to exchange and file with the hearing officer an opening brief. Only opening briefs filed within 30 days after the hearing shall be considered. DMAS and the provider shall have 10 days to exchange and file with the hearing officer a reply brief after the opening brief has been filed. Only reply briefs filed within 10 days after the opening brief has been filed shall be considered.

F. <u>E.</u> The hearing officer shall submit a recommended decision to the DMAS director with a copy to the provider within 120 days of receipt the filing of the formal appeal request notice. If the hearing officer does not submit a recommended decision within 120 days of the filing of the notice of formal appeal, then DMAS shall give written notice to the hearing officer and the Executive Secretary of the Supreme Court that a recommended decision is due.

G. <u>F.</u> Upon receipt of the hearing officer's recommended decision, the DMAS director shall notify DMAS and the provider in writing that any written exceptions to the hearing

officer's recommended decision shall be filed with the DMAS <u>Appeals Division</u> within 30 <u>14</u> days of receipt of the DMAS director's letter. Only exceptions filed within 30 <u>14</u> days of receipt of the DMAS director's letter shall be considered. The <u>DMAS director shall issue the final agency case decision</u> within <u>60 days of receipt of the hearing officer's</u> recommended decision.

<u>G. The DMAS director shall issue the final agency decision</u> within 60 days of receipt of the hearing officer's recommended decision in accordance with § 32.1-325.1 B of the Code of Virginia.

VA.R. Doc. No. R14-3105; Filed June 21, 2016, 10:32 a.m.

Fast-Track Regulation

<u>Title of Regulation:</u> 12VAC30-30. Groups Covered and Agencies Responsible for Eligibility Determination (adding 12VAC30-30-70).

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

<u>Public Hearing Information:</u> No public hearings are scheduled.

Public Comment Deadline: August 10, 2016.

Effective Date: August 26, 2016.

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

<u>Basis:</u> Section 32.1-325 of the Code of Virginia grants to the Board of Medical Assistance Services the authority to administer and amend the Plan for Medical Assistance. Section 32.1-324 of the Code of Virginia authorizes the Director of the Department of Medical Assistance Services (DMAS) to administer and amend the Plan for Medical Assistance according to the board's requirements. The Medicaid authority as established by § 1902(a) of the Social Security Act (42 USC § 1396a) provides governing authority for payments for services.

The new section, 12VAC30-30-70, is required by 42 CFR 435.1110, a federal regulation stating that DMAS "must provide Medicaid during a presumptive eligibility period to individuals who are determined by a qualified hospital, on the basis of preliminary information, to be presumptively eligible [for Medicaid]". The federal regulation states that the requirements of 42 CFR 435.1102 and 42 CFR 435.1103 apply to these determinations.

<u>Purpose:</u> The purpose of this action is to comply with federal regulations, which require DMAS to permit qualified hospitals to make presumptive eligibility determinations.

The regulations protect the health, safety, and welfare of citizens by promoting enrollment in Medicaid for individuals who may be eligible but who are not enrolled. The changes allow these individuals to receive Medicaid covered services during the presumptive eligibility period. The changes assure individuals timely access to care while a final eligibility determination is made and promote enrollment in Medicaid.

These changes assist both the individual with the cost of the medical care they receive and assist the hospital, which can be assured of payment for services rendered.

<u>Rationale for Using Fast-Track Rulemaking Process:</u> This regulatory change is expected to be noncontroversial because the federal government has required all states to make this change; it is nondiscretionary.

Further, the regulatory change is expected to be noncontroversial because DMAS engaged stakeholder groups in making certain choices that are permitted by the federal regulations. DMAS worked closely with the Virginia Hospital and Healthcare Association on both the content of the changes and on training materials for hospitals. As of August 2014, 57 hospitals across Virginia are qualified to make presumptive eligibility determinations.

<u>Substance:</u> The section of the State Plan for Medical Assistance affected by this action is Groups Covered and Agencies Responsible for Eligibility Determination (12VAC30-30).

Federal regulations require DMAS to implement these regulatory changes and to establish the requirements that hospitals must meet in order to participate. (The hospital must be a Medicaid provider, must notify DMAS of its election to make presumptive eligibility determinations, and must do so in accordance with state policies and procedures. The hospital must not have been disqualified for failing to follow these policies and procedures.) DMAS chose to allow hospitals to use an abbreviated online form to determine presumptive eligibility, rather than using the full Medicaid application for this purpose; individuals are not required to sign this online form. DMAS also chose to require hospitals to assist the individual with completing and submitting a full Medicaid application.

The federal requirements also establish a minimum set of groups that must be considered for possible presumptive eligibility, as follows: (i) pregnant women; (ii) infants and children younger than age 19 years, parents, and other caretaker relatives; (iii) adults if covered by the state; (iv) individuals with an income above 133% of the federal poverty level and younger than age 65 years if covered by the state; (v) individuals eligible for family planning services if covered by the state; (vi) former foster care children; and (vii) individuals needing treatment for breast or cervical cancer if covered by the state. The eligibility determination for selected groups (i), (ii), (v), (vi) and (vii) does not require that hospitals evaluate the resources of these individuals. Thus, these hospital eligibility determinations are more likely to be more accurate.

Virginia currently does not cover groups (iii) and (iv), thus these two groups are not covered under hospital presumptive eligibility. DMAS elected not to provide coverage to other

nonmandated groups because the other nonmandated groups require resource tests.

In accordance with federal requirements, presumptive eligibility is determined based on membership in one of the above groups: household income, state residency, and immigration status. State residency and immigration status were options permitted by the Centers for Medicare and Medicaid Services (CMS) and chosen by DMAS because this is consistent with the rest of Virginia Medicaid eligibility. Federal regulations establish when the presumptive eligibility period begins (the date the presumptive eligibility determination is made) and ends, which is the earlier of the (i) day on which a decision is made on a full Medicaid application; or (ii) last day of the month following the month that the hospital presumptive eligibility determination was made and no full Medicaid application was filed.

CMS required the Commonwealth to set performance standards for hospitals performing presumptive eligibility determinations. Virginia opted to set standards related to the percentage of individuals who submit a full Medicaid application and who are subsequently determined to be eligible for Medicaid as a result of that application. In Virginia, the standards are that 85% of individuals who are determined to be presumptively eligible by a hospital must file a full application for Medicaid. Of those individuals, 70% must be determined eligible for Medicaid based on their full application. If hospitals fail to meet these standards after corrective action plans are put into place, their authority to make presumptive eligibility determinations may be terminated.

<u>Issues:</u> The primary advantages of this regulatory action are that it will enable DMAS to comply with federal requirements; will promote Medicaid enrollment among individuals who are eligible for Medicaid but not enrolled; and will permit hospitals to receive Medicaid reimbursement for covered services rendered.

With regard to hospital reimbursement, services covered during a presumptive eligibility period will be considered Medicaid-covered services for year-end hospital cost reporting purposes. For hospitals that receive supplemental reimbursement for indigent care, the amount of indigent care reimbursement will be reduced due to the increased Medicaid reimbursement.

There are no known disadvantages to the public, the department, or the Commonwealth.

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. The proposed regulations establish rules for federally required Medicaid presumptive eligibility determinations made by hospitals for their patients seeking treatment.

Result of Analysis. The benefits likely exceed the costs for all proposed changes. An alternative or an additional standard

may improve the regulation in measuring a hospital's performance. Additional regulatory language about the length of the disqualification period may improve the regulation. Additional language may be needed to dissuade applicants from being untruthful.

Estimated Economic Impact. Starting in January 2014, the federal Affordable Care Act provided qualified hospitals an opportunity to make Medicaid presumptive eligibility determinations for their patients seeking treatment. States must allow all qualifying hospitals willing to abide by state policies and procedures to perform presumptive eligibility determinations. Federal regulations in 42 CFR 435.1101 and 42 CFR 435.1102 outline the details regarding the implementation of this requirement by the states. Virginia's presumptive eligibility rules were approved by the Centers for Medicare and Medicaid Services (CMS) in July 2015 and have already been implemented under the approved state plan. In fiscal year 2015, approximately \$3.5 million in total expenditures was paid for 19,423 claims involving 2,079 unique recipients.

Under the presumptive eligibility rules, Medicaid eligibility determinations are made by trained hospital staff based on an assessment of the individual's status as a member of a group (i.e., pregnant women, infants and children under age 19, parents and other caretaker relatives, individuals eligible for family planning services, former foster care children, individuals needing treatment for breast and cervical cancer), their income, state residency, and citizenship status. The hospital then assists the individual in completing and submitting a full Medicaid application for future Medicaid coverage. If the individual is found presumptively eligible, he or she is temporarily enrolled in Medicaid and health care providers receive payment for services provided during this interim period. A full application for Medicaid coverage may follow, with the determination of eligibility completed by a local department of social services, or the Department of Medical Assistance Services (DMAS). The presumptive eligibility begins on the date the determination is made and ends on the earlier of the day on which a decision is made on a full Medicaid application, or the last day of the month following the month that the hospital's presumptive eligibility determination was made and no full Medicaid application was filed. Payment for services covered is guaranteed during the presumptive eligibility period. There is no recoupment for Medicaid services provided during that period resulting from erroneous determinations made by qualified entities.

Pursuant to a request by CMS, the proposed regulation establishes two performance standards for hospitals performing presumptive eligibility determinations. In order to maintain their participation to make presumptive eligibility determinations, a hospital is required to ensure (i) that a certain percentage of individuals deemed presumptively eligible will file a full Medicaid application before the end of the presumptive eligibility period, and (ii) that a certain percentage of individuals deemed presumptively eligible will

be determined eligible based on the full application. The purpose of the proposed performance standards is to ensure that hospitals are making appropriate presumptive eligibility determinations and fulfilling their oversight responsibilities. If a hospital fails to follow these standards it may be disqualified from making such determinations.

DMAS recognizes if not carefully implemented, the proposed performance standards for participating hospitals could have unintended adverse effects on their ability to participate in the program through no fault of their own.

A performance standard must be under the control of the entity whose performance it measures. In this case, a hospital does not have control over whether the individuals deemed presumptively eligible will file a full Medicaid application. The individual may not want to file a full Medicaid application or may even refuse to do so. The individual's failure to follow through with the full application should not be held against the performance of a qualified hospital and put its participation in jeopardy. In order to avoid such unintended consequences, such cases will be excluded in calculating the performance metric when the hospital certifies that an attempt has been made but the individual declined to follow through with the full application.

Similarly, the hospital does not have control over whether the individual is providing accurate or even truthful information when filing the application for the presumptive eligibility. Additionally, comparison of determinations made at two different points in time may lead to erroneous conclusions as the applicant's financial circumstances may have changed between the interim and the full applications. Thus, a participating hospital will not be held liable if the information provided by the applicant results in a denial of eligibility following the full application; such cases will also be excluded from the data in calculating the performance metric. In the alternative, this performance standard may perhaps focus solely on whether the hospital made an error in its presumptive eligibility determination treating the information on the application as true.

DMAS notes that these two performance measures were suggested by CMS and any revision in these measures would necessitate a state plan amendment. It appears that the states have the option to choose different performance standards than those suggested by CMS.¹

The primary advantages of this regulatory action are that it enables DMAS to comply with federal requirements, assures individuals timely but limited access to care, promotes Medicaid enrollment among individuals who are eligible for Medicaid but not enrolled, and permits hospitals to receive Medicaid reimbursement for covered services rendered. Since the presumptive eligibility program has already been implemented since July 2015, no significant economic impact is expected upon promulgation of the proposed changes other than providing the rules in the regulations for the affected entities and the public. The proposed regulation may be improved by addressing the length of the disqualification period and when and how a reinstatement could occur if a hospital fails to meet the performance standards. It does not make sense to prohibit a hospital from participation in this program indefinitely.

Further, as discussed above, there is no recoupment for payments from hospitals for services provided during the presumptive eligibility period. Without such a guarantee, a hospital could not rely on the presumptive eligibility determination and may be inclined to refrain from participation. However, given the unique nature of this program, the applicant should be held liable when he or she intentionally provides false information. The proposed regulation may be further improved by making it clear that the applicant may be held liable or by requiring disclosure of such a potential liability on the application form. Such language would dissuade applicants from being untruthful and mitigate the Commonwealth's exposure to risk of fraud.

Businesses and Entities Affected. The proposed regulation primarily applies to hospitals wishing to participate in presumptive eligibility determinations and the individuals who may presumptively qualify for Medicaid. As of August 2014, there were 57 hospitals making presumptive eligibility determinations. In fiscal year 2015, there were 2,079 recipients identified as presumptively eligible.

Localities Particularly Affected. The proposed changes apply statewide.

Projected Impact on Employment. A hospital may voluntarily choose to participate in presumptive eligibility determinations. Such participation may increase their demand for labor to assist the individuals in the application process.

Effects on the Use and Value of Private Property. Participation in presumptive eligibility determinations helps hospitals receive payment from Medicaid for eligible individuals. In that sense, the proposed regulation has a positive impact on the asset values of participating hospitals.

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. Affected hospitals are not considered small businesses.

Alternative Method that Minimizes Adverse Impact. The proposed changes do not affect small businesses.

Adverse Impacts:

Businesses. The proposed changes are not anticipated to have an adverse impact on businesses.

Localities. The proposed amendments should not adversely affect localities.

Other Entities. The proposed changes are not anticipated to have an adverse impact on other entities.

¹See Answer #24, "Medicaid and CHIP FAQs: Implementing Hospital Presumptive Eligibility Programs," January 2014, Centers for Medicare & Medicaid Services.

<u>Agency's Response to Economic Impact Analysis:</u> The agency has reviewed the economic impact analysis prepared by the Department of Planning and Budget. The agency raises no issues with this analysis.

Summary:

This action creates a new section, 12VAC30-30-70, Hospital presumptive eligibility, in accordance with federal regulations that require the Department of Medical Assistance Services to allow qualified hospitals to make temporary Medicaid eligibility determinations for individuals who are seeking medical treatment. The Medicaid determinations are made by trained hospital staff based on an assessment of an individual's status as a member of an eligible group and an individual's income, state residency, and citizenship status. The hospital then assists the individual in completing and submitting a full Medicaid application for future Medicaid coverage.

12VAC30-30-70. Hospital presumptive eligibility.

<u>A.</u> Qualified hospitals shall administer presumptive eligibility in accordance with the provisions of this section. A qualified hospital is a hospital that:

1. Has entered into a valid provider agreement with DMAS, participates as a Virginia Medicaid provider, notifies DMAS of its election to make presumptive eligibility determinations, and agrees to make presumptive eligibility determinations consistent with DMAS policies and procedures; and

2. Has not been disqualified by DMAS for failure to make presumptive eligibility determinations in accordance with applicable state policies and procedures or for failure to meet any standards established by the Medicaid agency.

B. The eligibility groups or populations for which hospitals determine eligibility presumptively are: (i) pregnant women; (ii) infants and children younger than age 19 years; (iii) parents and other caretaker relatives; (iv) individuals eligible for family planning services; (v) former foster care children; and (vi) individuals needing treatment for breast and cervical cancer.

<u>C. The presumptive eligibility determination shall be based</u> on:

1. The individual's categorical or nonfinancial eligibility for the group, as listed in subsection B of this section, for which the individual's presumptive eligibility is being determined; 2. Household income shall not exceed the applicable income standard for the group, as the groups are listed in subsection B of this section, for which the individual's presumptive eligibility is being determined if an income standard is applicable for this group;

3. Virginia residency; and

4. Satisfactory immigration status.

D. Qualified hospitals shall ensure that at least 85% of individuals deemed by the hospital to be presumptively eligible will file a full Medicaid application before the end of the presumptive eligibility period.

<u>E.</u> Qualified hospitals shall ensure that at least 70% of individuals deemed by the hospital to be presumptively eligible are determined eligible for Medicaid based on the full application that is submitted before the end of the presumptive eligibility period.

<u>F. The presumptive eligibility period shall begin on the date</u> the presumptive eligibility determination is made. The presumptive eligibility period shall end on the earlier of:

1. The date the eligibility determination for regular Medicaid is made if an application for Medicaid is filed by the last day of the month following the month in which the determination of presumptive eligibility is made; or

2. The last day of the month following the month in which the determination of presumptive eligibility is made if no application for Medicaid is filed by last day of the month following the month in which the determination of presumptive eligibility is made.

