http://register.dls.virginia.gov Virginia Code Commission

Virginia Register of Regulations

VOL. 27 ISS. 9 PUBLISHED EVERY OTHER WEEK BY THE VIRGINIA CODE COMMISSION JANUARY 3, 2011

TABLE OF CONTENTS

THE VIRGINIA REGISTER OF REGULATIONS (USPS 001-831) is published biweekly by Matthew Bender & Company, Inc., 1275 Broadway, Albany, NY 12204-2694 for $197.00 per year. Periodical postage is paid in Albany, NY and at additional mailing offices. POSTMASTER: Send address changes to The Virginia Register of Regulations, 136 Carlin Road, Conklin, NY 13748-1531.

THE VIRGINIA REGISTER INFORMATION PAGE

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

ADOPTION, AMENDMENT, AND REPEAL OF REGULATIONS

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

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

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

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

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

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

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

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

FAST-TRACK RULEMAKING PROCESS

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

EMERGENCY REGULATIONS

Pursuant to § 2.2-4011 of the Code of Virginia, an agency, upon consultation with the Attorney General, and at the discretion of the Governor, may adopt emergency regulations that are necessitated by an emergency situation. An agency may also adopt an emergency regulation when Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment. The emergency regulation becomes operative upon its adoption and filing with the Registrar of Regulations, unless a later date is specified. Emergency regulations are limited to no more than 12 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. **26:20 VA.R. 2510-2515 June 7, 2010,** refers to Volume 26, Issue 20, pages 2510 through 2515 of the *Virginia Register* issued on June 7, 2010.

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

PUBLICATION SCHEDULE AND DEADLINES

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

January 2011 through December 2011

Volume: Issue	Material Submitted By Noon*	Will Be Published On
27:9	December 14, 2010 **(Tuesday)**	January 3, 2011
27:10	December 28, 2010 **(Tuesday)**	January 17, 2011
27:11	January 12, 2011	January 31, 2011
27:12	January 26, 2011	February 14, 2011
27:13	February 9, 2011	February 28, 2011
27:14	February 23, 2011	March 14, 2011
27:15	March 9, 2011	March 28, 2011
27:16	March 23, 2011	April 11, 2011
27:17	April 6, 2011	April 25, 2011
27:18	April 20, 2011	May 9, 2011
27:19	May 4, 2011	May 23, 2011
27:20	May 18, 2011	June 6, 2011
27:21	June 1, 2011	June 20, 2011
27:22	June 15, 2011	July 4, 2011
27:23	June 29, 2011	July 18, 2011
27:24	July 13, 2011	August 1, 2011
27:25	July 27, 2011	August 15, 2011
27:26	August 10, 2011	August 29, 2011
28:1	August 24, 2011	September 12, 2011
28:2	September 7, 2011	September 26, 2011
28:3	September 21, 2011	October 10, 2011
28:4	October 5, 2011	October 24, 2011
28:5	October 19, 2011	November 7, 2011
28:6	November 2, 2011	November 21, 2011
28:7	November 15, 2011 **(Tuesday)**	December 5, 2011

*Filing deadlines are Wednesdays unless otherwise specified.

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 the following regulation: **9VAC25-740, Water Reclamation and Reuse Regulation.** The purpose of the proposed action is to amend the Water Reclamation and Reuse Regulation that became effective October 1, 2008, to address changes to the regulation that have been identified by both the Department of Environmental Quality and the public that would improve the State Water Control Board's ability to implement a more effective water reclamation and reuse regulatory program. Two items that will be addressed among other changes to improve implementation of the regulation are (i) the inflexibility of the regulation to accept deviations from design or operational requirements that may discourage projects capable of producing or distributing reclaimed water suitable for reuse in a manner protective of the environment and public health; and (ii) the lack of provisions to authorize temporary water reclamation and reuse without a permit during periods of significant drought to conserve potable water supply.

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

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

Public Comment Deadline: February 14, 2011.

Agency Contact: Valerie Rourke, Department of Environmental Quality, 629 East Main Street, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4158, TTY (804) 698-4021, or email valerie.rourke@deq.virginia.gov.

VA.R. Doc. No. R11-2622; Filed December 10, 2010, 1:40 p.m.

Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the State Water Control Board intends to consider amending the following regulation: **9VAC25-194, General Virginia Pollutant Discharge Elimination System (VPDES) Permit for Car Wash Facilities.** The purpose of the proposed action is to amend and reissue the existing general permit that expires on October 15, 2012. The general permit will establish limitations and monitoring requirements for point source discharge of treated wastewaters from car wash facilities to surface waters.

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

Statutory Authority: § 62.1-44.15 of the Code of Virginia; § 402 of the Clean Water Act; 40 CFR Parts 122, 123, and 124.

Public Comment Deadline: February 2, 2011.

Agency Contact: George E. Cosby, Department of Environmental Quality, 629 East Main Street, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4067, FAX (804) 698-4032, or email george.cosby@deq.virginia.gov.

VA.R. Doc. No. R11-2693; Filed December 10, 2010, 1:37 p.m.

TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF AUDIOLOGY AND SPEECH-LANGUAGE PATHOLOGY

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 Audiology and Speech-Language Pathology intends to consider amending the following regulation: **18VAC30-20, Regulations Governing the Practice of Audiology and Speech-Language Pathology.** The purpose of the proposed action is to establish rules for the training, supervision, and practice of speech-language pathologists (SLP) in the performance of fiberoptic endoscopic evaluation of swallowing (FEES). There is a need for regulation because the board's policy statement (guidance document) states that an SLP who performs FEES must be "specially trained" and work under the supervision of a physician provided that protocols are in place for emergency response.

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

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

Public Comment Deadline: February 2, 2011.

Agency Contact: 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.

VA.R. Doc. No. R11-2689; Filed December 6, 2010, 9:29 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 the following regulation: **18VAC110-20, Regulations Governing the Practice of Pharmacy.** The

purpose of the proposed action is to comply with Chapter 28 of the 2010 Acts of Assembly, which requires the Board of Pharmacy to promulgate regulations authorizing community services boards and behavioral health authorities to possess, repackage, and dispense medications; and crisis stabilization units to store and administer a stock of drugs needed for emergency treatment.

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

Statutory Authority: §§ 54.1-3307 and 54.1-3420.2 of the Code of Virginia.

Public Comment Deadline: February 2, 2011.

Agency Contact: Caroline Juran, RPh, Acting 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. R11-2366; Filed December 14, 2010, 11:20 a.m.

TITLE 1. ADMINISTRATION

STATE BOARD OF ELECTIONS

REGISTRAR'S NOTICE: The State Board of Elections is claiming an exemption from the Administrative Process Act pursuant to § 2.2-4002 B 8 of the Code of Virginia, which exempts agency action relating to the conduct of elections or eligibility to vote.

Final Regulation

Title of Regulation: **1VAC20-20. Records Administration (adding 1VAC20-20-10, 1VAC20-20-20).**

Statutory Authority: § 24.2-103 of the Code of Virginia.

Effective Date: Effective upon the filing of the notice of the U.S. Attorney General's preclearance with Registrar of Regulations.

Agency Contact: Martha Brissette, Policy Analyst, State Board of Elections, 1100 Bank St., Richmond, VA 23219, telephone (804) 864-8925, or email martha.brissette@sbe.virginia.gov.

Summary:

Federal and state laws require Virginia election administrators to maintain the security and confidentiality of personal voter information, including social security number and full date of birth. This regulation provides a standard for encryption technology that localities may provide as an alternative to redacting personal information from applications and other documents before transmitting them electronically.

CHAPTER 20
RECORDS ADMINISTRATION

1VAC20-20-10. (Reserved.)

1VAC20-20-20. Electronic transmission of records containing sensitive personal information; encryption or redaction required.

State and local election staff shall use encryption technology meeting the Security Requirements for Cryptographic Modules, FIPS PUB 140-2, issued May 25, 2001, with change notices through December 3, 2002, of the National Institute of Technology (NIST) of the United States Department of Commerce (http://csrc.nist.gov/publications/fips/fips140-2/fips1402.pdf) to transmit electronically any records containing sensitive personal information. Electronic transmission includes email or facsimile transmission. For purposes of this regulation, sensitive personal information means: (i) more than four digits of a social security number or other unique identifier other than voter identification number; (ii) day and month of birth; or (iii) the residence address of voters qualified for protection under § 24.2-418 of the Code of Virginia. If encryption is not used, then all sensitive personal information must be redacted from the record before the record is transmitted electronically. "Redact" means alteration or truncation of data so that no sensitive personal information is accessible.

DOCUMENTS INCORPORATED BY REFERENCE (1VAC20-20)

Security Requirements for Cryptographic Modules, FIPS PUB 140-2, issued May 25, 2001, including change notices through December 3, 2002, National Institute of Standards and Technology, U.S. Department of Commerce; http://csrc.nist.gov/publications/fips/fips140-2/fips1402.pdf.