<u>G. Periods of presumptive eligibility are limited to one presumptive eligibility period per pregnancy and one per calendar year for all other covered groups.</u>

VA.R. Doc. No. R16-4431; Filed June 21, 2016, 10:07 a.m.

Emergency Regulation

<u>Title of Regulation:</u> 12VAC30-60. Standards Established and Methods Used to Assure High Quality Care (amending 12VAC30-60-303, 12VAC30-60-310; adding 12VAC30-60-301, 12VAC30-60-302, 12VAC30-60-304, 12VAC30-60-305, 12VAC30-60-306, 12VAC30-60-308, 12VAC30-60-313, 12VAC30-60-315; repealing 12VAC30-60-300, 12VAC30-60-307, 12VAC30-60-312).

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

Effective Dates: September 1, 2016, through February 28, 2018.

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

Preamble:

Section 2.2-4011 B of the Code of Virginia authorizes state agencies to adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation become effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of § 2.2-4006 A 4. Chapter 413 of the 2014 Acts of Assembly, Item 301 QQQQ of Chapter 3 of the 2015 Acts of the Assembly, and Item 306 PPP of Chapter 780 of the 2016 Acts of Assembly direct the Department of Medical Assistance Services (DMAS) to contract out communitybased screenings for children, track and monitor all requests for screenings that have not been completed within 30 days of an individual's request, establish reimbursement and tracking mechanisms, and promulgate regulations to implement these provisions to be effective within 280 days of enactment. This emergency regulatory action responds to the legislative mandates.

In 1984, the Code of Virginia was modified to add § 32.1-330, Preadmission screening required. Section 32.1-330 of the Code of Virginia requires that all individuals who will be eligible for community or institutional long-term services and supports (LTSS) as defined in the State Plan for Medical Assistance be evaluated to determine their needs for Medicaid-funded nursing facility services. Also, the Code of Virginia specifically requires DMAS to utilize employees of local departments of social services and local health departments for community screenings and acute care hospitals for inpatient screenings, respectively. While this screening structure, established in the early 1980s, worked effectively for many years, the evolution of Virginia's Medicaid service delivery system has outgrown the original design. Significant challenges have developed that require a change to the Virginia Administrative Code. Some community-based screenings have taken longer than 30 days to complete thereby creating a significant risk to individuals who have been unable to access Medicaid LTSS.

The existing regulations for nursing facility criteria and preadmission screening were first promulgated in 1994 and amended in 2002. The regulations include the criteria for receiving Medicaid-funded community-based and nursing facility long-term services and supports. This emergency regulation adds requirements for accepting, managing, and completing requests for community and hospital electronic screenings for community-based and nursing facility services, and using the electronic preadmission screening (ePAS) system.

One potential issue may be limited staff resources in community and hospital settings. The emergency regulation clarifies requirements of community and hospital preadmission teams and includes requirements to use the new automated ePAS system to enhance work efficiency. This emergency regulation also establishes the use by DMAS of a contractor or contractors and provides a framework for public or private entities to screen children and adults in communities where community preadmission screening teams are unable to complete screenings within 30 days of the initial request date for a screening. These strategies are designed to ensure prompt services to citizens requesting Medicaid-funded LTSS and to protect their health, safety, and welfare.

The current requirements for functional eligibility (12VAC30-60-303 B) for Medicaid-funded LTSS are being retained since these standards support the eligibility process for the DMAS home-based and community-based waiver programs (the Elderly or Disabled with Consumer Direction Waiver, the Technology Assisted Waiver, the Alzheimer's Assisted Living Waiver, the Program of All-Inclusive Care for the Elderly Program, and nursing facility care).

The regulations repeal the existing nursing facility criteria (12VAC30-60-300) in order to move the criteria to a new location within 12VAC30-60-303. To be clear, the functional criteria, based on the Uniform Assessment Instrument (UAI) form, are not changing in this regulatory action, and the use of the UAI for this purpose remains the same. This action simply moves the existing criteria to a new location in the chapter to assist the public and regulated entities to more easily understand the regulation.

The remaining current provisions in the Virginia Administrative Code are incomplete and fragmented. To remedy this, amendments include adding a definitions section (12VAC30-60-301) and sections describing the requirement for the request for screenings (12VAC30-60-304), screenings for Medicaid-funded LTSS (12VAC30-60-305), submission of screenings (12VAC30-306), ePAS requirements and submissions (12VAC30-60-310), individuals determined to not meet criteria (12VAC30-60-313), and ongoing evaluations for individuals receiving Medicaid-funded LTSS (12VAC30-60-315).

12VAC30-60-300. Nursing facility criteria. (Repealed.)

A. Medicaid funded long term care services may be provided in either a nursing facility or community based care setting. The criteria for assessing an individual's eligibility for Medicaid payment of nursing facility care consist of two components: (i) functional capacity (the degree of assistance an individual requires to complete activities of daily living) and (ii) medical or nursing needs. The criteria for assessing an individual's eligibility for Medicaid payment of community based care consist of three components: (i) functional capacity (the degree of assistance an individual requires to complete activities of daily living), (ii) medical or nursing needs and (iii) the individual's risk of nursing facility placement in the absence of community based waiver services. In order to qualify for either Medicaid funded

nursing facility care or Medicaid funded community based care, the individual must meet the same criteria.

B. The preadmission screening process preauthorizes a continuum of long term care services available to an individual under the Virginia Medical Assistance Program. Nursing Facilities' Preadmission Screenings to authorize Medicaid funded long term care are performed by teams composed by agencies contracting with the Department of Medical Assistance Services (DMAS). The authorization for Medicaid funded long term care must be rescinded by the nursing facility or community based care provider or by DMAS at any point that the individual is determined to no longer meet the criteria for Medicaid funded long term care. Medicaid funded long term care services are covered by the program for individuals whose needs meet the criteria established by program regulations. Authorization of appropriate non institutional services shall be evaluated before nursing facility placement is considered.

C. Prior to an individual's admission, the nursing facility must review the completed pre admission screening forms to ensure that appropriate nursing facility admission criteria have been documented. The nursing facility is also responsible for documenting, upon admission and on an ongoing basis, that the individual meets and continues to meet nursing facility criteria. For this purpose, the nursing facility will use the Minimum Data Set (MDS) The post admission assessment must be conducted no later than 14 days after the date of admission and promptly after a significant change in the resident's physical or mental condition. If at any time during the course of the resident's stay, it is determined that the resident does not meet nursing facility criteria as defined in the State Plan for Medical Assistance, the nursing facility must initiate discharge of such resident. Nursing facilities must conduct a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity and medical and nursing needs.

The Department of Medical Assistance Services shall conduct surveys of the assessments completed by nursing facilities to determine that services provided to the residents meet nursing facility criteria and that needed services are provided.

D. The community based provider is responsible for documenting upon admission and on an ongoing basis that the individual meets the criteria for Medicaid funded longterm care.

E. The criteria for nursing facility care under the Virginia Medical Assistance Program are contained herein. An individual's need for care must meet these criteria before any authorization for payment by Medicaid will be made for either institutional or non institutional long term care services. The Nursing Home Pre Admission Screening team is responsible for documenting on the state designated assessment instrument that the individual meets the criteria for nursing facility or community based waiver services and for authorizing admission to Medicaid funded long term care. The rating of functional dependencies on the assessment instrument must be based on the individual's ability to function in a community environment, not including any institutionally induced dependence.

12VAC30-60-301. Definitions.

<u>The following words and terms as used in 12VAC30-60-302</u> through 12VAC30-60-315 shall have the following meanings unless the context clearly indicates otherwise:

"Activities of daily living" or "ADLs" means personal care tasks such as bathing, dressing, toileting, transferring, and eating/feeding. An individual's degree of independence in performing these activities is a part of determining appropriate level of care and service needs.

<u>"Adult" means a person age 18 years or older who may need</u> <u>Medicaid-funded long-term services and supports (LTSS) or</u> who becomes eligible to receive Medicaid-funded LTSS.

<u>"Appeal" means the processes used to challenge actions</u> regarding services, benefits, and reimbursement provided by <u>Medicaid pursuant to 12VAC30-110 and Part XII</u> (12VAC30-20-500 et seq.) of 12VAC30-20.

"At risk" means the need for the level of care provided in a hospital, nursing facility, or an Intermediate Care Facility for Individuals with Intellectual Disability (ICF/IID) when there is reasonable indication that the individual is expected to need the services in the near future (that is, one month or less) in the absence of home or community-based services.

"Child" means a person up to the age of 18 years who may need Medicaid-funded LTSS or who becomes eligible to receive Medicaid-funded LTSS.

"Choice" means the individual is provided the option of either home and community-based services or institutional services and supports, including the Program of All-Inclusive Care for the Elderly (PACE), if available and appropriate, after the individual has been determined likely to need LTSS.

"Communication" means all forms of sharing information and includes oral speech and augmented or alternative communication used to express thoughts, needs, wants, and ideas, such as the use of a communication device, interpreter, gestures, and picture/symbol communication boards.

"Community-based screening" means the face-to-face process conducted pursuant to § 32.1-330 of the Code of Virginia to determine whether an individual meets the criteria for Medicaid-funded LTSS and that shall be conducted in the individual's place of residence or, at the request of the individual, an alternate location within the same jurisdiction.

<u>"Community-based services" or "CBS" means communitybased services waivers or the Program of All-Inclusive Care</u> for the Elderly (PACE).

"Community-based services provider" or "CBS provider" means a provider or agency enrolled with Virginia Medicaid to offer services to individuals eligible for home and community-based waivers services or PACE.

"Community-based team" or "CBT" means a nurse, social worker, or other assessors designated by the department and a physician who are employees of, or contracted with, the Virginia Department of Health or the local department of social services.

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

"Day" means calendar day unless specified otherwise.

<u>"DBHDS" means the Virginia Department of Behavioral</u> <u>Health and Developmental Services.</u>

<u>"DMAS" or "the department" means the Department of</u> <u>Medical Assistance Services.</u>

"DMAS designee" means the public or private entity with an agreement with the Department of Medical Assistance Services to complete preadmission screenings pursuant to § 32.1-330 of the Code of Virginia.

<u>"Electronic preadmission screening" or "ePAS" means the</u> <u>automated system for use by all entities contracted by DMAS</u> <u>to perform preadmission screenings pursuant to § 32.1-330 of</u> <u>the Code of Virginia.</u>

<u>"Face-to-face" means an in-person meeting with the</u> individual seeking Medicaid-funded LTSS that may also occur through technological means that permit visualization and real-time communication with the individual if circumstances prohibit in-person access to the individual.

<u>"Feasible alternative" means a range of services that can be</u> provided in the community, for less than the cost of comparable institutional care, in order to enable an individual to continue living in the community.

"Home and community-based services waiver" or "waiver services" means the range of community services and supports approved by the Centers for Medicare and Medicaid Services (CMS) pursuant to § 1915(c) of the Social Security Act to be offered to individuals as an alternative to institutionalization.

<u>"Hospital team" means persons designated by the hospital</u> who are responsible for conducting and submitting the PAS for inpatients to the DMAS automated system.

<u>"Inpatient" means an individual who has a physician's order for admission to an acute care hospital, rehabilitation hospital, or a rehabilitation unit in an acute care hospital.</u>

"Institutional screening" means the face-to-face process conducted pursuant to § 32.1-330 of the Code of Virginia for individuals who are inpatients in hospitals to determine whether an individual meets the criteria for Medicaid-funded LTSS.

"Licensed health care professional" or "LHCP" means a registered nurse, nurse practitioner, or physician currently employed or contracted by the Virginia Department of Health and licensed by the relevant health regulatory board of the Department of Health Professions who is practicing within the scope of his license.

<u>"Local department of social services" or "LDSS" means the</u> <u>entity established under § 63.2-324 of the Code of Virginia</u> by the governing city or county in the Commonwealth.

<u>"Local health department" or "LHD" means the entity</u> established under § 32.1-31 of the Code of Virginia.

"Long-term services and supports" or "LTSS" means a variety of services that help individuals with health or personal care needs and ADLs over a period of time that can be provided in the home, the community, assisted living facilities, or nursing facilities.

"Medicaid" means the program set out in the 42 USC § 1396 and administered by the Department of Medical Assistance Services consistent with Chapter 10 (§ 32.1-323 et seq.) of Title 32.1 of the Code of Virginia.

"Medicare" means the Health Insurance for the Aged and Disabled program as administered by the Centers for Medicare and Medicaid Services pursuant to 42 USC 1395ggg.

"Nursing facility" or "NF" means any nursing home as defined in § 32.1-123 of the Code of Virginia.

"Other assessor designated by DMAS" means an employee of the local department of social services holding the occupational title of family services specialist.

"Preadmission screening," "PAS," or "screening" means the process to (i) evaluate the functional, nursing, and social support needs of individuals referred for preadmission screening for certain long-term care services requiring NF eligibility; (ii) assist individuals in determining what specific services the individual needs; (iii) evaluate whether a service or a combination of existing community services are available to meet the individual's needs; and (iv) provide a list to individuals of appropriate providers for Medicaid-funded nursing facility or home and community-based services for those individuals who meet nursing facility level of care.

<u>"Program of All-Inclusive Care for the Elderly" or "PACE"</u> means the community-based service pursuant to § 32.1-330.3 of the Code of Virginia.

"Referral for screening" means information obtained from an interested person or other third party having knowledge of an individual who may need Medicaid-funded LTSS and may include, for example, a physician, PACE provider, service provider, family member, or neighbor who is able to provide sufficient information to enable contact with the individual.

"Reimbursement" means the evaluation of the submitted claims for completeness, accuracy, and service resulting in the payment by DMAS for the services represented on the claims.

<u>"Representative" means a person who is authorized to make</u> <u>decisions on behalf of the individual.</u>

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"Request date for screening" or "request date" means the date (i) that an individual or the individual's representative contacts the screening entity in the jurisdiction where the individual resides asking for assistance with LTSS or, (ii) for hospital inpatients, that a physician orders case management consultation or case management determines the need for LTSS upon discharge from a hospital.

"Request for screening" means (i) communication from an individual, individual's representative, adult protective services (APS), or child protective services (CPS) expressing the need for LTSS, or (ii) for hospital inpatients, a physician order for case management consultation or case management determination of the need for LTSS upon discharge from a hospital.

"Residence" means an individual's private home, apartment, assisted living facility, nursing facility, or jail/correctional facility, for example, if the individual to be screened is seeking Medicaid-funded LTSS and does not request an alternative screening location as allowed in 12VAC30-60-305 <u>A.</u>

"Screening entity" means the hospital screening team, community-based team (CBT), or DMAS designee contracted to perform preadmission screenings pursuant to § 32.1-330 of the Code of Virginia.

"Significant change in circumstances" means a change in an individual's condition that is expected to last longer than 30 days and shall not include short-term changes that resolve with or without intervention; a short-term illness or episodic event; or a well-established, predictive, cyclic pattern of clinical signs and symptoms associated with a previously diagnosed condition where an appropriate course of treatment is in progress.

"Submission" means the transmission of the screening findings and receipt of successfully processed results using the DMAS automated system.

<u>"Submission date" means the date that the screening entity</u> transmits to DMAS the screening findings using the DMAS automated system.

"Uniform Assessment Instrument" or "UAI" means the standardized multidimensional assessment instrument that is completed by the screening entity that assesses an individual's physical health, mental health, and psycho/social and functional abilities to determine if the individual meets the nursing facility level of care.

"VDH" means the Virginia Department of Health.

"VDSS" means the Virginia Department of Social Services.

<u>12VAC30-60-302.</u> Introduction; access to Medicaidfunded long-term services and supports.

A. Medicaid-funded long-term services and supports (LTSS) may be provided in either community-based or institutionalbased settings. To receive LTSS, the individual's condition shall first be evaluated using the designated assessment instrument, the Uniform Assessment Instrument (UAI), and other designated forms. Screening entities shall use the DMAS-designated forms (UAI, DMAS-95, DMAS-96, DMAS-95 Level I (MI/IDD/RC) and if appropriate, DMAS-95 Level II (for nursing facility placements only), and the DMAS-97) to perform preadmission screenings for LTSS.

<u>1. An individual's need for LTSS shall meet the established</u> <u>criteria (12VAC30-60-303) before any authorization for</u> <u>reimbursement by Medicaid is made for LTSS.</u>

<u>2. Appropriate community-based services shall be</u> <u>evaluated prior to consideration of nursing facility</u> <u>placement.</u>

<u>B. The evaluation shall be the preadmission screening (PAS)</u> or screening process, as designated in § 32.1-330 of the Code of Virginia, which shall preauthorize a continuum of LTSS covered by Medicaid.

1. Such screenings, using the UAI, shall be conducted by teams of representatives of (i) hospitals for individuals (adults and children) who are inpatients; (ii) local departments of social services and local health departments, known herein as CBTs, for individuals (adults) residing in the community and who are not inpatients; or (iii) a DMAS designee for individuals (children) residing in the community who are not inpatients. All of these entities shall be contracted with DMAS to perform this activity and be reimbursed by DMAS.

2. All screenings shall be comprehensive, accurate, standardized, and reproducible evaluations of individual functional capacities, medical or nursing needs, and risk for institutional placement.

<u>C.</u> The authorization for Medicaid-funded LTSS shall be rescinded by the community-based services provider, the NF, or DMAS when the individual is determined to no longer meet the criteria for Medicaid-funded LTSS. The individual shall have the right to appeal such rescission decision. The individual shall be responsible for all expenditures made after the date of the rescission decision in the event that the rescission is upheld on appeal.

<u>D. Individuals shall not be required to be financially eligible</u> for receipt of Medicaid or have submitted an application for Medicaid in order to be screened for LTSS.

E. Pursuant to § 32.1-330 of the Code of Virginia, individuals shall be screened if they are eligible for Medicaid or are anticipated to become eligible for Medicaid reimbursement of their NF care within six months of nursing facility placement.

12VAC30-60-303. Preadmission screening criteria for <u>Medicaid-funded</u> long-term care <u>services and supports</u>.

A. Functional dependency alone is <u>shall</u> not <u>be deemed</u> sufficient to demonstrate the need for nursing facility care or placement or authorization for community-based care <u>services</u>. <u>An individual shall be determined to meet the</u> <u>nursing facility criteria when:</u>

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1. The individual has both limited functional capacity and medical or nursing needs according to the requirements of this section; or

2. The individual is rated dependent in some functional limitations, but does not meet the functional capacity requirements, and the individual requires the daily direct services or supervision of a licensed nurse that cannot be managed on an outpatient basis (e.g., clinic, physician visits, home health services).

B. An individual shall only be considered to meet the nursing facility criteria when both the functional capacity of the individual and his medical or nursing needs meet the following requirements. Even when an individual meets nursing facility criteria, placement in a noninstitutional setting shall be evaluated before actual nursing facility placement is considered In order to qualify for Medicaid-funded LTSS, the individual shall meet the following criteria:

1. For Medicaid-funded nursing facility services to be authorized, the screening entity shall document that the individual has both functional and medical or nursing needs. The criteria for screening an individual's eligibility for Medicaid reimbursement of NF services shall consist of two components: (i) functional capacity (the degree of assistance an individual requires to complete ADLs) and (ii) medical or nursing needs. The rating of functional dependency on the UAI shall be based on the individual's ability to function in a community environment and exclude all institutionally induced dependencies.

2. For Medicaid-funded community-based services to be authorized, an individual shall not be required to be physically admitted to a NF. The criteria for screening an individual's eligibility for Medicaid reimbursement of community-based services shall consist of three components: (i) functional capacity needs (the degree of assistance an individual requires in order to complete ADLs), (ii) medical or nursing needs, and (iii) the individual's risk of NF placement within 30 days in the absence of community-based services.

1. C. Functional capacity.

a. <u>1</u>. When documented on <u>a completed state designated</u> preadmission screening assessment instrument <u>a UAI</u> that is completed in a manner consistent with the definitions of activities of daily living (<u>ADLs</u>) and directions provided by DMAS for the rating of those activities, individuals may be considered to meet the functional capacity requirements for nursing facility care when one of the following describes their functional capacity:

(1) <u>a.</u> Rated dependent in two to four of the Activities of Daily Living <u>ADLs</u>, and also rated semi-dependent or dependent in Behavior Pattern and Orientation, and semi-dependent in Joint Motion or dependent in Medication Administration.

(2) <u>b.</u> Rated dependent in five to seven of the Activities of Daily Living <u>ADLs</u>, and also rated dependent in Mobility.

(3) <u>c.</u> Rated semi-dependent in two to seven of the Activities of Daily Living <u>ADLs</u>, and also rated dependent in Mobility and Behavior Pattern and Orientation.

b. <u>2.</u> The rating of functional dependencies on the preadmission screening assessment instrument must shall be based on the individual's ability to function in a community environment, not including any institutionally induced dependence. The following abbreviations shall mean: I = independent; d = semi-dependent; D = dependent; MH = mechanical help; HH = human help.

(1) <u>a.</u> Bathing.

(a) (1) Without help (I) (b) (2) MH only (d) (c) (3) HH only (D) (d) (4) MH and HH (D) (e) (5) Performed by Others (D) (2) b. Dressing. (a) (1) Without help (I) (b) (2) MH only (d) (c) (3) HH only (D) (d) (4) MH and HH (D) (e) (5) Performed by Others (D) (f) (6) Is not Performed (D) (3) c. Toileting. (a) (1) Without help day or night (I) (b) (2) MH only (d) (c) (3) HH only (D) (d) (4) MH and HH (D) (e) (5) Performed by Others (D) (4) d. Transferring. (a) (1) Without help (I) (b) (2) MH only (d) (c) (3) HH only (D) (d) (4) MH and HH (D) (e) (5) Performed by Others (D) (f) (6) Is not Performed (D) (5) e. Bowel Function function. (a) (1) Continent (I) (b) (2) Incontinent less than weekly (d)

- (c) (3) External/Indwelling Device/Ostomy -- self care (d)
- (d) (4) Incontinent weekly or more (D)
- (e) (5) Ostomy -- not self care (D)
(6) <u>f.</u> Bladder Function <u>function</u>.

(a) (1) Continent (I)

(b) (2) Incontinent less than weekly (d)

(c) (3) External device/Indwelling Catheter/Ostomy -- self care (d)

(d) (4) Incontinent weekly or more (D)

(e) (5) External device -- not self care (D)

(f) (6) Indwelling catheter -- not self care (D)

 (\underline{g}) (7) Ostomy -- not self care (D)

(7) g. Eating/Feeding.

(a) (1) Without help (I)

(b) (2) MH only (d)

(c) (3) HH only (D)

(d) (4) MH and HH (D)

(e) (5) Spoon fed (D)

(f) (6) Syringe or tube fed (D)

(g) (7) Fed by IV or clysis (D)

(8) <u>h.</u> Behavior <u>Pattern</u> <u>pattern</u> and <u>Orientation</u> <u>orientation</u>.

(a) (1) Appropriate or Wandering/Passive less than weekly + Oriented (I)

(b) (2) Appropriate or Wandering/Passive less than weekly + Disoriented -- Some Spheres (I)

(c) (3) Wandering/Passive Weekly/or more + Oriented (I)

(d) (4) Appropriate or Wandering/Passive less than weekly + Disoriented -- All Spheres (d)

(e) (5) Wandering/Passive Weekly/Some or more + Disoriented -- All Spheres (d)

(f) (6) Abusive/Aggressive/Disruptive less than weekly + Oriented or Disoriented (d)

(g) (7) Abusive/Aggressive/Disruptive weekly or more + Oriented (d)

(h) (8) Abusive/Aggressive/Disruptive + Disoriented --All Spheres (D)

(9) <u>i.</u> Mobility<u>.</u>

(a) (1) Goes outside without help (I)

(b) (2) Goes outside MH only (d)

(c) (3) Goes outside HH only (D)

(d) (4) Goes outside MH and HH (D)

(e) (5) Confined -- moves about (D)

(f) (6) Confined -- does not move about (D)

(10) j. Medication Administration administration.

(a) (1) No medications (I)

(b) (2) Self administered -- monitored less than weekly (I)

(c) (3) By lay persons, Administered/Monitored (D)

(d) (4) By Licensed/Professional nurse Administered/Monitored (D)

(11) k. Joint Motion motion.

(a) (1) Within normal limits or instability corrected (I)

(b) (2) Limited motion (d)

(c) (3) Instability -- uncorrected or immobile (D)

e. <u>D. Medical or nursing needs.</u> An individual with medical or nursing needs is an individual whose health needs require medical or nursing supervision or care above the level that could be provided through assistance with Activities of Daily <u>Living ADLs</u>, <u>Medication Administration medication</u> <u>administration</u>, and general supervision and is not primarily for the care and treatment of mental diseases. Medical or nursing supervision or care beyond this level is required when any one of the following describes the individual's need for medical or nursing supervision:

(1) <u>1.</u> The individual's medical condition requires observation and assessment to assure evaluation of the person's need for modification of treatment or additional medical procedures to prevent destabilization, and the person has demonstrated an inability to self observe or evaluate the need to contact skilled medical professionals;

(2) <u>2.</u> Due to the complexity created by the person's multiple, interrelated medical conditions, the potential for the individual's medical instability is high or medical instability exists; or

(3) <u>3.</u> The individual requires at least one ongoing medical or nursing service. The following is a nonexclusive list of medical or nursing services that may, but need not necessarily, indicate a need for medical or nursing supervision or care:

(a) <u>a.</u> Application of aseptic dressings;

(b) b. Routine catheter care;

(c) c. Respiratory therapy;

(d) <u>d.</u> Supervision for adequate nutrition and hydration for individuals who show clinical evidence of malnourishment or dehydration or have recent history of weight loss or inadequate hydration that, if not supervised, would be expected to result in malnourishment or dehydration;

(e) e. Therapeutic exercise and positioning;

(f) \underline{f} . Routine care of colostomy or ileostomy or management of neurogenic bowel and bladder;

(g) g. Use of physical (e.g., side rails, poseys, locked wards) and/or or chemical restraints, or both;

(h) <u>h.</u> Routine skin care to prevent pressure ulcers for individuals who are immobile;

(i) <u>i.</u> Care of small uncomplicated pressure ulcers and local skin rashes;

(j) j. Management of those with sensory, metabolic, or circulatory impairment with demonstrated clinical evidence of medical instability;

(k) k. Chemotherapy;

(1) <u>1.</u> Radiation;

(m) <u>m.</u> Dialysis;

(n) n. Suctioning;

(o) <u>o.</u> Tracheostomy care;

(p) <u>p.</u> Infusion therapy; <u>or</u>

(q) <u>q.</u> Oxygen.

d. Even when an individual meets nursing facility criteria, provision of services in a noninstitutional setting shall be considered before nursing facility placement is sought.

C. E. When assessing an individual 21 years of age or younger screening a child, the teams who are screening entity who is conducting preadmission screenings for long term care services <u>LTSS</u> shall utilize the <u>electronic</u> Uniform Assessment Instrument <u>(UAI) interpretive guidance</u> as contained referenced in DMAS' Medicaid Memo dated October 3, 2012, entitled "Development of Special Criteria for the Purposes of Pre-Admission Screening," which can be accessed on the DMAS website at https://www.virginiamedicaid.dmas.virginia.gov/.

<u>12VAC30-60-304. Requests for screening for adults and children living in the community and adults and children in hospitals.</u>

A. Screenings for adults living in the community. Screenings for adults who are residing in the community but who are not inpatients in acute care hospitals shall be completed and submitted to the DMAS automated system within 30 days of the request date for screening.

1. Requests for screenings shall be accepted from either an individual, the individual's representative, or an adult protective services worker having an interest in the individual. The community-based team (CBT) in the jurisdiction where the individual resides shall conduct such screening. For the screening to be scheduled by the CBT, the individual shall either agree to participate or if refusing, shall be under order of a court of appropriate jurisdiction to have a screening.

a. The LDSS or LHD in receipt of the request for a screening shall contact the individual or his representative within seven days of the request date for screening to schedule a screening with the individual and any other persons who the individual selects to attend the screening.

b. When the CBT has not scheduled a screening to occur within 21 days of the request date for screening, and the screening is not anticipated to be complete within 30 days of the request date for screening due to the screening entity's inability to conduct the screening, the LDSS and LHD shall, no later than seven days of the request date for screening, notify DARS and VDH staff designated for technical assistance. After contact with the LDSS and LHD, if DARS and VDH confirm that the screening entity is unable to complete the screening within 30 days of the request date for screening, the designated VDH staff shall refer the CBT and screening request to the DMAS designee for scheduling of a screening and submission of documentation.

2. Referrals for screenings may also be accepted by LDSS or LHD from an interested person having knowledge of an individual who may need LTSS. When the LDSS or LHD receives such a referral, the LDSS or LHD shall obtain sufficient information from the referral source to initiate contact with the individual or his representative to discuss the PAS process. Within seven days of the referral date, the LDSS or LHD shall contact the individual or his representative to determine if the individual is interested in receiving LTSS and would participate in the screening. If the LDSS or LHD is unable to contact the individual or his representative, it shall document the attempt to contact the individual or his representative using the method adopted by the CBT.

a. After contact with the individual or his representative, or if the LDSS or LHD is unable to contact the individual or his representative, the LDSS or LHD shall advise the referring interested person that contact or attempt to contact has been made in response to the referral for screening.

b. Information about the results of the contact shall be shared with the interested person who made the referral only with either the individual's written consent or the written consent of his legal representative who has such authority on behalf of the individual.

<u>B.</u> Screenings for children living in the community. Screenings for children who are residing in the community shall be completed and submitted to the DMAS automated system within 30 days of the request date for screening.

1. A child who is residing in the community and is not an inpatient in an acute care hospital, rehabilitation unit of an acute care hospital, or a rehabilitation hospital, and who may need LTSS, shall receive a screening from a DMAS designee. Local CBTs shall forward requests for such screenings directly to the DMAS designee.

2. The request for screening of a child residing in the community shall initiate from the parent, the entity having legal custody of that child, an emancipated child, or a child protective services worker having an interest in the child.

3. Upon receipt of such a request, the DMAS designee shall schedule an appointment to complete the screening. Community settings where screenings may occur include the child's residence, other residences, children's residential facilities, or other settings with the exception of acute care

hospitals, rehabilitation units of acute care hospitals, and rehabilitation hospitals.

4. Referrals for screenings may also be accepted from an interested person having knowledge of a child who may need LTSS. The same process and timing and limitations on the sharing of the results shall apply to such referrals for screenings for children as set out for adults.

C. Screening in hospitals for adults and children who are inpatients. Screening in hospitals shall be completed when an adult or child who is an inpatient may need LTSS upon discharge.

1. As a part of the discharge planning process, the hospital team shall complete a screening when:

a. The individual's physician, in collaboration with the individual, the individual's representative, if there is one, parent, entity having legal custody, the managed care organization's care manager, or emancipated child makes a request of the hospital team; or

b. The individual, the individual's representative, if there is one, parent, entity having legal custody, the managed care organization's care manager, or emancipated child requests a consultation with hospital case management.

2. Such individual shall receive a screening conducted by the hospital team regardless of the primary payer source (e.g., Medicare, health maintenance organization) and whether or not they are eligible for Medicaid or are anticipated to become eligible for Medicaid within six months after admission to a NF.

12VAC30-60-305. Screenings in the community and hospitals for Medicaid-funded long-term services and supports.

A. Community screenings for adults.

1. Eligibility for Medicaid-funded long-term services and supports (LTSS) shall be determined by the communitybased team (CBT) after completion of a screening of the individual's needs and available supports. The CBT shall document a screening of all the supports available for that individual in the community (i.e., the immediate family, other relatives, other community resources, and other services in the continuum of LTSS).

2. Screenings shall be completed in the individual's residence unless the residence presents a safety risk for the individual or the CBT, or unless the individual or the representative requests that the screening be performed in an alternate location within the same jurisdiction. The individual shall be permitted to have another person or persons present at the time of the screening. The CBT shall determine the appropriate degree of participation and assistance given by other persons to the individual during the screening and accommodate the individual's preferences to the extent feasible.