VA.R. Doc. No. R11-2576; Filed December 9, 2010, 1:36 p.m.

Proposed Regulation

Title of Regulation: **1VAC20-20. Records Administration (adding 1VAC20-20-10, 1VAC20-20-30 through 1VAC20-20-80).**

Statutory Authority: § 24.2-103 of the Code of Virginia.

Public Hearing Information:

January 31, 2011 – 1 p.m. – State Board of Elections, Washington Building, Basement Level, Room B27, Richmond, VA

Public Comment Deadline: January 18, 2011.

Agency Contact: Martha Brissette, Policy Analyst, State Board of Elections, 1100 Bank St., Richmond, VA 23219, telephone (804) 864-8925, or email martha.brissette@sbe.virginia.gov.

Summary:

In 2009 the State Board of Elections undertook an in-depth review of its policies and reaffirmed those policies identified as stating current rules with which general registrars and electoral boards must comply. This proposed regulation restates the board policies so identified as regulations for publication in the Virginia Administrative Code where they will be more accessible to the public and the election community. The proposed regulation restatement is based on board policies 2010-

003, 2009-007, 2009-004, 2006-005, 2006-004, 2006-003, 2005-005, 2005-003, 2004-007, 2004-001, 1999-002, and 1946-001. The proposed regulation sets forth the general administration of the board.

1VAC20-20-10. Definitions.

The following word and term when used in this chapter shall have the following meaning unless the context clearly indicates otherwise:

"Board" means the Virginia State Board of Elections.

"Secretary" means the Secretary of the State Board of Elections.

1VAC20-20-30. Organization of State Board of Elections; seal.

A. The board shall have a chairman and a vice-chairman of the board, in addition to the ex-officio secretary. The chairman shall preside at all meetings and perform the usual functions of a presiding officer and such other duties as are imposed by these regulations or from time to time by the board. In the chairmen's absence, the vice-chairman shall perform these functions and duties. Each member, except the secretary, shall receive a per diem and expenses for attendance. Expenses shall be reported on forms approved by the Department of Accounts. The secretary is authorized to sign the vouchers for the payment of such expenses.

B. The secretary shall be authorized and it shall be the secretary's duty to employ such assistants and to purchase such equipment and supplies as are necessary from time to time, subject to the provisions of the law creating the board and the provisions of the laws and rules relating to the budgetary and personnel systems. The secretary or secretary's designee is authorized to execute necessary vouchers for the payment of the salaries of such assistants and for equipment and supplies so secured.

C. The secretary is authorized and directed to perform all duties of a routine and administrative character imposed upon the board by the law creating the same and other such duties delegated to the secretary by the board.

D. The secretary is authorized to do all things necessary to the proper execution of the law creating and governing the board and in the performance of the duties imposed upon it insofar as the same are not from their nature such as can be performed only by the board in its corporate capacity.

E. The secretary is authorized and directed to consult with and obtain the advice of the Attorney General, on behalf of and in the name of the board, whenever in the secretary's judgment occasion arises.

F. Routine and informal action of the board or of the secretary within the scope of the secretary's authority may be evidenced merely by the signature of the secretary.

G. Two members of the board shall constitute a quorum for the transaction of business at any duly constituted meeting.

H. Notice of each meeting of the board shall be given to all board members either by the secretary or the member calling the meeting at least three business days prior to the meeting except in the case of an emergency as defined in § 2.2-3701 of the Code of Virginia. Notice shall be given to the public as required by § 2.2-3707 of the Code of Virginia. All meetings shall be conducted in accordance with the requirements of the Virginia Freedom of Information Act (§ 2.2-3700 et seq. of the Code of Virginia). All meetings shall be open to the public unless the board goes into a closed meeting pursuant to § 2.2-3711 of the Code of Virginia.

I. A record of formal official and definitive actions of the board shall be preserved in a record book which may be bound or loose leaf.

J. The secretary shall keep the seal of the board and affix the seal to evidence formal action of the board.

1VAC20-20-40. Virginia's Help America Vote Act plan.

Virginia's plan under the Help America Vote Act of 2002, 42 USC § 15301 et seq., states policy of the board and performance goals for the board to document and measure.

1VAC20-20-50. Fee for nonattendance at annual training.

The board, at its discretion, will impose a fee for noncancellation of attendance at the annual training (workshop). This fee will be limited to individuals who register to attend the training and fail to cancel their attendance within three business days of the event. The fee will be limited to the cost incurred as a result of the noncancellation.

1VAC20-20-60. Delegations to Secretary of State Board of Elections.

A. In addition to the authority described in 1VAC20-20-30, the secretary has the delegations of authority to the secretary detailed in the board's minutes of December 2, 2004, as amended September 14, 2010. Board staff may (i) update that listing to correct citations and (ii) post the list to the Internet in order that additional delegations or other modifications may be proposed to the board by any interested person.

B. The secretary is authorized to prescribe the paper ballot reconciliation form under § 24.2-666 of the Code of Virginia and to develop, maintain, and prepare instructions for the operation of poll equipment before, during, and after the closing of the polls and in preparation of the statements of results.

C. The secretary shall monitor and control the quality and cost of the copies of Title 24.2 of the Code of Virginia and other election materials that the board provides to electoral boards for use at each precinct.

D. Subject to the board's policy oversight, the secretary has authority to conduct the board's administrative and programmatic operations and to discharge the board's duties consistent with specific delegations of authority.

E. The secretary is authorized to establish and maintain a central repository of forms and instructions approved for use in conducting elections. The forms and instructions shall be organized following a standard naming convention consisting of name taken from the first descriptive line, a statutory or other authority identifier, and revision date.

1VAC20-20-70. Duty to request assistance and to notify voters of denial of applications for voter registration or absentee ballots.

A. A general registrar experiencing difficulty processing applications for voter registration or absentee ballots in a timely manner should immediately notify the secretary to request staff support to assure compliance with federal and state laws.

B. A general registrar should provide applicants with specific reasons whenever their voter registration or absentee applications are denied. The board shall automate the notice process through standard correspondence and the statewide voter registration system.

1VAC20-20-80. Complaints.

A. Any person may make an informal complaint electronically or by telephone. Localities are primarily responsible for responding to all voter complaints they receive and may request board staff for assistance as needed.

B. A person may file a formal written complaint with the board as required by the Help America Vote Act of 2002, 42 USC § 15301 et seq., using the form and instructions available from the board. Formal complaints require review and response by the deputy secretary or secretary who may contact local election officials for information. Any complaints not meeting the criteria for formal complaints will be responded to informally by appropriate staff.

NOTICE: The form used in administering the above regulation is listed below. The form is not being published; however, the name of the form hyperlinks to the actual form. The form is also available for public inspection at the State Board of Elections, 1100 Bank Street, Richmond, Virginia 23219 or at the Office of the Registrar of Regulations, General Assembly Building, 2nd Floor, Richmond, Virginia 23219.

FORMS (1VAC20-20)

Virginia Voters' Election Day Complaint Form (rev. 6/10).

DOCUMENTS INCORPORATED BY REFERENCE (1VAC20-20)

Virginia State Plan, Help America Vote Act of 2002, adopted July 2003, amended August 2005 and July 2006, Virginia State Board of Elections.

Help America Vote Act of 2002 Performance Goals, Virginia State Board of Elections, June 19, 2006 (Virginia State Board of Elections Policy 2006-004).

State Board of Election Minutes of December 2, 2004, as amended September 14, 2010.

VA.R. Doc. No. R11-2691; Filed December 14, 2010, 11:40 a.m.

Final Regulation

Title of Regulation: **1VAC20-40. Voter Registration (adding 1VAC20-40-10 through 1VAC20-40-60).**

Statutory Authority: § 24.2-103 of the Code of Virginia.

Effective Date: Effective upon the filing of the notice of the U.S. Attorney General's preclearance with Registrar of Regulations.

Agency Contact: James B. Alcorn, Deputy Secretary, State Board of Elections, 1100 Bank Street, Richmond, VA 23219, telephone (804) 864-8944, or email james.alcorn@sbe.virginia.gov.

Summary:

As required by § 24.2-406 D of the Code of Virginia, the State Board of Elections in 2009 adopted and secured preclearance for a regulation on determining residency for voter registration. This regulation was published on the board's website as SBE Policy 2009-005 with approved correspondence before the board adopted procedures for using the Virginia Regulatory Town Hall and Virginia Register of Regulations for adopting regulations. The board adopted the previously approved SBE Policy 2009-005 with stylistic changes to conform to Virginia Administrative Code technical specifications. A clarifying definition of address was also adopted to provide guidance and assure uniform treatment of applicants requesting exclusion of residence addresses from published voter lists under § 24.2-418 of the Code of Virginia. The board made no changes to the final regulations since publication of the proposed regulation.

CHAPTER 40
VOTER REGISTRATION

Article 1
General Provisions

1VAC20-40-10. Definitions.

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

"Abode" or "place of abode" means a physical place where a person dwells. One may have multiple places of abode, such as a second home.

"Address" or "residence address" for purposes of voter registration and address confirmation means the address of residence in the precinct required for voter registration. An alternative mailing address may be included on a voter registration application when: (i) the residence address of the applicant cannot receive mail; or (ii) the voter is otherwise eligible by law to provide an alternative mailing address. Alternative mailing addresses must be sufficient to enable the delivery of mail by the United States Postal Service. The post office box for published lists may be provided either by the United States Postal Service or a commercial mail receiving agency (CMRA) described in the United States Postal Service Domestic Mail Manual.

"Domicile" means a person's primary home, the place where a person dwells and which he considers to be the center of his domestic, social, and civil life. Domicile is primarily a matter of intention, supported by an individual's factual circumstances. Once a person has established domicile, establishing a new domicile requires that he intentionally abandon his old domicile. For any applicant, the registrar shall presume that domicile is at the address of residence given by the person on the application. The registrar shall not solicit evidence to rebut this presumption if the application appears to be legitimate, except as provided in 1VAC20-40-40 B and C.

"Residence," "residency," or "resident" for all purposes of qualification to register and vote means and requires both domicile and a place of abode.

Article 2
Residency for Voter Registration

1VAC20-40-20. Required intent for voter registration.

A. Nothing in this article shall be construed to confer upon any person any privileges or benefits other than the right to register to vote and to be qualified to vote in an election.

B. Pursuant to the requirements of § 24.2-404 D of the Code of Virginia, the following shall apply only in determining a person's residence under Article II, Sec. 1 of the Constitution of Virginia and Title 24.2 of the Code of Virginia.

1. A person who intends to remain in a location for an unlimited time has established the intent required to establish domicile.

2. A person who intends to remain in his current location for an unlimited time has established the intent required to establish domicile even if he may leave upon the happening of a future contingency. Examples of such future contingencies include, but are not limited to, a change in job status or location, graduation from school, military transfer deployments or other relocations, and medical emergencies.

3. A person who presently intends to leave his current location at a fixed and certain date may not have established the intent required to establish domicile depending on the facts and circumstances of each case, as determined by the registrar, with all due consideration given to persons in the circumstances contained in 1VAC20-40-30 B.

4. A person who applies to register to vote in a precinct for the primary purpose of registering to vote or voting in that precinct has not established the intent to establish domicile there.

1VAC20-40-30. Presumptions.

A. Residency shall be broadly construed to provide the greatest opportunity to register and to vote. A residence can be established in a commercial, industrial, or other building that is not normally used for residential purposes if the building serves as the applicant's primary nighttime residence. A homeless person will be considered resident in the location where the homeless person usually sleeps at night. In cases involving nontraditional habitations, the location of the person's usual sleeping area shall be controlling as to the residency of that person.

B. No presumption in favor of or against residence may arise merely on the basis of a person's presence or absence in the following circumstances:

1. While employed in the service of the Commonwealth or United States, whether military or civilian;

2. While engaged in the navigation of the waters of the United States or of the high seas;

3. While employed by or enrolled as a student in any educational institution, or residing in any housing commonly occupied by students or faculty;

4. While confined in any jail or other correctional facility as a nonfelon;

5. While receiving treatment or being confined for any reason in a nursing home, hospital, rehabilitation or short term care facility, retirement or veterans' home, or like institution or private facility;

6. While remaining in a location only during the workweek in order to conduct business; or

7. While residing in an area within the boundaries of Virginia that has been ceded to or acquired by the federal government.

C. If a person resides in an area lacking a specific mailing address, the general registrar shall ask him to provide a mailing address along with a description indicating where the person resides. However, no person shall be denied

registration for failure to submit a mailing address. The description must identify the location with sufficient specificity to allow the general registrar to place the location in a defined precinct. The general registrar shall assign the person to the precinct containing the location where he resides.

D. A person whose home is destroyed or rendered uninhabitable does not lose residence at that home if he intends to return to the home when it is reconstructed or made habitable, unless he has either established a new domicile or has changed his voter registration.

E. A person whose residence is divided by a jurisdictional boundary line or election district boundary line shall be deemed to reside in the location of his bedroom or usual sleeping area.

F. The general registrar shall not automatically presume the residence of one spouse to be that of the other spouse, but shall determine the other spouse's residence in accordance with the applicable statutes and regulations.

G. A person loses voting residence in any county or city in Virginia by registering to vote or voting in any other county, city, or state. An otherwise qualified voter shall not lose their residence at an address until they have established their residence at another address.

1VAC20-40-40. Review of application.

A. Except as provided in § 24.2-411.1 of the Code of Virginia, if (i) application to register to vote is not signed or is missing information required by law, or (ii) the general registrar cannot determine from the information provided on the application the location at which the applicant intended to register, the general registrar shall deny the application and process it in accordance with § 24.2-422 of the Code of Virginia.

B. If an application to register to vote contains all information required by law but contains other apparent discrepancies, the general registrar may promptly resolve the discrepancies through informal means. Informal means include ascertainment of information through the statewide, voter registration system, the Division of Motor Vehicles, and any form of communication with the applicant.

C. If an application to register to vote contains all information required by law, and if any of the situations in the subdivisions of this subsection apply, the general registrar shall not deny the application, but shall ask the applicant to provide additional information in support of the application. The general registrar shall request the information in writing on a form prescribed by the board and the applicant shall respond in writing. The application shall not be accepted or denied while the registrar is awaiting the applicant's response. The general registrar shall act promptly to resolve the question of residency as soon as possible. In the event the applicant does not provide the requested information by the last day to register as established in § 24.2-416 of the Code of Virginia and the general registrar is unable to determine the applicant's residency through any other means, the general registrar shall deny the application in accordance with § 24.2-422 B of the Code of Virginia.

1. The applicant provides a mailing address in a different county, city, or state from his residential address. In this situation, the general registrar shall reconfirm the residential address and mailing address by asking the supplemental questions provided in 1VAC20-40-50 and mailing the questions to both the residential and mailing addresses;

2. The applicant provides a residential address that cannot receive mail, or from which mail sent by the registrar's office is returned. In this situation, the general registrar shall ask for an alternate mailing address;

3. The applicant provides an address that is temporary in nature. Temporary addresses shall include, but not be limited to, hotels, motels, motor homes, hospitals and other short term medical care facilities, houseboats, campgrounds or other facilities that have durational restrictions, such as a 30-day limitation, or any other transient address that would not be considered as a typical permanent residence address. Temporary addresses shall not include apartments or other facilities, such as dormitories, that provide for leases or other rental agreements of at least six months duration. The general registrar shall treat these addresses as permanent ones. In the event the applicant provides an address that is temporary in nature, the general registrar shall ask the supplemental questions provided in 1VAC20-40-50;

4. The applicant provides a residential address that is a commercial, industrial, or other building that is not normally used for residential purposes, or other nontraditional residential address; or

5. The application causes a conflict with another existing voter in the statewide, voter registration system, such as a duplication of the social security number with an existing voter.

1VAC20-40-50. Supplemental questions.

When warranted by the situations described in 1VAC20-40-40 C and where any other information on the voter registration application is unclear, the general registrar shall ask the following questions on a form prescribed by the board after notifying the applicant that any response he makes is subject to the same oath he took to sign the application:

1. Are you currently registered to vote at another address? The general registrar shall not ask this question unless the applicant failed to provide the information on the voter registration application.

a. If yes to subdivision 1 of this section, what is that address, and in what county, city, or state is that address located?

b. If yes to subdivision 1 of this section or as indicated on the voter registration application, do you wish to cancel your registration in that county, city, or state and register and establish residence in this county or city in Virginia?

2. Do you have a specific plan to move away from this county or city at a fixed date in the future?

1VAC20-40-60. Review of supplemental questions.

A. If the applicant answers the questions asked pursuant to 1VAC20-40-50 with information sufficient to assign him a polling place within the precinct and to cancel his current registration elsewhere, if any, the applicant shall be registered and added to the voting rolls of the locality and the jurisdiction where the voter was previously registered shall be notified to remove the registrant from their rolls.

B. If the applicant does not provide information sufficient to assign him a polling place within the precinct, the application shall be denied.

C. If the applicant indicates that the application was in error or filed incorrectly the registrar shall provide him voting information that could allow the applicant to register or vote absentee in the Commonwealth.

D. No new or changed voter registration application is effective until an applicant provides answers to the supplemental questions. Any such answers must be in writing and must be returned before the last day to register as established in § 24.2-416 of the Code of Virginia. Any supplemental information based upon an application made prior to the close of books shall be accepted and the applicant registered if the response is received before the last day to register as established in § 24.2-416 of the Code of Virginia.

VA.R. Doc. No. R11-2351; Filed December 10, 2010, 3:23 p.m.

Final Regulation

Title of Regulation: **1VAC20-60. Election Administration (adding 1VAC20-60-10, 1VAC20-60-20).**

Statutory Authority: § 24.2-103 of the Code of Virginia.