3. The CBT shall:

a. Observe the individual's ability to perform ADLs according to 12VAC30-60-303 and consider the individual's communication or responses to questions or his representative's communication or responses;

b. Observe and assess the individual's medical condition to ensure accurate evaluation of the individual's need for modification of treatment or additional medical procedures to prevent destabilization even when the individual has demonstrated an inability to self-observe or evaluate the need to contact skilled medical professionals; and

c. Identify the medical or nursing needs, or both, of the individual.

4. The CBT shall consider services and settings that may be needed by the individual in order for the individual to safely perform ADLs.

5. Upon completion of the screening and in consideration of the communication from the individual, his representative, if appropriate, and observations obtained during the screening, the CBT shall determine whether the individual meets the criteria set out in 12VAC30-60-303. If the individual meets the criteria for LTSS, the CBT shall inform and provide choice to the individual and his representative, if appropriate, of the feasible alternatives available through waiver services, PACE where appropriate and available, or placement in a NF. If waiver services or PACE, where available, are declined, the reason for the declination shall be recorded on the DMAS-97, Individual Choice, Institutional Care, or Waiver Services form. The CBT shall have this document signed by either the individual or his representative, if appropriate. In addition to the electronic document, a paper copy of the DMAS-97 form with the individual's or his representative's signature shall be retained in the individual's record by the screening entity.

6. If the individual meets criteria selects community-based services, the CBT shall also document that the individual is at risk of NF placement in the absence of waiver services by finding that at least one of the following conditions exists:

a. The individual has been cared for in the home prior to the screening and evidence is available demonstrating a deterioration in the individual's health care condition or a change in available supports preventing former services and supports from meeting the individual's needs. Examples of such evidence may include (i) recent hospitalizations, (ii) attending physician documentation, or (iii) reported findings from medical or social service agencies.

b. There has been no change in condition or available support but evidence is available that demonstrates the individual's functional, medical, or nursing needs are not being met. Examples of such evidence may include (i) recent hospitalizations, (ii) attending physician documentation, or (iii) reported findings from medical or social service agencies.

7. If the individual selects NF placement, the CBT shall complete a Level I screening, on the DMAS-95 Level I form, for mental illness, intellectual disability, or related condition as required by § 1919(e)(7) of the Social Security Act. When the Level I screening indicates that the individual may have mental illness, intellectual disability, or related condition or conditions, the CBT shall refer the individual to DBHDS for a Level II screening.

a. DBHDS shall perform the Level II screening, documenting it on the DMAS-95 Level II form.

b. DBHDS shall determine if the individual may benefit from additional specialized services upon NF placement. DBHDS shall provide the outcome of its Level II screening to the CBT for NF placements only.

c. The CBT shall provide the outcome of the Level II screening to the NF that admits the individual and agrees to provide the required specialized services indicated by the Level II outcome. The individual shall be permitted to exercise choice among Medicaid-funded LTSS programs throughout the process.

8. If the CBT determines that the individual does not meet the criteria set out in 12VAC30-60-303, the CBT shall notify in writing the individual and family/caregiver, as may be appropriate, that LTSS are being denied for the individual. The denial notice shall include the individual's right to appeal consistent with DMAS client appeals regulations (12VAC30-110).

B. Community screenings for children.

1. Eligibility for Medicaid-funded LTSS shall be determined by the DMAS designee. The DMAS designee shall document a complete assessment of the child's needs and available supports. The assessment shall be documented on the designated DMAS forms identified in 12VAC30-60-306. If the child meets criteria defined in 12VAC30-60-303, the DMAS designee shall provide the parent or entity having legal custody of the child, or the emancipated child, the choice of waiver services or nursing facility placement.

2. The DMAS designee shall determine the appropriate degree of participation and assistance given by other persons to the individual during the screening in recognition of the individual's preferences to the extent feasible.

3. The DMAS designee shall:

a. Observe the child's ability to perform ADLs according to 12VAC30-60-303 and consider the parent's, legal guardian's, or emancipated child's communications or responses to questions; b. Observe and assess the child's medical condition to assure accurate evaluation of the child's need for modification of treatment or additional medical procedures to prevent destabilization even when the child has demonstrated an inability to self-observe or evaluate the need to contact skilled medical professionals; and

c. Identify the medical or nursing needs, or both, of the child.

4. The DMAS designee shall consider services and settings that may be needed by the child in order for the child to safely perform ADLs.

5. Upon completion of the screening and in consideration of the communication from the individual, his representative, if appropriate, and observations obtained during the screening, the DMAS designee shall determine whether the individual meets the criteria set out in 12VAC30-60-303. If the individual meets the criteria for LTSS, the DMAS designee shall inform and provide choice to the individual and his representative, if appropriate, of the feasible alternatives available through waiver services, PACE where appropriate and available, or placement in a NF. If waiver services or PACE, where available, are declined, the reason for declining shall be recorded on the DMAS-97, Individual Choice, Institutional Care or Waiver Services form. The DMAS designee shall have this document signed by either the individual or his representative, if appropriate. In addition to the electronic document, a paper copy of the DMAS-97 form with the individual's or his representative's signature shall be retained in the individual's record by the screening entity.

6. If the individual who meets criteria selects communitybased services, the CBT shall also document that the individual is at risk of NF placement in the absence of waiver services by finding that at least one of the following conditions exists:

a. The individual has been cared for in the home prior to the screening and evidence is available demonstrating a deterioration in the individual's health care condition or a change in available supports preventing former services and supports from meeting the individual's needs. Examples of such evidence may include (i) recent hospitalizations, (ii) attending physician documentation, or (iii) reported findings from medical or social service agencies.

b. There has been no change in condition or available support but evidence is available that demonstrates the individual's functional, medical, or nursing needs are not being met. Examples of such evidence may include (i) recent hospitalizations, (ii) attending physician documentation, or (iii) reported findings from medical or social service agencies.

7. If the parent, entity having legal custody of the child, or emancipated child selects NF placement, the DMAS designee shall complete a Level I screening, on the

DMAS-95 Level I form, for mental illness, intellectual disability, or related condition as required by § 1919(e)(7) of the Social Security Act. When the Level I screening indicates that the child may have mental illness, intellectual disability, or related condition, the DMAS designee shall refer the child to DBHDS for a Level II screening.

a. DBHDS shall perform the Level II screening, documenting it on the DMAS-95 Level II form.

b. DBHDS shall determine if the child may benefit from additional specialized services upon NF placement. DBHDS shall provide the outcome of its Level II screening to the DMAS designee.

c. The DMAS designee shall provide the outcome of the Level II screening to the NF that admits the child and agrees to provide the required specialized services indicated by the Level II outcome. The child, parent, entity having legal custody, or emancipated child shall be permitted to exercise choice among Medicaid-funded LTSS programs throughout the process.

8. If the DMAS designee determines that the child does not meet the criteria to receive LTSS as set out in 12VAC30-60-303, the DMAS designee shall notify in writing the parent, entity having legal custody of the child, or the emancipated child and family/caregiver, as may be appropriate, that LTSS are being denied for the child. The denial notice shall include the child's right to appeal consistent with DMAS client appeals regulations (12VAC30-110).

<u>C. Screenings for adults and children in hospitals. For the purpose of this subsection, the term "individual" shall mean either an adult or a child.</u>

1. Eligibility for Medicaid-funded LTSS for individuals who are inpatients shall be determined by the hospital screening team, which shall document a complete assessment of the individual's needs and available supports.

2. Screenings shall be completed in the hospital prior to discharge. The individual shall be permitted to have another person present at the time of the screening. The hospital screening team shall determine the appropriate degree of participation and assistance given by other persons to the individual during the screening.

3. The hospital screening team shall:

a. Observe the individual's ability to perform ADLs according to 12VAC30-60-303, excluding all institutionally induced dependencies, and consider the individual's communication or responses to questions, or his representative's communications or responses to questions;

b. Observe and assess the individual's medical condition to ensure accurate evaluation of the individual's need for modification of treatment or additional medical procedures or services to prevent destabilization even when an individual has demonstrated an inability to selfobserve or evaluate the need to contact skilled medical professionals; and

c. Identify the medical or nursing needs, or both, of the individual.

4. In developing the individual's discharge plans, the hospital screening team shall consider services and settings that may be needed by the individual in order for him to safely perform ADLs.

5. Upon completion of the screening and in consideration of the communication from the individual, his representative, if appropriate, and observations obtained during the screening, the hospital screening team shall determine whether the individual meets the criteria set out in 12VAC30-60-303. If the individual meets the criteria for LTSS, the hospital screening team shall inform and provide choice to the individual and his representative, if appropriate, of the feasible alternatives available through waiver services, PACE where appropriate and available, or placement in a NF. If waiver services or PACE, where available, are declined, the reason for declining shall be recorded on the DMAS-97, Individual Choice, Institutional Care or Waiver Services form. The hospital screening team shall have this document signed by either the individual or his representative, if appropriate. In addition to the electronic document, a paper copy of the DMAS-97 form with the individual's or his representative's signature shall be retained in the individual's record by the hospital screening team.

6. If the individual or his representative, if appropriate, selects NF placement, the hospital screening team shall complete a Level I screening, on the DMAS-95 Level I form, for mental illness, intellectual disability, or related condition as required by § 1919(e)(7) of the Social Security Act. When the Level I screening indicates the presence of mental illness, intellectual disability, or related condition, the hospital screening team shall refer the individual to DBHDS for a Level II screening prior to discharge to determine if the individual may benefit from additional specialized services upon NF admission.

<u>a. DBHDS shall perform the Level II screening,</u> <u>documenting it on the DMAS-95 Level II form.</u>

b. DBHDS shall determine if the individual may benefit from additional specialized services upon NF placement. DBHDS shall provide the outcome of its Level II screening on the DMAS-95 Level I (MI/MR/RC) and if appropriate, the DMAS-95 Level II form for NF placements only.

c. The hospital screening team shall provide the outcome of the Level II screening to the NF that admits the individual and agrees to provide the required specialized services indicated by the Level II outcome. The individual or his representative, as appropriate, shall be

permitted to exercise choice among Medicaid-funded LTSS programs throughout the process.

7. If the hospital screening team determines that the individual does not meet the criteria for LTSS set out in 12VAC30-60-303, the hospital screening team shall notify in writing the individual and family/caregiver, as may be appropriate, that LTSS are being denied for the individual. The denial notice shall include the individual's right to appeal consistent with DMAS client appeals regulations (12VAC30-110).

12VAC30-60-306. Submission of screenings.

<u>A. The screening entity shall complete and submit the following forms to DMAS electronically on ePAS:</u>

<u>1. DMAS 95 - MI/MR/ID/RC (Supplemental Assessment Process Form Level I):</u>

<u>2. DMAS - 96 (Medicaid-Funded Long-Term Care Service</u> <u>Authorization Form), as appropriate;</u>

<u>3. DMAS - 97 (Individual Choice – Institutional Care or Waiver Services);</u>

4. DMAS - 95 MI/MR Supplement II; and

5. UAI (Uniform Assessment Instrument).

<u>B.</u> For screenings performed in the community, the screening entity shall submit to DMAS on ePAS each PAS form listed in subsection A of this section within 30 days of the individual's request date for screening.

C. For screenings performed in a hospital, the hospital team shall submit to DMAS on ePAS each screening form listed in subsection A of this section, which shall be completed prior to the individual's discharge. For individuals who will be admitted to a Medicare-funded skilled NF or to a Medicarefunded rehabilitation hospital (or rehabilitation unit) directly upon discharge from the hospital, the hospital screener shall have up to an additional three days post-discharge to submit the screening forms via ePAS.

12VAC30-60-307. Summary of pre-admission nursing facility criteria. (Repealed.)

A. An individual shall be determined to meet the nursing facility criteria when:

1. The individual has both limited functional capacity and requires medical or nursing management according to the requirements of 12VAC30 60 303, or

2. The individual is rated dependent in some functional limitations, but does not meet the functional capacity requirements, and the individual requires the daily direct services or supervision of a licensed nurse that cannot be managed on an outpatient basis (e.g., clinic, physician visits, home health services).

B. An individual shall not be determined to meet nursing facility criteria when one of the following specific care needs solely describes his or her condition:

1. An individual who requires minimal assistance with activities of daily living, including those persons whose only need in all areas of functional capacity is for prompting to complete the activity;

2. An individual who independently uses mechanical devices such as a wheelchair, walker, crutch, or cane;

3. An individual who requires limited diets such as a mechanically altered, low salt, low residue, diabetic, reducing, and other restrictive diets;

4. An individual who requires medications that can be independently self administered or administered by the caregiver;

5. An individual who requires protection to prevent him from obtaining alcohol or drugs or to address a social or environmental problem;

6. An individual who requires minimal staff observation or assistance for confusion, memory impairment, or poor judgment;

7. An individual whose primary need is for behavioral management which can be provided in a community based setting;

12VAC30-60-308. Nursing facility admission and level of care determination requirements.

<u>A. Prior to an individual's admission, the NF shall review</u> the completed preadmission screening forms to ensure that applicable NF admission criteria have been met and documented.

<u>B. The Department of Medical Assistance Services shall</u> <u>conduct reviews of Minimum Data Set individuals' data</u> <u>submitted by NFs.</u>

12VAC30-60-310. <u>ePAS requirements and submission.</u> [Reserved]

12VAC30-60-312. Evaluation to determine eligibility for Medicaid payment of nursing facility or home and community-based care services. (Repealed.)

A. The screening team shall not authorize Medicaid funded nursing facility services for any individual who does not meet nursing facility criteria. Once the nursing home preadmission screening team has determined whether or not an individual meets the nursing facility criteria, the screening team must determine the most appropriate and cost effective means of meeting the needs of the individual. The screening team must document a complete assessment of all the resources available for that individual in the community (i.e., the immediate family, other relatives, other community resources and other services in the continuum of long term care which are less intensive than nursing facility level of care services). The screening team shall be responsible for preauthorizing Medicaid-funded long-term care according to the needs of each individual and the support required to meet those needs. The screening team shall authorize Medicaid funded nursing facility care for an individual who meets the nursing facility

criteria only when services in the community are either not a feasible alternative or the individual or the individual's representative rejects the screening team's plan for community services. The screening team must document that the option of community based alternatives has been explained, the reason community based services were not chosen, and have this document signed by the client or client's primary caregivers.

B. The screening team shall authorize community based waiver services only for an individual who meets the nursing facility criteria and is at risk of nursing home placement without waiver services. Waiver services are offered to such an individual as an alternative to avoid nursing facility admission pursuant to 42 CFR 441.302 (c)(1).

C. Federal regulations which govern Medicaid funded home and community-based services require that services only be offered to individuals who would otherwise require institutional placement in the absence of home and community based services. The determination that an individual would otherwise require placement in a nursing facility is based upon a finding that the individual's current condition and available support are insufficient to enable the individual to remain in the home and thus the individual is at risk of institutionalization if community based care is not authorized. The determination of the individual's risk of nursing facility placement shall be documented either on the state designated pre admission screening assessment or in a separate attachment for every individual authorized to receive community based waiver services. To authorize communitybased waiver services, the screening team must document that the individual is at risk of nursing facility placement by finding that one of the following conditions is met:

1. Application for the individual to a nursing facility has been made and accepted;

2. The individual has been cared for in the home prior to the assessment and evidence is available demonstrating a deterioration in the individual's health care condition or a change in available support preventing former care arrangements from meeting the individual's need. Examples of such evidence may be, but shall not necessarily be limited to:

a. Recent hospitalizations;

b. Attending physician documentation; or

c. Reported findings from medical or social service agencies.

3. There has been no change in condition or available support but evidence is available that demonstrates the individual's functional, medical and nursing needs are not being met. Examples of such evidence may be, but shall not necessarily be limited to:

a. Recent hospitalizations;

b. Attending physician documentation; or

c. Reported findings from medical or social service agencies.

<u>12VAC30-60-313.</u> Individuals determined to not meet criteria for Medicaid-funded long-term services and supports.