Effective Date: Effective upon the filing of the notice of the U.S. Attorney General's preclearance with Registrar of Regulations.

Agency Contact: James B. Alcorn, Deputy Secretary, State Board of Elections, 1100 Bank Street, Richmond, VA 23219, telephone (804) 864-8944, or email james.alcorn@sbe.virginia.gov.

Summary:

This regulation provides standards to assist general registrars in determining what omissions are always material and cause a petition to call for a referendum election to be rendered invalid and what omissions are not material. The proposed regulation invalidated the entire petition if the petition circulator signed the petition in the "Signature of Registered Voter" field. However, its companion proposed regulation 1VAC20-50, Material Omissions on Candidate Petitions, merely invalidated the signature of the circulator and not the entire petition. The State Board of Elections determined to resolve the inconsistency in favor of only invalidating the circulator's signature and adopted a revised final version accordingly.

CHAPTER 60
ELECTION ADMINISTRATION

1VAC20-60-10. Definitions.

(Reserved.)

1VAC20-60-20. Material omissions on referendum petitions.

A. Pursuant to the requirements of § 24.2-684.1 of the Code of Virginia, a petition should not be rendered invalid if it contains an error or omission not material to its proper processing.

B. The following omissions are always material and any petition containing such omissions should be rendered invalid if:

1. The petition submitted is not the double-sided, two-page document, or a copy thereof, provided by the State Board of Elections;

2. The "question" or "referendum issue" is not stated in a manner set forth by law on the front of the petition;

3. The circulator has not signed the petition affidavit and provided his current address;

4. The circulator is not a registered voter or qualified to register and vote on the issue;

5. The circulator has not signed the affidavit for each petition page he circulated in the presence of a notary;

6. The circulator has not had a notary sign the affidavit for each petition submitted; [or]

7. [~~The circulator has signed the petition in the "Signature of Registered Voter" field; or 8.~~] Any combination of the aforementioned scenarios exist.

C. [If the circulator signs the petition in the "Signature of Registered Voter" field, his signature shall be invalidated but the petition page shall be valid notwithstanding any other error or omission.

D.] Subdivision B 3 of this section does not apply to a school board referendum submitted pursuant to § 24.2-57.2 or 24.2-165 of the Code of Virginia.

[~~D.~~ E.] The petition should not be rendered invalid if:

1. An older version of the petition is used (provided that the information presented complies with current laws, regulations [,] and guidelines);

2. The "election information" including: (i) county, city, or town in which the election will be held; (ii) election type; and (iii) date of election are omitted;

3. The circulator has not indicated the county, city, or town of his voter registration or voter eligibility in the affidavit;

4. The circulator has not provided the last four digits of his social security number in the affidavit;

5. The notary has not affixed a photographically reproducible seal; or

6. The notary has not included his registration number and commission expiration date.

NOTICE: The form used in administering the above regulation is listed below. The form is not being published; however, the name of the form hyperlinks to the actual form. The form is also available for public inspection at the State Board of Elections, 1100 Bank Street, Richmond, Virginia 23219, or at the Office of the Registrar of Regulations, General Assembly Building, 2nd Floor, Richmond, Virginia 23219.

[FORMS (1VAC20-60)

Commonwealth of Virginia Petition of Qualified Voters For Referendum, SBE-684.1(1) (rev. 11/09).]

VA.R. Doc. No. R11-2570; Filed December 9, 2010, 1:36 p.m.

Proposed Regulation

Title of Regulation: **1VAC20-60. Election Administration (adding 1VAC20-60-30, 1VAC20-60-40, 1VAC20-60-50).**

Statutory Authority: § 24.2-103 of the Code of Virginia.

Public Hearing Information:

January 31, 2011 - 1 p.m. - State Board of Elections, Washington Building, Basement Level, Room B27, Richmond, VA

Public Comment Deadline: January 18, 2010.

Agency Contact: Martha Brissette, Policy Analyst, State Board of Elections, 1100 Bank St., Richmond, VA 23219, telephone (804) 864-8925, or email martha.brissette@sbe.virginia.gov.

Summary:

The regulation (i) provides the rules for use of cell phones or other electronic devices in polling places, (ii) specifies when a vote is considered to be cast, and (iii) establishes safeguards to be used if an optical scan ballot container becomes overfilled with ballots.

1VAC20-60-30. Electronic devices in polling place.

A. Representatives of candidates and political parties authorized to observe the election may use cell phones or other electronic devices provided that the device contains no camera or video recording capacity. The officers of election are responsible to monitor the use of electronic devices for observation of the election and may regulate or prohibit any use the officers determine will hinder or delay a voter or officer of election or otherwise impede the orderly conduct of the election.

Whether a particular call or calls by any authorized representative is deemed to interfere or disrupt the voting process is within the discretion of the officers of election at each precinct as a majority. Any authorized representative may be required to cease the call, make or receive any such calls outside the precinct, or be removed from the polling precinct. Any action taken pursuant to this section is within the judgment of the officers of election as a majority.

B. Use of cell phones and other electronic devices by other persons at polling places shall be monitored by the officers of election who may regulate or prohibit any use the officer determines will hinder or delay a voter or officer of election or otherwise impede the orderly conduct of the election. Use of electronic devices may not interfere nor disrupt the voting process, nor attempt to solicit or attempt to influence any person in casting his vote. Once a voter enters the prohibited area at the polls as designated in § 24.2-604 of the Code of Virginia, the use of a cell phone or other electronic communication device may be prohibited if deemed a violation of § 24.2-1006 of the Code of Virginia, or if otherwise deemed disruptive to the voting process.

C. Grounds for regulating or prohibiting use of electronic devices include but are not limited to (i) the making or receiving of calls that interfere with or become disruptive to the voting process; (ii) the making or receiving of calls in an attempt to solicit or influence any person in casting his vote; or (iii) the person using the device is conducting himself in a noisy or riotous manner at or about the polls so as to disturb the election.

D. An officer of election may require any individual using an electronic device subject to regulation under subsection C of this section to cease such use, make or receive calls outside the precinct, or remove the use of the device from the polling place.

E. The determination of the officers of election of any dispute concerning the use of electronic devices shall be subject to immediate appeal to the local electoral board.

1VAC20-60-40. When ballot cast; over and under votes.

A. A voter, voting in person on election day or voting absentee in-person, has not voted until a permanent record of the voter's intent is preserved.

B. A permanent record is preserved by a voter pressing the vote or cast button on a direct recording electronic machine, inserting an optical scan ballot into an electronic counter, or placing a paper ballot in an official ballot container.

C. A vote has not been cast by the voter unless and until the voter or an officer of election or assistant at the direction of and on behalf of the voter pursuant to § 24.2-649 of the Code of Virginia completes these actions to preserve a permanent record of the vote.

D. If any voter's ballot was not so cast by or at the direction of the voter, then the ballot cannot be cast by any officer of election or other person present.

E. Precinct counting machines, such as precincts that require optical scanning equipment, shall accept ballots that have been overvoted or undervoted.

1VAC20-60-50. Overfull optical scan ballot container.

If an optical scan reader in use in a registrar's office or a polling place malfunctions because the connected ballot container includes too many ballots, election officials may open the ballot container and empty the ballots with the following safeguards:

1. The optical scan ballot container shall be opened in plain sight of any authorized party representatives or other observers and, once the ballots have been deposited into an auxiliary ballot container, both ballot containers shall be remain in plain sight in the polling place.

2. Any such auxiliary ballot container used shall meet the requirements of § 24.2-623 of the Code of Virginia.

3. A minimum of two officers of election, representing both political parties, shall execute such a transfer of ballots.

VA.R. Doc. No. R11-2692; Filed December 14, 2010, 11:40 a.m.

Proposed Regulation

Title of Regulation: **1VAC20-80. Recounts and Contested Elections (adding 1VAC20-80-10, 1VAC20-80-20).**

Statutory Authority: § 24.2-103 of the Code of Virginia.

Public Comment Deadline: January 18, 2011.

Agency Contact: Peter J. Goldin, Policy Analyst, State Board of Elections, 1100 Bank Street, 1st Floor, Richmond, VA 23219, telephone (804) 864-8930, or email peter.goldin@sbe.virginia.gov.

Summary:

This proposed regulation details standards to assist local election officials and courts in conducting recounts for contested elections.

CHAPTER 80
RECOUNTS AND CONTESTED ELECTIONS

1VAC20-80-10. (Reserved.)

1VAC20-80-20. Recounts and Contested Elections.

A. Standards for any recounts or contests requested in the Commonwealth of Virginia shall be governed by Chapter 8 (§ 24.2-800 et seq.) of Title 24.2 of the Code of Virginia.

B. Upon notification by the court that a recount requested has been filed pursuant to § 24.2-801 of the Code of Virginia, the State Board of Elections shall promptly transmit to the appropriate court and electoral board or boards copies of the instructions corresponding to the types of ballots and equipment used in each county or city involved in the recount.

C. In preparation for the recount and pursuant to § 24.2-802 A of the Code of Virginia, the clerks of the circuit courts shall:

1. Secure all paper ballots and other election materials in sealed boxes;

2. Place all of the sealed boxes in a vault or room not open to the public or to anyone other than the clerk and his staff;

3. Cause such vault or room to be securely locked except when access is necessary for the clerk and his staff; and

4. Certify that these security measures have been taken in whatever form is deemed appropriate by the chief judge.

D. After a recount has been requested pursuant to § 24.2-801 of the Code of Virginia, and prior to the preliminary hearing specified in § 24.2-802 B of the Code of Virginia, the electoral board of each county or city in which the recount is to be held shall provide the court and all parties to the recount with:

1. The recommended location and number of recount teams needed to recount paper ballots and to redetermine the votes cast on direct recording electronic devices of the type that prints returns for the election district at large in which the recount is being held.

2. The recommended location and number of recount teams needed to insert the ballots read by an electronic counting device into one or more counting devices that have been programmed to count only votes cast for parties to the recount or for or against the question in a referendum recount. Such machines shall also be programmed to reject all undervoted and overvoted ballots as required by § 24.2-802 D of the Code of Virginia. The examination of undervoted and overvoted ballots may take place at the same location before the votes are totaled for that precinct, if so directed by the court. If a different team of officers would be used to examine the undervoted and

overvoted ballots, such teams shall be included in the total number recommended for this item.

3. A complete list of all officers of election who served at the election to be recounted, with the political party they represented at that election listed beside their names, the precinct where each officer served, each officer's address and phone number or numbers, and an indication of which officers served as chief or assistant chief officers. Such list shall note recommended recount officials who the court may appoint if the officials and alternates recommended by the parties to the recount are not of sufficient number to conduct the recount within a reasonable period. Such list shall be provided by the local electoral boards for both parties to the recount, or by the Secretary of the State Board of Elections in the case of a recount for federal or statewide office or a statewide ballot issue, prior to the preliminary hearing, or as soon thereafter as possible, to assist them in preparing their selections of officers to be recount officials or alternates.

4. A list of the members of the electoral board and the political parties they represent. Such list shall be provided by the local electoral boards to both parties to the recount or by the Secretary of the State Board of Elections in the case of a recount for federal or statewide office or a statewide ballot issue.

E. To facilitate the conduct of any pending or expected recount for a federal or statewide office or statewide ballot issue, the Secretary of the State Board of Elections may coordinate the gathering of the recommendations and information from the electoral boards and provide such recommendations and information to the court prior to the preliminary hearing specified in § 24.2-802 B of the Code of Virginia on behalf of the electoral boards. The electoral board of each county or city in which the recount is to be held shall provide the requested information to the Secretary of the State Board of Elections.

F. Pursuant to § 24.2-802 A of the Code of Virginia, the procedures issued by the State Board of Elections, and any other procedures directed by the court, shall be as uniform as possible throughout the entire district in which the recount is being conducted, given the differences in types of equipment and ballots used in the election.

G. For any paper ballot that is to be counted manually and can be counted manually, the guidelines adopted by the State Board of Elections for hand-counting shall be used in determining the voter's intent ("Ballot Examples for Handcounting Paper or Paper-Based Ballots for Virginia Elections or Recounts").

H. The State Board of Elections and the appropriate electoral boards shall provide any other assistance requested by the court.

DOCUMENTS INCORPORATED BY REFERENCE (1VAC20-80)

Ballot Examples for Handcounting Paper or Paper-Based Ballots for Virginia Elections or Recounts, adopted August 2001, revised May 2002, November 2005, and June 2007, State Board of Elections.

VA.R. Doc. No. R11-2444; Filed December 14, 2010, 11:40 a.m.

TITLE 2. AGRICULTURE

BOARD OF AGRICULTURE AND CONSUMER SERVICES

Proposed Regulation

Title of Regulation: **2VAC5-420. Regulations for the Enforcement of the Virginia Gasoline and Motor Fuel Law (repealing 2VAC5-420-10 through 2VAC5-420-80).**

Statutory Authority: § 59.1-156 of the Code of Virginia.

Public Hearing Information: No public hearings are scheduled.

Public Comment Deadline: March 4, 2011.

Agency Contact: Erin Williams, Policy and Planning Coordinator, Department of Agriculture and Consumer Services, P.O. Box 1163, Richmond, VA 23218, telephone (804) 786-1308, FAX (804) 371-7479, TTY (800) 828-1120, or email erin.williams@vdacs.virginia.gov.

Basis: Section 59.1-156 of the Code of Virginia establishes the discretionary authority for the Board of Agriculture and Consumer Services to adopt regulations for the efficient enforcement of the Virginia Motor Fuels and Lubricating Oils Law (Chapter 12 (§ 59.1-149 et seq.) of Title 59.1 of the Code of Virginia).

Purpose: The 2009 General Assembly Session amended the Motor Fuels and Lubricating Oils Law by incorporating by reference the inspection and testing specifications adopted by the National Conference on Weights and Measures and published by the National Institute of Standards and Technology in Handbook 130, Uniform Laws and Regulations in the Areas of Legal Metrology and Engine Fuel Quality. The incorporation by reference of national specifications will help ensure the uninterrupted flow and availability of motor fuels throughout Virginia, will facilitate the introduction to market of new motor fuels such as biodiesel, and will ensure that specifications and methods of testing of motor fuels in Virginia remain current and conform continually to corresponding national standards. Thus, the regulation is no longer needed and can be repealed.

Substance: This action seeks to repeal 2VAC5-420, Regulations for the Enforcement of the Virginia Gasoline and

Motor Fuel Law, because the essential elements of the regulation have been incorporated into the Virginia Motor Fuels and Lubricating Oils Law and the regulation is no longer needed.

Issues: The repeal of the regulation will benefit the public because the incorporation by reference of national specifications will help ensure the uninterrupted flow and availability of motor fuels throughout Virginia, facilitate the introduction to market of new motor fuels such as biodiesel, and ensure that specifications and methods of testing of motor fuels in Virginia remain current and conform continually to corresponding national standards. This regulatory action poses no disadvantages to the public or the Commonwealth.

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

Summary of the Proposed Amendments to Regulation. The Virginia Department of Agriculture and Consumer Services proposes to repeal these regulations.

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

Estimated Economic Impact. The regulations prescribe certain requirements for the enforcement of the Virginia Motor Fuels and Lubricating Oils Law, Title 59.1, Chapter 12 of the Code of Virginia, including specifications for the inspection and testing of motor fuels. HB 2446 of the 2009 session of the Virginia General Assembly amended the Motor Fuels and Lubricating Oils Law by incorporating by reference certain national inspection and testing specifications for motor fuels. Given that the essential elements of the regulations have now been incorporated by reference into the Virginia Motor Fuels and Lubricating Oils Law, the proposed repeal will have no impact beyond perhaps reducing a small amount of potential confusion.

Businesses and Entities Affected. The regulations affect motor fuel retailers and refineries. The repeal of the regulations will not significantly affect these firms since the essential elements of the regulations have now been incorporated by reference into the Virginia Motor Fuels and Lubricating Oils Law.

Localities Particularly Affected. The proposed amendments do not disproportionately affect particular localities.

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

Effects on the Use and Value of Private Property. The proposed amendments are unlikely to significantly affect the use and value of private property.

Small Businesses: Costs and Other Effects. The proposed amendments are unlikely to significantly affect small businesses.

Small Businesses: Alternative Method that Minimizes Adverse Impact. The proposed amendments are unlikely to significantly affect small businesses.

Real Estate Development Costs. The proposed amendments are unlikely to significantly affect real estate development costs.

Legal Mandate. The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Administrative Process Act and Executive Order Number 107 (09). Section 2.2-4007.04 requires that such economic impact analyses include, but need not be limited to, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. Further, if the proposed regulation has adverse effect on small businesses, § 2.2-4007.04 requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis presented above represents DPBs best estimate of these economic impacts.

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

Summary:

This proposed regulatory action repeals 2VAC5-420, Regulations for the Enforcement of the Virginia Gasoline and Motor Fuel Law. The regulation prescribes certain requirements for the enforcement of the Virginia Motor Fuels and Lubricating Oils Law (Chapter 12 (§ 59.1-149 et seq.) of Title 59.1 of the Code of Virginia), including specifications for the inspection and testing of motor fuels. Chapter 650 of the 2009 Acts of Assembly amended the Motor Fuels and Lubricating Oils Law by incorporating by reference certain national inspection and testing specifications for motor fuels. Given that the essential elements of the regulation have now been incorporated by reference into the Virginia Motor Fuels and Lubricating Oils Law, the regulation is no longer needed and can be repealed.

VA.R. Doc. No. R10-2120; Filed December 13, 2010, 4:35 p.m.

DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES

Final Regulation

REGISTRAR'S NOTICE: The following regulatory action is exempt from the Administrative Process Act in accordance with § 2.2-4002 A 13 of the Code of Virginia, which excludes the Commissioner of Agriculture and Consumer Services and the Board of Agriculture and Consumer Services in promulgating regulations pursuant to § 3.2-5206 of the Code of Virginia.

Title of Regulation: **2VAC5-490. Regulations Governing Grade "A" Milk (amending 2VAC5-490-10, 2VAC5-490-15, 2VAC5-490-32, 2VAC5-490-35, 2VAC5-490-36, 2VAC5-490-37, 2VAC5-490-40, 2VAC5-490-50, 2VAC5-490-73, 2VAC5-490-105, 2VAC5-490-131, 2VAC5-490-138, 2VAC5-490-140; adding 2VAC5-490-30.1).**

Statutory Authority: § 3.2-5206 of the Code of Virginia.

Effective Date: December 10, 2010.

Agency Contact: John A. Beers, 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 john.beers@vdacs.virginia.gov.

Summary:

The final amendments adopt the provisions of the 2009 revision of the Pasteurized Milk Ordinance (PMO). The PMO is a federal model regulation for states to adopt to govern the production, processing, distribution, and sale of grade A milk and milk products.

The changes to the final regulations (i) adopt by reference the 2009 version of "Evaluation of Milk Laboratories" published by the Food and Drug Administration Laboratory Quality Assurance Team in place of the 2007 version referenced in the proposed regulation and (ii) correct a typographical error to make the last sentence in 2VAC5-490-35 D read correctly.

Part I
Definitions and Standards of Identity

2VAC5-490-10. Definitions and standards of identity.

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

"A hazard that is reasonably likely to occur" means a hazard for which a prudent milk plant, receiving station or transfer station operator would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that, in the absence of these controls, the hazard will occur in the particular type of milk, milk product, condensed milk, condensed milk product, dry milk, or dry milk product being processed.

"Abnormal milk" means milk that is visibly changed in color, odor or texture.

"Acidified milk" means "acidified milk" as defined in 21 CFR 131.111.

"Acidified milk product" means a product with an acidity of not less than 0.50% expressed as lactic acid, which product is obtained by the addition of food grade acids to pasteurized cream, half-and-half, heavy cream, light cream, lowfat milk, milk, skim milk, or sour cream.

"Acidified sour cream" means "acidified sour cream" as defined in 21 CFR 131.162.

"Adulterated milk" or "adulterated milk product" means any milk, milk product, condensed milk product, or dry milk product which meets one or more of the conditions specified in Section 402 of the Federal Food, Drug and Cosmetic Act, as amended (21 USC § 342).

"Aseptically processed milk" means milk that is hermetically sealed in a container and so thermally processed before or after packaging in conformance with 21 CFR Part 113 and the provisions of this chapter so as to render the product free of microorganisms capable of reproducing in the product under nonrefrigeration conditions of storage and distribution and that is free of viable microorganisms (including spores) capable of causing disease in humans.

"Aseptically processed milk product" means any milk or milk product that is hermetically sealed in a container and so thermally processed before or after packaging in conformance with 21 CFR Part 113 and the provisions of this chapter so as to render the product free of microorganisms capable of reproducing in the product under normal nonrefrigeration conditions of storage and distribution and that is free of viable microorganisms (including spores) capable of causing disease in humans.

"Aseptic processing" means that the product has been subjected to sufficient heat processing and packaged in a hermetically sealed container, to conform to the applicable requirements of 21 CFR Part 113 and the provisions of this chapter and to maintain the commercial sterility of the product under normal nonrefrigerated conditions.

"Audit" means an evaluation of the entire milk plant, receiving station or transfer station facility and HACCP System to ensure compliance with the voluntary HACCP program requirements of this chapter.

"Automatic milking installation" means the entire installation of one or more automatic milking units, including the hardware and software utilized in the operation of individual automatic milking units, the animal selection system, the automatic milking machine, the milk cooling

system, the system for cleaning and sanitizing the automatic milking unit, the teat cleaning system, and the alarm systems associated with the process of milking cooling, cleaning and sanitation.

"Boiled custard" means "eggnog" as defined in 21 CFR 131.170.

"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.

"Buttermilk" means the fluid milk product that remains after the manufacture of butter from milk or cream and contains not less than 8.25% of milk solids not fat.

"Cancel" means to permanently nullify, void, or delete a grade A permit issued by the State Regulatory Authority.

"Centralized deviation log" means a centralized log or file identifying data detailing any deviation of critical limits and the corrective actions taken.

"CFR" means the Code of Federal Regulations.

"Clean" means the surfaces of equipment and facilities have had an effective and thorough removal of product, soils, and contaminants.

"Coffee cream" means "light cream."

"Commercially sterile" means (i) the food has been thermally processed by the application of heat to render the food free of viable microorganisms (including spores) of public health significance and microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution; or (ii) the food has been processed with the application of heat and the water activity of the food has been controlled to render the food free of microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution.

"Concentrated milk" means "concentrated milk" as defined in 21 CFR 131.115.

"Concentrated milk product" means any of the following foods: homogenized concentrated milk, homogenized concentrated skim milk, concentrated lowfat milk, concentrated milk, and concentrated skim milk, which when combined with potable water according to the instructions printed on the food's container, conforms to the definition of the corresponding milk product in this chapter.

"Condensed buttermilk" means the product resulting from the removal of a considerable portion of water from buttermilk.

"Condensed and dry milk product" means grade A condensed milk, grade A condensed and dry whey, grade A dry milk product, or grade A dry milk and whey product.

"Condensed milk" means concentrated milk as defined in 21 CFR 131.115. This definition does not include:

1. Any sterilized milk or milk product, when the sterilized milk or milk product is hermetically sealed in a container and processed, either before or after sealing, so as to prevent microbial spoilage; or

2. Any evaporated milk or sweetened condensed milk, except when the evaporated milk or sweetened condensed milk is combined with other substances in the commercial preparation of any pasteurized, ultra-pasteurized, or aseptically processed milk or milk product.

"Condensed whey" means "condensed whey" as defined in 21 CFR 184.1979(a)(2).

"Consumer" means any person who uses any grade A milk, grade A milk product, or milk product.

"Corrective action" means procedures followed when a deviation occurs.

"Cottage cheese" means "cottage cheese" as defined in 21 CFR 133.128.

"Cottage cheese dry curd" means "dry curd cottage cheese."

"Cream" means "cream" as defined in 21 CFR 131.3(a).

"Critical control point" means a step at which control can be applied and is essential to prevent or eliminate a milk, milk product, condensed milk, condensed milk product, dry milk, or dry milk product safety hazard or reduce it to an acceptable level.

"Critical limit" means a maximum value or a minimum value to which a biological, chemical, or physical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of a milk, milk product, condensed milk, condensed milk product, dry milk, or dry milk product safety hazard.

"Cultured half-and-half" means "sour half-and-half."

"Cultured milk" means "cultured milk" as defined in 21 CFR 131.112.

"Cultured sour cream" means "sour cream."

"Dairy farm" means any place or premises where any cow, goat, sheep, water buffalo, or other mammal (except humans) is kept, from which cow, goat, sheep, water buffalo, or other mammal (except humans) milk or any milk product is ~~provided,~~ sold or offered for sale for human consumption or provided to a milk plant, cheese plant, frozen desserts plant, transfer station, or receiving station.

"Deficiency" means an element that is inadequate or missing from the requirements of a HACCP System or with the voluntary HACCP program requirements of this chapter.

"Deny" means the State Regulatory Authority will not issue a grade A permit to the applicant.

"Deviation" means a failure to meet a critical limit.

"Drug" means: (i) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; (ii) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; (iii) articles other than food intended to affect the structure or any function of the body of man or other animals; and (iv) articles intended for use as a component of any articles specified in clause (i), (ii), or (iii) of this definition, but does not include devices or their components, parts, or accessories.

"Dry buttermilk" means "dry buttermilk" as defined in 7 CFR 58.251.

"Dry buttermilk product" means "dry buttermilk product" as defined in 7 CFR 58.251.

"Dry cream" means "dry cream" as defined in 21 CFR 131.149.

"Dry curd cottage cheese" means "dry curd cottage cheese" as defined in 21 CFR 133.129.

"Dry milk product" means a product resulting from the drying of any milk or milk product and any product resulting from the combination of a dry milk product with other safe and suitable dry ingredients.

"Dry whey" means "dry whey" as defined in 21 CFR 184.1979.

"Dry whey product" means a product resulting from the drying of whey or whey products and any product resulting from the combination of dry whey products with other wholesome dry ingredients.

"Dry whole milk" means "dry whole milk" as defined in 21 CFR 131.147.

"Eggnog" means "eggnog" as defined in 21 CFR 131.170.

"Eggnog-flavored milk" means a milk product, to which an emulsifier and a maximum of 0.5% stabilizer may have been added consisting of a mixture of (i) at least 3.25% butterfat, (ii) at least 0.5% egg yolk solids, (iii) sweetener, and (iv) flavoring.