An individual shall be determined not to meet criteria for Medicaid-funded LTSS when one of the following specific care needs solely describes the individual's condition:

1. The individual requires minimal assistance with ADLs, including those individuals whose only need in all areas of functional capacity is for prompting to complete the activity;

2. The individual independently uses mechanical devices such as a wheelchair, walker, crutch, or cane;

<u>3. The individual requires limited diets such as a mechanically altered, low-salt, low-residue, diabetic, reducing, and other restrictive diets;</u>

4. The individual requires medications that can be independently self-administered or administered by the caregiver;

5. The individual requires protection to prevent him from obtaining alcohol or drugs or to address a social or environmental problem;

<u>6. The individual requires minimal staff observation or assistance for confusion, memory impairment, or poor judgment; or</u>

7. The individual's primary need is for behavioral management that can be provided in a community-based setting.

12VAC30-60-315. Ongoing evaluations for individuals receiving Medicaid-funded long-term services and supports.

A. Once an individual is admitted to community-based services, the CBS provider shall be responsible for conducting ongoing evaluations to ensure that the individual meets, and continues to meet, the waiver program or PACE criteria. These ongoing evaluations shall be conducted using the Level of Care form (DMAS 99 LOC).

B. Once an individual is admitted to a NF, the NF shall be responsible for conducting ongoing evaluations to ensure that the individual meets, and continues to meet, the NF criteria. For this purpose, the NF shall use the federally required Minimum Data Set (MDS) form. The post-admission evaluation shall be conducted no later than 14 days after the date of NF admission and promptly after an individual's significant change in circumstances.

<u>C.</u> For individuals who are enrolled in a managed care organization (MCO) that is responsible for providing LTSS, the MCO shall conduct ongoing evaluations by qualified MCO staff to ensure the individual continues to meet criteria for LTSS.

Virginia Register of Regulations

<u>NOTICE</u>: The following forms used in administering the regulation were filed by the agency. The forms are not being published; however, online users of this issue of the Virginia Register of Regulations may click on the name of a form with a hyperlink to access it. The forms are also available from the agency contact or may be viewed at the Office of the Registrar of Regulations, General Assembly Building, 2nd Floor, Richmond, Virginia 23219.

FORMS (12VAC30-60)

Certificate of Medical Necessity -- Durable Medical Equipment and Supplies, DMAS 352 (rev. 8/95).

Request for Hospice Benefits, DMAS 420 (rev. 1/99).

Screening for Mental Illness, Mental Retardation/Intellectual Disability, or Related Conditions, DMAS-95/IDD/RC (rev. 12/2015)

<u>Medicaid Funded Long-Term Services and Supports</u> <u>Authorization Form, DMAS-96 (rev. 12/2015)</u>

Individual Choice - Institutional Care or Waiver Services Form, DMAS-97 (rev. 8/2012)

Virginia Uniform Assessment Instrument

Virginia Uniform Assessment Instrument, DMAS-98 (eff. 2/2016), including:

UAI-A; UAI-B; Eligibility Communication Document; Screening for Mental Illness, Mental Retardation/Intellectual Disability, or Related Conditions; MI/MR Supplemental: Level II; Medicaid Funded Long-Term Care Service Authorization Form; Individual Choice - Institutional Care or Waiver Services Form; and Attachment to Public Pay Short Form Assessment

<u>Community-Based Care Level of Care Review Instrument,</u> <u>DMAS-99LOC (undated)</u>

VA.R. Doc. No. R16-4355; Filed June 21, 2016, 10:25 a.m.

Final Regulation

<u>Title of Regulation:</u> 12VAC30-80. Methods and Standards for Establishing Payment Rates; Other Types of Care (amending 12VAC30-80-20, 12VAC30-80-40; adding 12VAC30-80-36).

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

Effective Date: August 10, 2016.

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

Summary:

The amendments implement a prospective payment methodology for Medicaid outpatient hospital services as provided in Item 301 TT of Chapter 3 of the 2014 Acts of Assembly, Special Session I. The enhanced ambulatory patient group (EAPG) reimbursement methodology for outpatient hospital services, which is currently in place through emergency regulations, assigns outpatient procedures and ancillary services that reflect similar patient characteristics and resource utilization to EAPG codes.

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

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

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

B. Reasonable costs will be determined from the filing of a uniform cost report by participating providers. The cost reports are due not later than 150 days after the provider's fiscal year end. If a complete cost report is not received within 150 days after the end of the provider's fiscal year, the Program shall take action in accordance with its policies to assure that an overpayment is not being made. The cost report will be judged complete when DMAS has all of the following:

1. Completed cost reporting [form(s) form] provided by DMAS, with signed [certification(s) certification];

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

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

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

5. Depreciation schedule or summary;

6. Home office cost report, if applicable; and

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

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

D. The services that are cost reimbursed are:

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

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

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

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

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

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

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

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

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

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

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

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

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

(d) A visit in which the recipient's condition requires immediate hospital admission or the transfer to another

facility for further treatment or a visit in which the recipient dies.

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

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

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

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

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

(1) Type One hospitals.

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

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

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

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

(2) Type Two hospitals.

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

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

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

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

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

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

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

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

2. Rehabilitation agencies or comprehensive outpatient rehabilitation.

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

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

<u>12VAC30-80-36.</u> Fee-for-service providers: outpatient hospitals.

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

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

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

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

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

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

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

B. Effective January 1, 2014, the prospective enhanced ambulatory patient group (EAPG) based payment system described in this subsection shall apply to reimbursement for outpatient hospital services (with the exception of laboratory services referred to the hospital but not associated with an outpatient hospital visit, which will be reimbursed according to the laboratory fee schedule).

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

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

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

a. When using base years prior to January 1, 2014, for all services, excluding all laboratory services and emergency services described in subdivision 3 c of this subsection, a percentage of costs as reported in the available cost

reports for the base period for each type of hospital as defined in 12VAC30-70-221.

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

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

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

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

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

4. Inflation adjustment to base year costs. Each July, the Virginia moving average values as compiled and published by Global Insight (or its successor), under contract with DMAS, shall be used to update the base year costs to the midpoint of the rate year. The most current table available prior to the effective date of the new rates shall be used to inflate base year amounts to the upcoming rate year. Thus, corrections made by Global Insight (or its successor) in the moving averages that were used to update rates for previous state fiscal years shall be automatically incorporated into the moving averages that are being used to update rates for the upcoming state fiscal year. Inflation shall be applied to the costs identified in subdivision 3 a of this subsection.

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

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

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

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

b. Effective for dates of service on or after July 1, 2014, DMAS shall calculate the hospital-specific base rate as the sum of 50% of the cost-based base rate and 50% of the EAPG base rate.

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

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

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

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

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

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

managed care organizations if DMAS determines that it is reliable.

12VAC30-80-40. Fee-for-service providers: pharmacy.

Payment for pharmacy services (excluding outpatient hospital) shall be the lowest of subdivisions 1 through 5 of this section (except that subdivisions 1 and 2 of this section will not apply when prescriptions are certified as brand necessary by the prescribing physician in accordance with the procedures set forth in 42 CFR 447.512(c) if the brand cost is greater than the Centers for Medicare and Medicaid Services (CMS) upper limit of VMAC cost) subject to the conditions, where applicable, set forth in subdivisions 6 and 7 of this section:

1. The upper limit established by the CMS for multiple source drugs pursuant to 42 CFR 447.512 and 447.514, as determined by the CMS Upper Limit List plus a dispensing fee. If the agency provides payment for any drugs on the HCFA Upper Limit List, the payment shall be subject to the aggregate upper limit payment test.

2. The methodology used to reimburse for generic drug products shall be the higher of either (i) the lowest Wholesale Acquisition Cost (WAC) plus 10% or (ii) the second lowest WAC plus 6.0%. This methodology shall reimburse for products' costs based on a Maximum Allowable Cost (VMAC) list to be established by the single state agency.

a. In developing the maximum allowable reimbursement rate for generic pharmaceuticals, the department or its designated contractor shall: (1) Identify three different suppliers, including manufacturers that are able to supply pharmaceutical products in sufficient quantities. The drugs considered must be listed as therapeutically and pharmaceutically equivalent in the Food and Drug Administration's most recent version of the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book). Pharmaceutical products that are not available from three different suppliers, including manufacturers, shall not be subject to the VMAC list.

(2) Identify that the use of a VMAC rate is lower than the Federal Upper Limit (FUL) for the drug. The FUL is a known, widely published price provided by CMS; and

(3) Distribute the list of state VMAC rates to pharmacy providers in a timely manner prior to the implementation of VMAC rates and subsequent modifications. DMAS shall publish on its website, each month, the information used to set the Commonwealth's prospective VMAC rates, including, but not necessarily limited to:

(a) The identity of applicable reference products used to set the VMAC rates;

(b) The Generic Code Number (GCN) or National Drug Code (NDC), as may be appropriate, of reference products;

(c) The difference by which the VMAC rate exceeds the appropriate WAC price; and

(d) The identity and date of the published compendia used to determine reference products and set the VMAC rate. The difference by which the VMAC rate exceeds the appropriate WAC price shall be at least or equal to 10% above the lowest-published wholesale acquisition cost for products widely available for purchase in the Commonwealth and shall be included in national pricing compendia.

b. Development of a VMAC rate that does not have a FUL rate shall not result in the use of higher-cost innovator brand name or single source drugs in the Medicaid program.

c. DMAS or its designated contractor shall:

(1) Implement and maintain a procedure to add or eliminate products from the list, or modify VMAC rates, consistent with changes in the fluctuating marketplace. DMAS or its designated contractor will regularly review manufacturers' pricing and monitor drug availability in the marketplace to determine the inclusion or exclusion of drugs on the VMAC list; and

(2) Provide a pricing dispute resolution procedure to allow a dispensing provider to contest a listed VMAC rate. DMAS or its designated contractor shall confirm receipt of pricing disputes within 24 hours, via telephone or facsimile, with the appropriate documentation of relevant information, e.g. for example, invoices. Disputes shall be resolved within three business days of

confirmation. The pricing dispute resolution process will include DMAS' or the contractor's verification of accurate pricing to ensure consistency with marketplace pricing and drug availability. Providers will be reimbursed, as appropriate, based on findings. Providers shall be required to use this dispute resolution process prior to exercising any applicable appeal rights.

3. The provider's usual and customary charge to the public, as identified by the claim charge.

4. The Estimated Acquisition Cost (EAC), which shall be based on the published Average Wholesale Price (AWP) minus a percentage discount established by the General Assembly (as set forth in subdivision 7 of this section) or, in the absence thereof, by the following methodology set out in subdivisions a through c of this subdivision.

a. Percentage discount shall be determined by a statewide survey of providers' acquisition cost.

b. The survey shall reflect statistical analysis of actual provider purchase invoices.

c. The agency will conduct surveys at intervals deemed necessary by DMAS.

5. [MAC Maximum allowable cost (MAC)] methodology for specialty drugs. Payment for drug products designated by DMAS as specialty drugs shall be the lesser of subdivisions 1 through 4 of this section or the following method, whichever is least:

a. The methodology used to reimburse for designated specialty drug products shall be the WAC price plus the WAC percentage. The WAC percentage is a constant percentage identified each year for all GCNs.

b. Designated specialty drug products are certain products used to treat chronic, high-cost, or rare diseases; the drugs subject to this pricing methodology and their current reimbursement rates are listed on the DMAS website at the following internet address: http://www.dmas.virginia.gov/downloads/pdfs/pharmspecial mac list.pdf

http://www.dmas.virginia.gov/Content_pgs/pharmhome.aspx.

c. The MAC reimbursement methodology for specialty drugs shall be subject to the pricing review and dispute resolution procedures described in subdivisions 2 c (1) and 2 c (2) of this section.

6. Payment for pharmacy services will be as described above in subdivisions 1 through 5 of this section; however, payment for legend drugs will include the allowed cost of the drug plus only one dispensing fee per month for each specific drug. Exceptions to the monthly dispensing fees shall be allowed for drugs determined by the department to have unique dispensing requirements. The dispensing fee for brand name and generic drugs is \$3.75.

7. An EAC of AWP minus 13.1% shall become effective July 1, 2011. The dispensing fee for brand name and

generic drugs of \$3.75 shall remain in effect, creating a payment methodology based on the previous algorithm (least of subdivisions of this section) plus a dispensing fee where applicable.

8. Home infusion therapy.

a. The following therapy categories shall have a pharmacy service day rate payment allowable: hydration therapy, chemotherapy, pain management therapy, drug therapy, and total parenteral nutrition (TPN). The service day rate payment for the pharmacy component shall apply to the basic components and services intrinsic to the therapy category. Submission of claims for the per diem rate shall be accomplished by use of the CMS 1500 claim form.

b. The cost of the active ingredient or ingredients for chemotherapy, pain management, and drug therapies shall be submitted as a separate claim through the pharmacy program, using standard pharmacy format. Payment for this component shall be consistent with the current reimbursement for pharmacy services. Multiple applications of the same therapy shall be reimbursed one service day rate for the pharmacy services. Multiple applications of different therapies shall be reimbursed at 100% of standard pharmacy reimbursement for each active ingredient.

9. Supplemental rebate agreement. The Commonwealth complies with the requirements of § 1927 of the Social Security Act and Subpart I (42 CFR 447.500 et seq.) of 42 CFR Part 447 with regard to supplemental drug rebates. In addition, the following requirements are also met:

a. Supplemental drug rebates received by the state in excess of those required under the national drug rebate agreement will be shared with the federal government on the same percentage basis as applied under the national drug rebate agreement.

b. Prior authorization requirements found in § 1927(d)(5) of the Social Security Act have been met.

c. Nonpreferred drugs are those that were reviewed by the Pharmacy and Therapeutics Committee and not included on the preferred drug list. Nonpreferred drugs will be made available to Medicaid beneficiaries through prior authorization.

d. Payment of supplemental rebates may result in a product's inclusion on the PDL.

10. Each drug administered in an outpatient hospital setting and reimbursed based on the enhanced ambulatory patient group methodology, as described in 12VAC30-80-36, shall be reimbursed separately at a rate greater than zero to be eligible for drug rebate claiming.

VA.R. Doc. No. R14-3799; Filed June 21, 2016, 10:17 a.m.

Notice of Extension of Emergency Regulation

<u>Title of Regulation:</u> 12VAC30-120. Waivered Services (amending 12VAC30-120-360 through 12VAC30-120-395, 12VAC30-120-410, 12VAC30-120-420).

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

Expiration Date Extended Through: December 29, 2016.

The Governor has approved the Department of Medical Assistance Services request to extend the expiration date of the above-referenced emergency regulation for six months as provided for in § 2.2-4011 D of the Code of Virginia. Therefore, the emergency regulation will continue in effect through December 29, 2016. The emergency regulation implements several mandates from various legislative actions to (i) require individuals who are participating in a home and community-based care services waiver, specifically the Elderly or Disabled with Consumer Direction Waiver, to also be enrolled in Medicaid contracted managed care organizations and (ii) require expedited enrollment for Medicaid individuals into Medicaid contracted managed care organizations, especially for pregnant women. The emergency regulation was published in 31:11 VA.R. 947-955 January 26, 2015, and a final regulation to replace the emergency regulation was published in 32:22 VA.R. 2953-2961 June 27, 2016.

<u>Contact Information:</u> Victoria Simmons, Regulatory Coordinator, Department of Medical Assistance Services, 600 East Broad Street, Suite 1300, Richmond, VA 23219, telephone (804) 371-6043, FAX (804) 786-1680, TTY (800) 343-0634, or email victoria.simmons@dmas.virginia.gov.

VA.R. Doc. No. R15-4135; Filed June 17, 2016, 5:22 p.m.

Notice of Extension of Emergency Regulation

<u>Title of Regulation:</u> 12VAC30-135. Demonstration Waiver Services (adding 12VAC30-135-400 through 12VAC30-135-498).

<u>Statutory Authority:</u> § 32.1-325 of the Code of Virginia; § 1115 of the Social Security Act.

Expiration Date Extended Through: December 29, 2016.