~~"Evaporated milk" means "evaporated milk" as defined in 21 CFR 131.130.~~

"Flavored milk" means milk to which a flavor or sweetener has been added.

"Flavored milk product" means any milk product to which a flavor or sweetener has been added.

"Fortified milk" means milk, other than vitamin D milk, the vitamin or mineral content of which milk has been increased.

"Fortified milk product" means any milk product, other than a vitamin D milk product, the vitamin or mineral content of which milk product has been increased.

"Frozen milk concentrate" means the frozen milk product which, when water is added in accordance with instructions on the package containing the frozen milk product, the reconstituted milk product contains the percentage of milkfat and the percentage of milk solids not fat of milk.

"Goat milk" means the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one or more healthy goats which, when sold in retail packages, contains not less than 2.5% milkfat and not less than 7.5% nonfat milk solids not fat.

"Grade A condensed and dry whey" means condensed or dry whey which complies with the provisions of the "Grade "A" Pasteurized Milk Ordinance, ~~2005~~ 2009 Revision" and this chapter.

"Grade A condensed milk" means condensed milk which complies with the provisions of the "Grade "A" Pasteurized Milk Ordinance, ~~2005~~ 2009 Revision" and this chapter.

"Grade A dry milk product" means any dry milk product which complies with the provisions of the "Grade "A" Pasteurized Milk Ordinance, ~~2005~~ 2009 Revision" and this chapter.

"Grade A dry milk and whey product" means any dry milk or whey product which has been produced for use in any grade A pasteurized, ultra-pasteurized, or aseptically processed milk product; and which has been manufactured under the provisions of the "Grade "A" Pasteurized Milk Ordinance, ~~2005~~ 2009 Revision" and this chapter.

"Grade A permit" means the written document issued by the state regulatory authority to the person who operates a: (i) dairy farm to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing; (ii) milk plant; (iii) receiving station; (iv) transfer station; (v) milk condensing plant; (vi) milk drying plant; (vii) whey condensing plant; or (viii) whey drying plant; after the State Regulatory Authority has inspected and approved the person's operation and determined the person's compliance with the provisions of this chapter for the operations specified in this definition.

"HACCP" means hazard analysis critical control point.

"HACCP plan" means the written document, which is based upon the principles of HACCP and delineates the procedures to be followed.

"HACCP system" means the implemented HACCP plan and prerequisite programs, including other applicable requirements of the voluntary HACCP program of this chapter.

"Half-and-half" means "half-and-half" as defined in 21 CFR 131.180.

"Hazard" means a biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

"Hazard analysis" means the process of collecting and evaluating information on hazards associated with the milk, milk product, condensed milk, condensed milk product, dry milk, or dry milk product under consideration, to decide which are reasonably likely to occur and must be addressed in the HACCP plan.

"Heavy cream" means "heavy cream" as defined in 21 CFR 131.150.

"Lactose-reduced lowfat milk" means the product resulting from the addition of safe and suitable enzymes to convert enough lactose to glucose or galactose so that less than 30% of the lactose remains in the lowfat milk from which the product is made.

"Lactose-reduced milk" means the product resulting from the addition of safe and suitable enzymes to convert enough lactose to glucose or galactose so that less than 30% of the lactose remains in the milk from which the product is made.

"Lactose-reduced skim milk" means the product resulting from the addition of safe and suitable enzymes to convert enough lactose to glucose or galactose so that less than 30% of the lactose remains in the skim milk from which the product is made.

"Light cream" means "light cream" as defined in 21 CFR 131.155.

"Light whipping cream" means "light whipping cream" as defined in 21 CFR 131.157.

"Lowfat dry milk" means "lowfat dry milk" as defined in 21 CFR 131.123.

"Lowfat yogurt" means "lowfat yogurt" as defined in 21 CFR 131.203.

"Low-sodium lowfat milk" means the milk product resulting from the treatment of lowfat milk by a process of passing the lowfat milk through an ion exchange resin process, or by any other process which has been recognized by the Food and Drug Administration that effectively reduces the sodium content of the product to less than 10 milligrams in 100 milliliters.

"Low-sodium milk" means the milk product resulting from the treatment of milk by a process of passing the milk through an ion exchange resin process, or by any other process which has been recognized by the Food and Drug Administration that effectively reduces the sodium content of the product to less than 10 milligrams in 100 milliliters.

"Low-sodium skim milk" means the milk product resulting from the treatment of skim milk by a process of passing the skim milk through an ion exchange resin process, or by any other process which has been recognized by the Food and Drug Administration that effectively reduces the sodium content of the product to less than 10 milligrams in 100 milliliters.

"Market milk" means milk.

"Market milk product" means milk product.

"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 condensing plant" means any plant in which milk or any milk product is condensed or dried, or in which milk or any milk product is received, separated, or otherwise processed for drying and packaging.

"Milk drying plant" means any plant in which milk or any milk product is condensed or dried, or in which milk or any milk product is received, separated, or otherwise processed for drying and packaging.

"Milkfat" means the fat of milk.

"Milkhouse" means the building or room in which there is conducted on a grade A dairy farm (i) the cooling, handling, and storing of milk and (ii) the washing, sanitizing, and storing of milk containers and utensils.

"Milk plant" means any place, premises, or establishment where any milk or milk product is collected, handled, processed, stored, pasteurized, ultra-pasteurized, aseptically processed, condensed, dried, bottled, or prepared for distribution.

"Milk producer" means any person who operates a dairy farm and who provides, sells, or offers milk for sale for human consumption or to a milk plant, receiving station, or transfer station.

"Milk product" means~~: (i) acidified lowfat milk, acidified nonfat milk, acidified milk, acidified milk product, acidified reduced fat milk, 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 and half, cultured milk, cultured lowfat milk, cultured nonfat milk, cultured reduced fat milk, cultured skim milk, cultured sour cream, cultured sour half and half, 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, heavy whipping cream, lactose reduced lowfat milk, lactose reduced nonfat milk, lactose-reduced milk, lactose-reduced reduced fat milk, lactose reduced skim milk, light cream, light whipping cream, lowfat cottage cheese, lowfat milk, lowfat yogurt, low-sodium lowfat milk, low-sodium nonfat milk, low sodium milk, low sodium reduced fat milk, low sodium skim milk, milk, nonfat milk, nonfat yogurt, recombined milk, recombined milk product, reconstituted milk, reconstituted milk product, reduced fat milk, 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 (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. Nothing in this definition shall be deemed to include any evaporated milk, evaporated skim milk, condensed milk (sweetened or unsweetened), infant formula, ice cream or other dessert, dietary product, dry milk product (except as defined herein), canned eggnog in a rigid metal container, or butter or cheese, except when butter or cheese is combined with other substances to produce any pasteurized or aseptically processed food as specified in this definition~~ grade A milk and grade A milk products meeting the requirements of 2VAC5-490-15.

"Misbranded milk" or "misbranded milk product" means any milk, milk product, or condensed and dry milk product that: (i) satisfies any of the conditions specified in § 403 of the Federal Food Drug, and Cosmetic Act, as amended (21 USC 343), (ii) does not conform to its definition; or (iii) is not labeled in accordance with 2VAC5-490-40.

"Nonconformity" means a failure to meet specified requirements of the HACCP system.

"Nonfat dry milk" means "nonfat dry milk" as defined in 21 CFR 131.125.

"Nonfat dry milk fortified with vitamins A and D" means "nonfat dry milk fortified with vitamins A and D" as defined in 21 CFR 131.127.

"Nonfat yogurt" means "nonfat yogurt" as defined in 21 CFR 131.206.

"Normal storage" means storage at a temperature of 45°F or cooler, but does not include freezing.

"Official laboratory" means a biological, chemical, or physical laboratory operated by the Commonwealth of Virginia.

"Officially designated laboratory" means: (i) a commercial laboratory authorized by the State Regulatory Authority to examine milk, milk product, condensed and dry milk product, producer samples of Grade "A" raw milk for pasteurization, or commingled milk tank truck samples of raw milk or milk products or (ii) a milk-industry laboratory authorized by the State Regulatory Authority to examine milk producer samples of raw milk for pasteurization, and for drug residues and bacterial limits, samples of raw milk commingled in a tank truck.

"Pasteurization" or "pasteurized" means the process of heating every particle of milk~~,~~ or milk product~~, or whey~~ in equipment designed and operated in conformance with this chapter, to one of the temperatures given in the following table and held continuously at or above that temperature for at least the corresponding specified time for the equipment indicated:

Temperature	Time	Equipment
145°F*	30 minutes	Vat Pasteurization
161°F*	15 seconds	High Temperature Short Time
191°F	1.0 second	High Temperature Short Time
194°F	0.5 second	High Temperature Short Time
201°F	0.1 second	High Temperature Short Time
204°F	0.05 second	High Temperature Short Time
212°F	0.01 second	High Temperature Short Time

*If: (i) the fat content of the milk or milk product is 10% or ~~more~~ greater; (ii) the total solids content of the milk or milk product is 18% or greater; or ~~(ii)~~ (iii) the milk or milk product contains added sweeteners~~; (iii) the product is condensed milk; or (iv) the milk product is a condensed milk product~~, then pasteurization means increasing the specified temperature by 5°F.