The Governor has approved the Department of Medical Assistance Services request to extend the expiration date of the above-referenced emergency regulation for six months as provided for in § 2.2-4011 D of the Code of Virginia. Therefore, the emergency regulation will continue in effect through December 29, 2016. The emergency regulation established the Governor's Access Plan Demonstration Waiver to improve access to health care for a segment of the uninsured population in Virginia who have significant behavioral and medical needs, improve health and behavioral health outcomes of participants in this program, and serve as a bridge to closing the insurance coverage gap for uninsured Virginians. The emergency regulation was published in 31:10 VA.R. 864-882 January 12, 2015, and an amendment to

certain sections of the emergency regulation was published in 31:23 VA.R. 2128-2137 July 13, 2015.

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

VA.R. Doc. No. R15-4171; Filed June 17, 2016, 5:22 p.m.

TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF AUDIOLOGY AND SPEECH-LANGUAGE PATHOLOGY

Final Regulation

<u>Titles of Regulations:</u> 18VAC30-20. Regulations Governing the Practice of Audiology and Speech-Language Pathology (repealing 18VAC30-20-10 through 18VAC30-20-320).

18VAC30-21. Regulations Governing Audiology and Speech-Language Pathology (adding 18VAC30-21-10 through 18VAC30-21-170).

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

Effective Date: August 10, 2016.

<u>Agency Contact:</u> Leslie L. Knachel, Executive Director, Board of Audiology and Speech-Language Pathology, 9960 Mayland Drive, Suite 300, Richmond, VA 23233-1463, telephone (804) 367-4630, FAX (804) 527-4413, or email leslie.knachel@dhp.virginia.gov.

Summary:

The action repeals 18VAC30-20 and adopts new regulations in 18VAC30-21 to organize sections and provisions more logically and with more clarity. Provisions of the regulation include (i) a change in continuing competency requirements from 30 hours within two years to 10 hours annually, offered by an approved sponsor or provider; (ii) less burdensome rules for licensure and reentry into practice; (iii) elimination of barriers to provisional licensure, including requirements pursuant to Chapter 436 of the 2013 Acts of Assembly; (iv) more explicit rules for patient confidentiality and maintenance of records and regarding violations of professional boundaries; and (v) performance of flexible endoscopic evaluation of swallowing.

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

<u>CHAPTER 21</u> <u>REGULATIONS GOVERNING AUDIOLOGY AND</u> <u>SPEECH-LANGUAGE PATHOLOGY</u>

<u>Part I</u>

General Provisions

18VAC30-21-10. Definitions.

<u>A. The words and terms "audiologist," "board," "practice of audiology," "practice of speech-language pathology," "speech-language disorders," and "speech-language pathologist" when used in this chapter shall have the meanings ascribed to them in § 54.1-2600 of the Code of Virginia.</u>

<u>B. The following words and terms when used in this chapter</u> shall have the following meanings unless the context clearly indicates otherwise:

"Active practice" means a minimum of 160 hours of professional practice as an audiologist or speech-language pathologist for each 12-month period immediately preceding application for licensure. Active practice may include supervisory, administrative, educational, research, or consultative activities or responsibilities for the delivery of such services.

<u>"ASHA" means the American Speech-Language-Hearing Association.</u>

<u>"Client" means a patient or person receiving services in audiology or speech-language pathology.</u>

<u>"Contact hour" means 60 minutes of time spent in continuing learning activities.</u>

"School speech-language pathologist" means a person licensed pursuant to § 54.1-2603 of the Code of Virginia to provide speech-language pathology services solely in public school divisions.

"Supervision" means that the audiologist or speech-language pathologist is responsible for the entire service being rendered or activity being performed, is available for consultation, and is providing regular monitoring and documentation of clinical activities and competencies of the person being supervised.

18VAC30-21-20. Required licenses; posting of licenses.

<u>A. There shall be separate licenses for the practices of audiology and speech-language pathology. It is prohibited for any person to practice as an audiologist or a speech-language pathologist unless the person has been issued the appropriate license.</u>

<u>B.</u> A licensee shall post his license in a place conspicuous to the public in each facility in which the licensee is employed and holds himself out to practice. If it is not practical to post the license, the licensee shall provide a copy of his license upon request.

18VAC30-21-30. Records; accuracy of information.

<u>A. All changes of name, address of record, or public address, if different from the address of record, shall be furnished to the board within 30 days after the change occurs.</u>

B. A licensee who has changed his name shall submit as legal proof to the board a copy of the marriage certificate, a certificate of naturalization, or a court order evidencing the change. A duplicate license with the changed name shall be issued by the board upon receipt of such evidence and the required fee.

<u>C. All notices required by law and by this chapter to be</u> mailed by the board to any registrant or licensee shall be validly served when mailed to the latest address of record on file with the board.

18VAC30-21-40. Fees required.

<u>A. The following fees shall be paid as applicable for licensure:</u>

1. Application for audiology or speech- language pathology license	<u>\$135</u>	
2. Application for school speech-language pathology license	<u>\$70</u>	
3. Verification of licensure requests from other states	<u>\$20</u>	
4. Annual renewal of audiology or speech- language pathology license	<u>\$75</u>	
5. Late renewal of audiology or speech- language pathology license	<u>\$25</u>	
<u>6. Annual renewal of school speech-</u> language pathology license	<u>\$40</u>	
7. Late renewal of school speech-language pathology license	<u>\$15</u>	
8. Reinstatement of audiology or speech- language pathology license	<u>\$135</u>	
9. Reinstatement of school speech-language pathology license	<u>\$70</u>	
10. Duplicate wall certificate	<u>\$25</u>	
11. Duplicate license	<u>\$5</u>	
12. Returned check	<u>\$35</u>	
13. Inactive license renewal for audiology or speech-language pathology	<u>\$40</u>	
14. Inactive license renewal for school speech-language pathology	<u>\$20</u>	
15. Application for provisional license	<u>\$50</u>	
16. Renewal of provisional license		
Fees shall be made payable to the Treasurer of Virginia		

and shall not be refunded once submitted.

Part II Requirements for Licensure

18VAC30-21-50. Application requirements.

<u>A.</u> A person seeking a provisional license or licensure as an audiologist, a speech-language pathologist, or a school speech-language pathologist shall submit:

1. A completed and signed application;

2. The applicable fee prescribed in 18VAC30-21-40;

3. Documentation as required by the board to determine if the applicant has met the qualifications for licensure;

4. An attestation that the applicant has read, understands, and will comply with the statutes and regulations governing the practice of audiology or speech-language pathology; and

5. If licensed or certified in another United States jurisdiction, verification of the status of the license or certification from each jurisdiction in which licensure or certification is held.

B. An incomplete application package shall be retained by the board for a period of one year from the date the application is received by the board. If an application is not completed within the year, an applicant shall reapply and pay a new application fee.

18VAC30-21-60. Qualifications for initial licensure.

A. The board may grant an initial license to an applicant for licensure in audiology or speech-language pathology who:

1. Holds a current and unrestricted Certificate of Clinical Competence issued by ASHA or certification issued by the American Board of Audiology or any other accrediting body recognized by the board. Verification of currency shall be in the form of a certified letter from a recognized accrediting body issued within six months prior to filing an application for licensure; and

2. Has passed the qualifying examination from an accrediting body recognized by the board.

<u>B. The board may grant a license to an applicant as a school</u> <u>speech-language pathologist who</u> [\pm <u>1. Holds holds</u>] <u>a</u> <u>master's degree in speech-language-pathology</u> [\pm <u>and</u>

2. Holds an endorsement in speech language pathology from the Virginia Department of Education.

C. Any individual who holds an active, renewable license issued by the Virginia Board of Education with a valid endorsement in speech-language pathology on June 30, 2014, shall be deemed qualified to obtain a school speech-language pathologist license from the board until July 1, 2016, or the date of expiration of such person's license issued by the Virginia Board of Education, whichever is later.]

18VAC30-21-70. Provisional licensure.

<u>A. Provisional license to qualify for initial licensure. An applicant may be issued a provisional license in order to obtain clinical experience required for certification by ASHA,</u>

the American Board of Audiology, or any other accrediting body recognized by the board. To obtain a provisional license in order to qualify for initial licensure, the applicant shall submit documentation that he has:

<u>1. Passed the qualifying examination from an accrediting body recognized by the board; and</u>

2. Either:

a. For provisional licensure in audiology, successfully completed all the didactic coursework required for the doctoral degree as documented by a college or university whose audiology program is accredited by the Council on Academic Accreditation of ASHA or an equivalent accrediting body; or

b. For provisional licensure in speech-language pathology, successfully completed all the didactic coursework required for a graduate program in speechlanguage pathology as documented by a college or university whose program is accredited by the Council on Academic Accreditation of the American Speech-Language-Hearing Association or an equivalent accrediting body.

B. Provisional license to qualify for endorsement or reentry into practice. An applicant may be issued a provisional license in order to qualify for licensure by endorsement pursuant to 18VAC30-21-80, reactivation of an inactive license pursuant to subsection C of 18VAC30-21-110, or reinstatement of a lapsed license pursuant to subsection B of 18VAC30-21-120.

C. All provisional licenses shall expire 18 months from the date of issuance and may be renewed for an additional six months by submission of a renewal form and payment of a renewal fee. Renewal of a provisional license beyond 24 months shall be for good cause shown as determined by a committee of the board.

D. The holder of a provisional license in audiology shall only practice under the supervision of a licensed audiologist, and the holder of a provisional license in speech-language pathology shall only practice under the supervision of a licensed speech-language pathologist. The provisional licensee shall be responsible and accountable for the safe performance of those direct client care tasks to which he has been assigned.

<u>E. Licensed audiologists or speech-language pathologists</u> providing supervision shall:

1. Notify the board electronically or in writing of the intent to provide supervision for a provisional licensee;

2. Have an active, current license and at least three years of active practice as an audiologist or speech-language pathologist prior to providing supervision;

<u>3. Document the frequency and nature of the supervision of provisional licensees;</u>

4. Be responsible and accountable for the assignment of clients and tasks based on their assessment and evaluation of the provisional licensee's knowledge and skills; and

5. Monitor clinical performance and intervene if necessary for the safety and protection of the clients.

<u>F. The identity of a provisional licensee shall be disclosed to</u> the client prior to treatment and shall be made a part of the client's file.

18VAC30-21-80. Qualifications for licensure by endorsement.

An applicant for licensure in audiology or speech-language pathology who has been licensed in another United States jurisdiction may apply for licensure in Virginia in accordance with application requirements in 18VAC30-20-50 and submission of documentation of:

1. Ten continuing education hours for each year in which he has been licensed in the other jurisdiction, not to exceed 30 hours, or a current and unrestricted Certificate of Clinical Competence in the area in which he seeks licensure issued by ASHA or certification issued by the American Board of Audiology or any other accrediting body recognized by the board. Verification of currency shall be in the form of a certified letter from a recognized accrediting body issued within six months prior to filing an application for licensure;

2. Passage of the qualifying examination from an accrediting body recognized by the board;

3. Current status of licensure in another United States jurisdiction showing that no disciplinary action is pending or unresolved. The board may deny a request for licensure to any applicant who has been determined to have committed an act in violation of 18VAC30-21-160; and

4. Evidence of active practice in another United States jurisdiction for at least one of the past three years or practice for six months with a provisional license in accordance with 18VAC30-21-70 and by providing evidence of a recommendation for licensure by his supervisor.

Part III

Renewal and Continuing Education

18VAC30-21-90. Renewal requirements.

A. A person who desires to renew his license shall, not later than December 31 of each year, submit the renewal notice and applicable renewal fee. A licensee who fails to renew his license by the expiration date shall have a lapsed license, and practice with a lapsed license may constitute grounds for disciplinary action by the board.

B. A person who fails to renew his license by the expiration date may renew at any time within one year of expiration by submission of a renewal notice, the renewal fee and late fee, and statement of compliance with continuing education requirements.

18VAC30-21-100. Continuing education requirements for renewal of an active license.

A. In order to renew an active license, a licensee shall complete at least 10 contact hours of continuing education prior to December 31 of each year. Up to 10 contact hours of continuing education in excess of the number required for renewal may be transferred or credited to the next renewal year.

B. Continuing education shall be activities, programs, or courses related to audiology or speech-language pathology, depending on the license held, and offered or approved by one of the following accredited sponsors or organizations sanctioned by the profession:

<u>1. The Speech-Language-Hearing Association of Virginia</u> or a similar state speech-language-hearing association of another state;

2. The American Academy of Audiology;

3. The American Speech-Language-Hearing Association;

4. The Accreditation Council on Continuing Medical Education of the American Medical Association offering Category I continuing medical education;

5. Local, state, or federal government agencies;

6. Colleges and universities;

7. International Association of Continuing Education and Training; or

8. Health care organizations accredited by the Joint Commission on Accreditation of Healthcare Organizations.

<u>C. If the licensee is dually licensed by this board as an audiologist and speech-language pathologist, a total of no more than 15 hours of continuing education are required for renewal of both licenses with a minimum of 7.5 contact hours in each profession.</u>

<u>D. A licensee shall be exempt from the continuing education</u> requirements for the first renewal following the date of initial licensure in Virginia under 18VAC30-20-60.

E. The licensee shall retain all continuing education documentation for a period of three years following the renewal of an active license. Documentation from the sponsor or organization shall include the title of the course, the name of the sponsoring organization, the date of the course, and the number of hours credited.

<u>F.</u> The board may grant an extension of the deadline for continuing education requirements, for up to one year, for good cause shown upon a written request from the licensee prior to the renewal date of December [<u>31st 31</u>].

<u>G. The board may grant an exemption for all or part of the</u> requirements for circumstances beyond the control of the licensee, such as temporary disability, mandatory military service, or officially declared disasters.

<u>H. The board shall periodically conduct an audit for compliance with continuing education requirements.</u>

Licensees selected for an audit conducted by the board shall complete the Continuing Education Activity and Assessment Form and provide all supporting documentation within 30 days of receiving notification of the audit.

<u>I. Failure to comply with these requirements may subject the licensee to disciplinary action by the board.</u>

Part IV

Reactivation and Reinstatement

<u>18VAC30-21-110.</u> Inactive licensure; reactivation for audiologists [and or] speech-language pathologists.

A. An audiologist or speech-language pathologist who holds a current, unrestricted license in Virginia may, upon a request on the renewal application and submission of the required fee, be issued an inactive license. The holder of an inactive license shall not be required to maintain continuing education requirements and shall not be entitled to perform any act requiring a license to practice audiology or speech-language pathology in Virginia.

B. A licensee whose license has been inactive and who requests reactivation of an active license shall file an application, pay the difference between the inactive and active renewal fees for the current year, and provide documentation of current ASHA certification or of having completed 10 continuing education hours equal to the requirement for the number of years in which the license has been inactive, not to exceed 30 contact hours.

<u>C. A licensee who does not reactivate within five years shall</u> meet the requirements of subsection B of this section and shall either:

<u>1. Meet the requirements for initial licensure as prescribed</u> by 18VAC30-21-60; or

2. Provide documentation of a current license in another jurisdiction in the United States and evidence of active practice for at least one of the past three years or practice in accordance with 18VAC30-21-70 with a provisional license for six months and submit a recommendation for licensure from his supervisor.

D. If the licensee holds licensure in any other state or jurisdiction, he shall provide evidence that no disciplinary action is pending or unresolved. The board may deny a request for reactivation to any licensee who has been determined to have committed an act in violation of 18VAC30-21-160.

18VAC30-21-120. Reinstatement of a lapsed license for audiologists or speech-language pathologists.

A. When a license has not been renewed within one year of the expiration date, a person may apply to reinstate his license by submission of a reinstatement application, payment of the reinstatement fee, and submission of documentation of current ASHA certification or at least 10 continuing education hours for each year the license has been lapsed, not to exceed 30 contact hours, obtained during the time the license in Virginia was lapsed. B. A licensee who does not reinstate within five years shall meet the requirements of subsection A of this section and shall either:

<u>1. Reinstate by meeting the requirements for initial</u> licensure as prescribed by 18VAC30-21-60; or

2. Provide documentation of a current license in another United States jurisdiction and evidence of active practice for at least one of the past three years or practice in accordance with 18VAC30-21-70 with a provisional license for six months and submit a recommendation for licensure from his supervisor.

C. If the licensee holds licensure in any other state or jurisdiction, he shall provide evidence that no disciplinary action is pending or unresolved. The board may deny a request for reinstatement to any licensee who has been determined to have committed an act in violation of 18VAC30-21-160.

18VAC30-21-130. Reactivation or reinstatement of a school speech-language pathologist.

A. A school speech-language pathologist whose license has been inactive and who requests reactivation of an active license shall file an application and pay the difference between the inactive and active renewal fees for the current year. A school speech-language pathologist whose license has lapsed and who requests reinstatement shall file an application and pay the reinstatement fee as set forth in 18VAC30-20-40.

<u>B. The board may reactivate or reinstate licensure as a</u> school speech-language pathologist to an applicant who:

1. Holds a master's degree in speech-language-pathology; and

2. Holds a current endorsement in speech-language pathology from the Virginia Department of Education.

<u>C. The board may deny a request for reactivation or reinstatement to any licensee who has been determined to have committed an act in violation of 18VAC30-21-160.</u>

[<u>18VAC30-21-131.</u> Performance of flexible endoscopic evaluation of swallowing.

A. For the purposes of this section, an endoscopic procedure shall mean a flexible endoscopic evaluation of swallowing limited to the use of flexible endoscopes to observe, collect data, and measure the parameters of swallowing for the purposes of functional assessment and therapy planning.

<u>B.</u> A speech-language pathologist who performs an endoscopic procedure shall meet the following qualifications:

<u>1. Completion of a course or courses or an educational</u> program offered by a provider approved in 18VAC30-20-100 that includes at least 12 hours on endoscopic procedures;

2. Successful performance of at least 25 flexible endoscopic procedures under the immediate and direct supervision of a board-certified otolaryngologist or another

speech-language pathologist who has successfully performed at least 50 flexible endoscopic procedures beyond the 25 required for initial qualification and has been approved in writing by a board-certified otolaryngologist to provide that supervision; and

3. Current certification in basic life support.

C. The speech-language pathologist who qualifies to perform an endoscopic procedure pursuant to subsection B of this section shall maintain documentation of course completion and written verification from the supervising otolaryngologist or speech-language pathologist of successful completion of flexible endoscopic procedures.

D. An endoscopic procedure shall only be performed by a speech-language pathologist on referral from an otolaryngologist or other qualified physician.

E. A speech-language pathologist shall only perform an endoscopic procedure in a facility that has protocols in place for emergency medical backup. A flexible endoscopic evaluation of swallowing shall only be performed by a speech-language pathologist in either:

1. A licensed hospital or nursing home under the general supervision of a physician who is readily available in the event of an emergency, including physical presence in the facility or available by telephone; or

2. A physician's office at which the physician is on premises and available to provide onsite supervision.

F. The speech-language pathologist shall promptly report any observed abnormality or adverse reaction to the referring physician, an appropriate medical specialist, or both. The speech-language pathologist shall provide a report of an endoscopic procedure to the referring physician in a timely manner and, if requested, shall ensure access to a visual recording for viewing.

<u>G. A speech-language pathologist is not authorized to</u> possess or administer prescription drugs except as provided in § 54.1-3408 B of the Code of Virginia.

<u>H. A speech-language pathologist who has been performing flexible endoscopic evaluations of swallowing prior to October 7, 2015, may continue to perform such evaluations provided he has written verification from a board-certified otolaryngologist that he has the appropriate training, knowledge, and skills to safely perform such evaluations.</u>]

Part V Standards of Practice

18VAC30-21-140. Supervision of unlicensed assistants.

A. If a licensed audiologist or speech-language pathologist has unlicensed assistants, he shall document supervision of them, shall be held fully responsible for their performance and activities, and shall ensure that they perform only those activities which do not constitute the practice of audiology or speech-language pathology and which are commensurate with their level of training. <u>B. A licensee may delegate to an unlicensed assistant such activities or functions that are nondiscretionary and do not require the exercise of professional judgment for performance.</u>

<u>C. The identity of the unlicensed assistant shall be disclosed</u> to the client prior to treatment and shall be made a part of the client's file.

18VAC30-21-150. Prohibited conduct.

A. No person, unless otherwise licensed to do so, shall prepare, order, dispense, alter, or repair hearing aids or parts of or attachments to hearing aids for consideration. However, audiologists licensed under this chapter may make earmold impressions and prepare and alter earmolds for clinical use and research.

<u>B. No person licensed as a school speech-language</u> pathologist shall conduct the practice of speech-language pathology outside of the public school setting.

18VAC30-21-160. Unprofessional conduct.

The board may refuse to issue a license to any applicant, suspend a license for a stated period of time or indefinitely, reprimand a licensee or place his license on probation with such terms and conditions and for such time as it may designate, impose a monetary penalty, or revoke a license for any of the following:

1. Guarantee of the results of any speech, voice, language, or hearing consultative or therapeutic procedure or exploitation of clients by accepting them for treatment when benefit cannot reasonably be expected to occur or by continuing treatment unnecessarily:

<u>2. Diagnosis or treatment of speech, voice, language, and hearing disorders solely by written correspondence, provided this shall not preclude:</u>

<u>a. Follow-up by written correspondence or electronic</u> <u>communication concerning individuals previously seen:</u> <u>or</u>

b. Providing clients with general information of an educational nature;

3. Failure to comply with provisions of § 32.1-127.1:03 of the Code of Virginia related to the confidentiality and disclosure of client records or related to provision of client records to another practitioner or to the client or his personal representative;

4. Failure to properly manage and keep timely, accurate, legible, and complete client records, to include the following:

a. For licensees who are employed by a health care institution, school system, or other entity, in which the individual practitioner does not own or maintain his own records, failure to maintain client records in accordance with the policies and procedures of the employing entity; or

b. For licensees who are self-employed or employed by an entity in which the individual practitioner does own and is responsible for client records, failure to maintain a client record for a minimum of six years following the last client encounter with the following exceptions:

(1) For records of a minor child, the minimum time is six years from the last client encounter or until the child reaches the age of 18 or becomes emancipated, whichever is longer; or

(2) Records that have previously been transferred to another practitioner or health care provider or provided to the client or his personal representative as documented in a record or database maintained for a minimum of six years;

5. Engaging or attempting to engage in a relationship with a client that constitutes a professional boundary violation in which the practitioner uses his professional position to take advantage of the vulnerability of a client or a client's family, including but not limited to sexual misconduct with a client or a member of the client's family or other conduct that results or could result in personal gain at the expense of the client:

6. Incompetence or negligence in the practice of the profession;

7. Failure to comply with applicable state and federal statutes or regulations specifying the consultations and examinations required prior to the fitting of a new or replacement prosthetic aid for any communicatively impaired person;

8. Failure to refer a client to an appropriate health care practitioner when there is evidence of an impairment for which assessment, evaluation, care, or treatment might be necessary;

9. Failure to supervise persons who assist in the practice of audiology or speech-language pathology as well as failure to disclose the use and identity of unlicensed assistants;

10. Conviction of a felony or a misdemeanor involving moral turpitude;

11. Violating or cooperating with others in violating any of the provisions of Chapters 1 (§ 54.1-100 et seq.), 24 (§ 54.1-2400 et seq.), or 26 (§ 54.1-2600 et seq.) of Title 54 of the Code of Virginia or the regulations of the board;

12. Publishing or causing to be published in any manner an advertisement relating to his professional practice that is false, deceptive, or misleading;

13. Inability to practice with skill and safety;

14. Fraud, deceit, or misrepresentation in provision of documentation or information to the board or in the practice of audiology or speech-language pathology;

15. Aiding and abetting unlicensed activity; or

16. Revocation, suspension, restriction, or any other discipline of a license or certificate to practice or surrender

of license or certificate while an investigation or administrative proceedings are pending in another regulatory agency in Virginia or another jurisdiction.

18VAC30-21-170. Criteria for delegation to an agency subordinate.

A. Decision to delegate. In accordance with subdivision 10 of § 54.1-2400 of the Code of Virginia, the board may delegate an informal fact-finding proceeding to an agency subordinate upon determination that probable cause exists that a practitioner may be subject to a disciplinary action.

<u>B. Criteria for delegation. Cases that may not be delegated</u> to an agency subordinate are those that involve:

<u>1. Intentional or negligent conduct that causes or is likely</u> to cause injury to a patient;

<u>2. Mandatory suspension resulting from action by another jurisdiction or a felony conviction;</u>

3. Impairment with an inability to practice with skill and safety;

4. Sexual misconduct;

5. Unauthorized practice.

C. Criteria for an agency subordinate.

1. An agency subordinate authorized by the board to conduct an informal fact-finding proceeding may include board members and professional staff or other persons deemed knowledgeable by virtue of their training and experience in administrative proceedings involving the regulation and discipline of health professionals.

2. The executive director shall maintain a list of appropriately qualified persons to whom an informal fact-finding proceeding may be delegated.

3. The board may delegate to the executive director the selection of the agency subordinate who is deemed appropriately qualified to conduct a proceeding based on the qualifications of the subordinate and the type of case being heard.

<u>NOTICE:</u> The following forms used in administering the regulation were filed by the agency. The forms are not being published; however, online users of this issue of the Virginia Register of Regulations may click on the name of a form with a hyperlink to access it. The forms are also available from the agency contact or may be viewed at the Office of the Registrar of Regulations, General Assembly Building, 2nd Floor, Richmond, Virginia 23219.

FORMS (18VAC30-21)

Continuing Education Form (rev. 3/2015)

VA.R. Doc. No. R11-2759; Filed June 18, 2016, 11:21 a.m.

Volume 32, Issue 23

Virginia Register of Regulations

BOARD OF VETERINARY MEDICINE

Final Regulation

<u>Title of Regulation:</u> 18VAC150-20. Regulations Governing the Practice of Veterinary Medicine (amending 18VAC150-20-70).

Statutory Authority: §§ 54.1-2400 and 54.1-3805.2 of the Code of Virginia.

Effective Date: August 10, 2016.

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

Summary:

The amendment increases the number of continuing education hours required for renewal of a veterinary technician license to eight hours per year.

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

18VAC150-20-70. Licensure renewal requirements.

A. Every person licensed by the board shall, by January 1 of every year, submit to the board a completed renewal application and pay to the board a renewal fee as prescribed in 18VAC150-20-100. Failure to renew shall cause the license to lapse and become invalid, and practice with a lapsed license may subject the licensees to disciplinary action by the board. Failure to receive a renewal notice does not relieve the licensee of his responsibility to renew and maintain a current license.

B. Veterinarians shall be required to have completed a minimum of 15 hours, and veterinary technicians shall be required to have completed a minimum of six eight hours, of approved continuing education for each annual renewal of licensure. Continuing education credits or hours may not be transferred or credited to another year.

1. Approved continuing education credit shall be given for courses or programs related to the treatment and care of patients and shall be clinical courses in veterinary medicine or veterinary technology or courses that enhance patient safety, such as medical recordkeeping or compliance with requirements of the Occupational Health and Safety Administration (OSHA).

2. An approved continuing education course or program shall be sponsored by one of the following:

a. The AVMA or its constituent and component/branch associations, specialty organizations, and board certified specialists in good standing within their specialty board;

b. Colleges of veterinary medicine approved by the AVMA Council on Education;

c. International, national, or regional conferences of veterinary medicine;

d. Academies or species specific interest groups of veterinary medicine;

e. State associations of veterinary technicians;

f. North American Veterinary Technicians Association;

g. Community colleges with an approved program in veterinary technology;

h. State or federal government agencies;

i. American Animal Hospital Association (AAHA) or its constituent and component/branch associations;

j. Journals or veterinary information networks recognized by the board as providing education in veterinary medicine or veterinary technology; or

k. An organization or entity approved by the Registry of Approved Continuing Education of the American Association of Veterinary State Boards.

3. A licensee is exempt from completing continuing education requirements and considered in compliance on the first renewal date following his initial licensure by examination.

4. The board may grant an exemption for all or part of the continuing education requirements due to circumstances beyond the control of the licensee, such as temporary disability, mandatory military service, or officially declared disasters.

5. The board may grant an extension for good cause of up to one year for the completion of continuing education requirements upon written request from the licensee prior to the renewal date. Such an extension shall not relieve the licensee of the continuing education requirement.

6. Licensees are required to attest to compliance with continuing education requirements on their annual license renewal and are required to maintain original documents verifying the date and subject of the program or course, the number of continuing education hours or credits, and certification from an approved sponsor. Original documents must be maintained for a period of two years following renewal. The board shall periodically conduct a random audit to determine compliance. Practitioners selected for the audit shall provide all supporting documentation within 10 days of receiving notification of the audit.

7. Continuing education hours required by disciplinary order shall not be used to satisfy renewal requirements.

C. A licensee who has requested that his license be placed on inactive status is not authorized to perform acts that are considered the practice of veterinary medicine or veterinary technology and, therefore, shall not be required to have continuing education for annual renewal. To reactivate a license, the licensee is required to submit evidence of completion of continuing education hours as required by

§ 54.1-3805.2 of the Code of Virginia equal to the number of years in which the license has not been active for a maximum of two years.

VA.R. Doc. No. R14-18; Filed June 18, 2016, 11:18 a.m.

EXECUTIVE ORDER NUMBER 55 (2016)

Directing the Commissioner of the Department of Motor Vehicles to Extend the Validity of Expiring Driver's Licenses

Importance of the Issue

On Saturday May 21, 2016, an internal power disruption temporarily interrupted the electronic services provided by the Commonwealth's data center. This disruption greatly impacted the ability of many Virginians to renew their driver's licenses. On May 23, 2016, I verbally directed the Commissioner of the Department of Motor Vehicles to extend the validity period for expiring licenses for a period of one week. This unforeseen disruption of services places citizens at risk of suffering fines and others costs resulting from their inability to timely renew their driver's licenses.

Therefore, by virtue of the authority vested in me as Governor, and subject always to my continuing and ultimate authority and responsibility to act in such matters, I hereby confirm, ratify, and memorialize in writing that verbal directive issued on May 23, 2016, whereby it was determined that the Department of Motor Vehicles suffered a disruption in service that prevented the Department from processing applications for renewal of driver's licenses.

In order to prevent any further hardship to the citizens of Virginia, and in accordance with my authority contained in §§ 46.2-330 (A) and 46.2-345 of the Code of Virginia, I hereby order the following measures:

I hereby direct the Commissioner of the Department of Motor Vehicles, and such other executive branch agencies as deem appropriate in their discretion, to extend the validity period of Virginia driver's license, permits and commercial driver's licenses issued by the Commonwealth that expire May 21, 2016, through May 22, 2016, until May 28, 2016.

Effective Date of this Executive Order

This Executive Order shall be effective retroactively from May 21, 2016, and shall remain in full force and effect until May 28, 2016.

Given under my hand and under the Seal of the Commonwealth of Virginia, this 24th day of May, 2016.

/s/ Terence R. McAuliffe Governor

EXECUTIVE ORDER NUMBER 56 (2016)

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

Part I - Importance of the Issue

On June 23, 2016, I verbally declared a state of emergency to exist for the Commonwealth of Virginia based on record level flooding of the Jackson River watershed. The extended rain showers, flash flooding, and high winds have the potential to impact life safety and create significant transportation issues throughout the Commonwealth.

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 June 23, 2016, whereby I proclaimed that a state of emergency exists, and I directed that appropriate assistance be rendered by agencies of both state and local governments to prepare for potential impacts of the flooding, 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 also directed 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 system 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 flooding, 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.

Governor

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 \$1,600,000 in state sum sufficient funds for state and local government 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, \$100,000 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 (CERT), 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 sitting, 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 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.

Part II - Effective Date of this Executive Order

This Executive Order shall be effective as of June 23, 2016, and shall remain in full force and effect until September 30, 2016 unless sooner amended or rescinded by further executive order. Termination of the Executive Order is not intended to terminate any federal-type benefits granted or to be granted due to injury or death as a result of service under this Executive Order.

Given under my hand and under the Seal of the Commonwealth of Virginia, this 24th day of June, 2016.

/s/ Terence R. McAuliffe Governor

GENERAL NOTICES/ERRATA

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 Criminal Justice Services Board is currently reviewing each of the regulations listed below to determine whether the regulation 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). Public comment is sought on the review of any issue relating to each 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.

6VAC20-50, Rules Relating to Compulsory Minimum Training Standards for Jailors or Custodial Officers, Courthouse and Courtroom Security Officers and Process Service Officers

6VAC20-180, Crime Prevention Specialists

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

The comment period begins July 11, 2016, and ends August 11, 2016.

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

DEPARTMENT OF ENVIRONMENTAL QUALITY

Twittys Creek Solar LLC Notice of Intent - Small Renewable Energy Project (Solar) Permit by Rule

Twittys Creek Solar, LLC has notified the Department of Environmental Quality of its intent to submit the necessary documentation for a permit by rule for a small renewable energy project (solar) in Charlotte County, pursuant to 9VAC15-60. The project is located west of the intersection of Highway 59 and Ingleside Lane and will have a maximum capacity of 15 megawatts alternating current. The array will utilize approximately 65,100 ground-mounted photovoltaic solar modules, or equivalent, feeding into six 2.5 megawatt inverters, or equivalent, before interconnection. <u>Contact Information:</u> Mary E. Major, Department of Environmental Quality, 629 East Main Street, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4423, FAX (804) 698-4510, or email mary.major@deq.virginia.gov.

Application for No Discharge Zones within Gloucester County

Purpose of notice: The Virginia Department of Environmental Quality (DEQ) is announcing its intent to apply to the U.S. Environmental Protection Agency (EPA) for two federal no discharge zones (NDZs) and is seeking public comment on the draft application.

Public meeting: Wednesday, July 27, 2016, 6 p.m. at the Abingdon Elementary School, in library room B103, 7087 Powhatan Drive, Hayes, VA 23072.

Meeting description: To provide a summary of a draft application for designation of selected waterbodies within Gloucester County (Sarah Creek and Perrin River) as federal no discharge zones (NDZs). The NDZ designation would prohibit the overboard discharge of treated sewage effluent from marine sanitation devices (MSDs) in these waterways.

Description of study: Section 62.1-44.33of the Code of Virginia resolves that all tidal creeks in Virginia be designated federal no discharge zones premised on the improvement of impaired tidal creeks and directs the DEQ to pursue this designation. It is currently illegal to discharge raw sewage in U.S. territorial waters. In a NDZ, this ban is expanded to include sewage treated by on-board marine sanitation devices. A NDZ is determined by EPA upon application from the state and is contingent on the state demonstrating (1) the need for enhanced protection of water quality, (2) the availability of sufficient local alternatives to overboard discharge (i.e., pump-outs), and (3) local stakeholder support. DEQ is seeking this designation as one component of a "pollution diet" for small tidal Chesapeake Bay tributaries, which are frequently impaired for shellfish harvest due to elevated levels of fecal bacteria. The Go Green Committee of Gloucester County has partnered with the Virginia Institute of Marine Science to conduct an analysis of boat usage and pump-out availability for Sarah Creek and Perrin River in Gloucester County, and DEQ has concluded that existing pump-out facilities are adequate to service estimated peak-demand. A draft application to EPA for NDZ designation has been prepared and will be available for public comment on the DEO review and website at http://www.deq.virginia.gov/Programs/Water/WaterQualityInfor mationTMDLs/TMDL/NoDischargeZoneDesignations.aspx the day after the public meeting. Presentations provided at the meeting will also be available on the website.

How to comment: DEQ will accept written comments beginning Thursday, July 28, 2016, by email or postal mail. Comments should include the name, address, and telephone number of the person commenting and be received by DEQ

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during the comment period, which will expire Friday, August 26, 2016.

Contact for additional information and send comments to: Anne Schlegel, TMDL Coordinator, Department of Environmental Quality, Central Office, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4046, or email anne.schlegel@deq.virginia.gov.

STATE BOARD OF HEALTH

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 Health is conducting a periodic review and small business impact review of **12VAC5-610**, **Sewage Handling and Disposal Regulations**.

The review of this regulation will be guided by the principles in Executive Order 17 (2014).

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

The comment period begins July 11, 2016, and ends August 1, 2016.

Comments may be submitted online to the Virginia Regulatory Town Hall http://www.townhall.virginia.gov/L/Forums.cfm. Comments may also be sent to Dwayne Roadcap, Director, Division of Onsite Sewage, Water Services, Environmental Engineering and Marina Programs, Virginia Department of Health, 109 Governor Street, Richmond, VA 23219, telephone (804) 864-7458. FAX (804)864-7475, or email dwayne.roadcap@vdh.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.

VIRGINIA LOTTERY

Director's Orders

The following Director's Orders of the Virginia Lottery were filed with the Virginia Registrar of Regulations on June 20, 2016, and June 27, 2016. The orders may be viewed at the Virginia Lottery, 900 East Main Street, Richmond, Virginia, or at the office of the Registrar of Regulations, 201 North 9th Street, 2nd Floor, Richmond, Virginia.

Director's Order Number Ninety-Four (16)

Virginia Lottery's Scratch Game 1703 "BIG BILLS" Final Rules for Game Operation (effective June 6, 2016)

Director's Order Number Ninety-Five (16)

Virginia Lottery's Scratch Game 1684 "Hot Winnings" Final Rules for Game Operation (effective June 6, 2016)

Director's Order Number Ninety-Six (16)

Certain Virginia Print 'n Play Games; End of Games

Virginia Lottery's Print 'n Play Blackjack (22 16)

Virginia Lottery's Print 'n Play Bonus Bingo (19 16)

Virginia Lottery's Print 'n Play Daily Crossword (17 16)

Virginia Lottery's Print 'n Play Hot 'n Spicy Bingo (2016)

Virginia Lottery's Print 'n Play Smokin' Hot Crossword (13 16)

(This Director's Order is effective on July 9, 2016, and shall remain in full force and effect unless amended or rescinded by further Director's Order)

Director's Order Number Ninety-Seven (16)

Virginia Lottery's "Q1 FY17 eXTRA Chances Scratcher Promotion" Final Rules for Operation (effective June 28, 2016)

DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

2016 Notice of Intent to Amend Medicaid Reimbursement Rates - Virginia State Plan for Medical Assistance (pursuant to § 1902(a)(13) of the Social Security Act (USC § 1396a(a)(13)))

Revised Notice dated June 15, 2016

The Virginia Department of Medical Assistance Services (DMAS) hereby affords the public notice of its intention to amend the Virginia State Plan for Medical Assistance to provide for changes to the Amount, Duration, and Scope of Medical and Remedial Care Services (12VAC30-50); Methods and Standards for Establishing Payment Rates - Inpatient Hospital Services (12VAC30-70); Methods and Standards for Establishing Payment Rates; Other Types of Care (12VAC30-80); and Methods and Standards for

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Establishing Payment Rates for Long-Term Care (12VAC30-90).

This notice is intended to satisfy the requirements of 42 CFR § 447.205 and of § 1902(a)(13) of the *Social Security Act*, 42 USC § 1396a(a)(13). A copy of this notice is available for public review from the contact listed at the end of this notice.

DMAS is specifically soliciting input from stakeholders, providers, and beneficiaries, on the potential impact of the proposed reduction in the hospital inflation adjustment on beneficiary access to care. Comments or inquiries may be submitted, in writing, within 30 days of this notice publication to Mr. Lessard and such comments are available for review at the same address. Comments may also be submitted, in writing, on the Town Hall public comment forum attached this notice to at http://townhall.virginia.gov/L/Email Notice.cfm?GNid=606 &CFID=24385644&CFTOKEN=4dabe0a4218fb3ac-504D2605-EA48-541B-F92DE31D6CF24206.

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

DMAS is making these changes in its methods and standards for setting payment rates for services in order to comply with the legislative mandates set forth in the Item 306 of Chapter 780 of the 2016 Acts of Assembly.

Reimbursement Changes Affecting Hospitals (12VAC30-70)

12VAC30-70-351 is being amended to reduce fiscal year (FY) 2017 inflation by 50% for inpatient and outpatient hospital operating (including freestanding psychiatric and long stay hospitals), graduate medical education (GME) and indirect medical education (IME) payments, disproportionate share hospital (DSH) payments and outpatient hospital rates with the exception of 100% of inflation for inpatient and outpatient hospital operating, GME, and IME payments for Children's Hospital of King's Daughters.

The expected decrease in annual aggregate expenditures is \$13,895,790.

12VAC30-70-221 and 12VAC30-70-381 are being amended to change the methodology for costing claims used to rebase weights from a fee-for-service global cost-to-charge methodology to a methodology that uses per diems and costto-charge ratios by cost center for the fee-for-service and managed care claims, effective July 1, 2016. In a similar fashion, each hospital's total costs by claim using this methodology will be divided by the total charges for the hospital cost-to-charge ratio.

The expected increase in annual aggregate expenditures is \$0.

12VAC30-70-281 is being amended to create GME supplemental payments for new primary care and high-need specialty residencies, effective July 1, 2017.

The expected increase in annual aggregate expenditures is \$2,500,000.

<u>Reimbursement Changes Affecting Other Providers</u> (12VAC30-80)

12VAC30-80-32 is being amended to increase rates for existing substance use disorder services and add rates for new substance use disorder services, effective April 1, 2017, and peer support services, effective January 1, 2017.

The expected annual increase in expenditures for the rate increase is \$1,460,647, and the expected annual increase for expenditures for new services is \$2,871,908. Administrative expenses of the program are expected to be \$872,269 for a total annual aggregate increase of \$5,204,824.

12VAC30-80-30 is being amended to implement a supplemental payment for Children's National Health System physicians, effective July 1, 2016. The total supplemental Medicaid payment shall be based on the upper payment limit approved by CMS and all other Virginia Medicaid fee-forservice payments but not to exceed \$551,000.

The expected increase in annual aggregate expenditures is \$551,000.

<u>Reimbursement</u> Changes Affecting Nursing Facilities (12VAC30-90)

12VAC30-90-264 is being amended to convert the specialized care rate methodology to a fully prospective state fiscal year rate, effective July 1, 2016. This would be accomplished consistent with the existing cost-based methodology by adding inflation to the per diem costs subject to existing ceilings for direct, indirect and ancillary costs from the most recent settled cost report prior to the state fiscal year for which the rates are being established. The same inflation adjustment shall apply to plant costs for specialized care facilities that do not have prospective capital rates that are based on fair rental value. The department shall use the state fiscal year inflation rate recently adopted for regular nursing facilities. Partial year inflation shall be applied to per diem costs if the provider fiscal year end is different than the state fiscal year. Ceilings shall also be maintained by state fiscal year.

The expected increase in annual aggregate expenditures is \$0.

<u>Contact Information</u>: William Lessard, Director, Division of Provider Reimbursement, Department of Medical Assistance Services, 600 East Broad Street, Suite 1300, Richmond, VA 23219, telephone (804) 225-4593, FAX (804) 786-1680, or email william.lessard@dmas.virginia.gov.

VIRGINIA WASTE MANAGEMENT BOARD

Notice of Periodic Review and Small Business Impact Review

Pursuant to Executive Order 17 (2014) and §§ 2.2-4007.1 and 2.2-4017 of the Code of Virginia, the Department of Environmental Quality on behalf of the Waste Management Board is conducting a periodic review and small business impact review of **9VAC20-190**, Litter Receptacle Regulations.

The review of this regulation will be guided by the principles in Executive Order 17 (2014).

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

The comment period begins July 11, 2016, and ends August 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 Melissa Porterfield, Policy Analyst, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4238, FAX (804) 698-4019, or email melissa.porterfield@deq.virginia.gov.

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

STATE WATER CONTROL BOARD

Proposed Consent Special Order for Wakefield Peanut Company, LLC

An enforcement action has been proposed for Wakefield Peanut Company, LLC for alleged violations that occurred at its property located at 11253 General Mahone Highway, Sussex County, Virginia. The proposed consent special order requires corrective actions to resolve the noncompliance and payment of a civil charge. A description of the proposed action is available at the Department of Environmental below Quality office named online or at www.deq.virginia.gov. David Robinett will accept comments by email at david.robinett@deq.virginia.gov, FAX at (804) 527-5106, or postal mail at Department of Environmental Quality, Piedmont Regional Office, 4949-A Cox Road, Glen Allen, VA 23060-6295, from July 13, 2016, to August 14, 2016;

Total Maximum Daily Loads for the McClure River, Big Spraddle Branch, Buffalo Creek, and Roaring Fork in Dickenson County

The Department of Environmental Quality (DEQ) seeks written and oral comments from interested persons on the development of total maximum daily loads (TMDLs) for the McClure River, Big Spraddle Branch, Buffalo Creek, and Roaring Fork in Dickenson County. These streams are listed on the 2012 § 303(d) TMDL Priority List and Report as impaired due to violations of the state's water quality standards for bacteria.

Section 303(d) of the Clean Water Act and § 62.1-44.19:7 C of the State Water Control Law requires DEQ to develop TMDLs for pollutants responsible for each impaired water contained in Virginia's § 303(d) TMDL Priority List and Report.

The impaired segments include: 21.76 miles of the McClure River from the headwaters downstream to the Road Branch confluence near Steinman; 2.31 miles of Big Spraddle Branch, a tributary to the McClure River west of Stratton; 3.25 miles of Buffalo Creek, a tributary to the McClure River north of Nora; 1.08 miles of Roaring Fork, a tributary to the McClure River upstream of Nora.

The first public meeting on the development of the TMDL to address the bacteria impairments for these segments will be held on July 14, 2016, from 6 p.m. to 8 p.m. at the McClure Kiwanis Building located at the intersection of State Route 63 (Dante Mountain Road) and State Route 773 (Herndon Road) in the McClure Community, Dickenson County, Virginia.

The public comment period will begin July 14, 2016, and end August 15, 2015.

An advisory committee to assist in development of this TMDL may be established. Any person interested in assisting should notify the DEQ contact person by the end of the comment period and provide name, address, phone number, email address, and the organization being represented (if any). Notification of the composition of the panel will be sent to all applicants.

A component of a TMDL is the wasteload allocations (WLAs); therefore, this notice is provided pursuant to § 2.2-4006 A 14 of the Code of Virginia for any future adoption of the TMDLs associated WLAs. Information on the development of the TMDLs for these impairments is available upon request. Questions or information requests should be addressed to Martha Chapman. All written comments should include name, address, and telephone number of the person submitting the comments and should be

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sent to DEQ contact person Martha Chapman, Department of Environmental Quality, Southwest Regional Office, 355-A Deadmore Street, Abingdon, VA 24210, telephone (276) 676-4800, or email martha.chapman@deq.virginia.gov.

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/cumultab.pdf.

Filing Material for Publication in the Virginia Register of *Regulations*: Agencies use the Regulation Information System (RIS) to file regulations and related items for publication in the Virginia Register of Regulations. The Registrar's office works closely with the Department of Planning and Budget (DPB) to coordinate the system with the Virginia Regulatory Town Hall. RIS and Town Hall complement and enhance one another by sharing pertinent regulatory information.

ERRATA

STATE BOARD OF HEALTH

Title of Regulation: 12VAC5-421. Food Regulations.

Publication: 32:22 VA.R. 2866 June 27, 2016

Correction to Title of Regulation:

Page 2866, column 2, delete "12VAC5-421-750,"

VA.R. Doc. No. R16-2701

DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

<u>Titles of Regulations:</u> 12VAC30-50. Amount Duration, and Scope of Medical and Remedial Care Services (amending 12VAC30-50-226).

12VAC30-60. Standards Established and Methods Used to Assure High Quality Care (amending 12VAC30-60-143).

Publication: 32:22 VA.R. 2936-2951 June 27, 2016

Correction to Final Regulation:

Page 2950, column 2, 12VAC30-60-143 I 18, line 4, replace "4160" with "[<u>4160 416</u>]"

Page 2951, column 1, 12VAC30-60-143 I 18, line 1, replace "80" with "[<u>80 8</u>]"

Page 2951, column 1, 12VAC 30-60-143 I 18, line 4, replace "20" with "[<u>20 2</u>]"

VA.R. Doc. No. R14-3451; Filed June 23, 2016, 11:51 a.m.