*If the dairy product is cream for butter-making, then "pasteurization" means heating to at least 165°F and holding continuously in a vat pasteurizer for not less than 30 minutes or pasteurizing by the High Temperature Short Time method at a minimum temperature of not less than 185°F for not less than 15 seconds.

*If the milk product is eggnog, then "pasteurization" means heating to at least the following temperatures for the corresponding time specifications and equipment:

Temperature	Time	Equipment
155°F	30 minutes	Vat Pasteurization
175°F	25 seconds	High Temperature Short Time
180°F	15 seconds	High Temperature Short Time

Nothing in this definition shall be construed as barring any other process which has been recognized by the Food and Drug Administration as being equally efficacious as pasteurization, so long as that other process has been approved by the State Regulatory Authority.

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

"Prerequisite programs" means procedures, including Good Manufacturing Practices, that address operational conditions that provide the foundation for the HACCP system.

"Public" means any person in the Commonwealth.

"Pull date" means the date affixed to a consumer package or container of grade A pasteurized milk or grade A pasteurized milk product which is the date after the day of manufacturing and processing of the package or container and the last day on which the grade A pasteurized milk or grade A pasteurized milk product as determined by the milk plant may be offered for sale to consumers under normal storage.

"Raw milk" means: (i) any milk or any milk product which has not been pasteurized, ultra-pasteurized, or aseptically processed; or (ii) or any milk or any milk product which has been pasteurized, ultra-pasteurized, or aseptically processed and which has been exposed to microbiological contamination before, during, or after packaging.

"Receiving station" means any place, premises, or establishment where raw milk is: (i) received, collected, handled, stored, or cooled; and (ii) prepared for further transporting.

"Recombined milk" means the food which, when combined with potable water according to the instructions printed on the food's container, conforms to the milk fat and nonfat milk solids requirements for milk, as specified in the definition of "milk."

"Recombined milk product" means the food which, when combined with potable water according to the instructions printed on the food's container, conforms to the milk fat and milk nonfat solids requirements for the milk product designated on the food's container.

"Reconstituted milk" means "recombined milk."

"Reconstituted milk product" means "recombined milk product."

"Reduced lactose whey" means "reduced lactose whey" as defined in 21 CFR 184.1979a.

"Reduced minerals whey" means "reduced minerals whey" as defined in 21 CFR 184.1979b.

"Revoke" means to permanently annul, repeal, rescind, countermand, or abrogate a Grade A permit issued by the State Regulatory Authority.

"Safe and suitable" means "safe and suitable" as defined in 21 CFR 130.3(d).

"Sanitization" means the application of any effective method or substance to a clean surface for the destruction of pathogens, and of other organisms as far as is practicable, and when used does not adversely affect: (i) the equipment which comes in contact with milk, milk product, or condensed and dry milk product; (ii) the milk, milk product, or condensed and dry milk product; or (iii) the health of consumers.

"Septage" means material accumulated in a pretreatment system or privy.

"Sewage" means water-carried and nonwater-carried human excrement; kitchen, laundry, shower, bath, or lavatory wastes separately or together with such underground, surface, storm and other water and liquid industrial wastes as may be present from residences, buildings, vehicles, industrial establishments or other places.

"Sheep milk" means the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one or more healthy sheep.

"Sour cream" means "sour cream" as defined in 21 CFR 131.160.

"State Regulatory Authority" means the Commissioner of Agriculture and Consumer Services or his agent when carrying out any duty specified in § 3.2-5207 of the Code of Virginia or the State Health Commissioner or his agent when carrying out any duty specified in § 3.2-5208 of the Code of Virginia.

"Suspend" means to temporarily nullify, void, debar, or cease for a period of time a grade A permit issued by the State Regulatory Authority.

"Sweetened condensed milk" means "sweetened condensed milk" as defined in 21 CFR 131.120.

"Table cream" means "light cream" as defined in 21 CFR 131.155.

"Transfer station" means any place, premises, or establishment where milk or milk products are transferred directly from one milk tank truck to another.

"Trim" means to shorten the hair on the udder and tail of milking cows and goats by clipping, singeing, cutting, or other means.

"Ultra-pasteurized" means, when used to describe any milk or milk product, that the milk or milk product has been thermally processed at a temperature of 280°F (138°C) or hotter for at least two seconds, either before or after packaging, so as to produce a product that has an extended shelf life under normal storage.

"Validation" means the element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control the hazards.

"Verification" means those activities, other than monitoring, that determine the validity of the HACCP plan and that the HACCP system is operating according to the plan.

"Vitamin A milk" means milk, the vitamin A content of which has been increased to at least 2000 International Units per quart.

"Vitamin A milk product" means a milk product, the vitamin A content of which has been increased to at least 2000 International Units per quart.

"Vitamin D milk" means milk, the vitamin D content of which has been increased to at least 400 International Units per quart.

"Vitamin D milk product" means a milk product, the vitamin D content of which has been increased to at least 400 International Units per quart.

"Water buffalo milk" means the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one or more healthy water buffalo.

"Whey" means "whey" as defined in 21 CFR 184.1979.

"Whey condensing plant" means a plant in which whey is condensed or in which whey is received and processed for drying and packaging.

"Whey drying plant" means a plant in which whey is dried or in which whey is received and processed for drying and packaging.

"Whey product" means any fluid product removed from whey, or made by the removal of any constituent from whey, or by the addition of any wholesome substance to whey or parts thereof.

"Whipped cream" means "heavy cream" as defined in 21 CFR 131.150 or "light whipping cream" as defined in 21 CFR 131.157, into which air or gas has been incorporated.

"Whipped light cream" means "light whipped cream" as defined in 21 CFR 131.155, into which air or gas has been incorporated.

"Whipping cream" means "light whipping cream" as defined in 21 CFR 131.157.

"Yogurt" means "yogurt" as defined in 21 CFR 131.200.

Part II
Grade A Milk and Milk Products

2VAC5-490-15. Grade A milk and milk products.

~~Grade A milk, milk products, and condensed and dry milk products shall comply with the specific standard of identity established for each milk product, condensed milk product or dry milk product and the requirements of this chapter.~~

A. Grade A milk and milk products regulated under this chapter include:

1. All milk and milk products with a standard of identity provided for in 21 CFR Part 131, with the exception of 21 CFR 131.120 sweetened condensed milk;

2. Cottage cheese as defined by 21 CFR 133.128 and dry curd cottage cheese as defined by 21 CFR 131.129;

3. Whey and whey products as defined in 21 CFR 184.1979, 21 CFR 184.1979a, 21 CFR 184.1979b, and 21 CFR 184.1979c; whey product; dry whey product; and grade A condensed and dry whey and whey products;

4. Modified versions of these foods listed in subdivisions 1 and 2 of this subsection, pursuant to 21 CFR 130.10 – Requirements for foods named by use of a nutrient content claim and a standardized term;

5. Milk and milk products as defined in subdivisions 1, 2, 3, and 4 of this subsection, packaged in combination with other food or foods not included in this section that are appropriately labeled with a statement of identity to describe the food in final package form (e.g. "cottage cheese with pineapple" or "fat free milk with plant sterols"); and

6. Products not included in subdivisions 1 through 5 of this subsection shall be grade A milk products if they contain a minimum of (i) 2.0% milk protein as determined by total kjeldahl nitrogen (TKN) X 6.38; and (ii) 65% by weight milk, milk product, or a combination of milk products.

B. Safe and suitable nongrade A dairy ingredients may be utilized in the production of grade A milk and milk products included under 2VAC5-490-15 A when added to a level needed for a functional or technical effect; limited by good manufacturing practices (GMPs); and are either (i) prior sanctioned or otherwise approved by the federal Food and Drug Administration, (ii) generally recognized as safe (GRAS), or (iii) an approved food additive listed in the Code of Federal Regulations with the exception that for those grade A milk and milk products for which a federal standard of identity has been established only ingredients provided for under the standard of identity for each grade A milk or milk product may be utilized. Nongrade A dairy ingredients shall not be used to increase the weight or volume of grade A milk or milk products or to displace any grade A dairy ingredients nor shall using nongrade A dairy ingredients to increase the

weight or volume of grade A milk or milk products be considered a suitable functional or technical effect.

C. Grade A milk and milk products shall also include those milk and milk products included under 2VAC5-490-15 A and 2VAC5-490-15 B that have been aseptically processed and then packaged.

D. Grade A milk and milk products shall not include:

1. A milk or milk product in which the milkfat of the milk or milk product has been substituted in part or in whole by any other animal or vegetable fat; provided that other fat sources may be included when they are used for purposes currently accepted in any other grade A milk or milk product, such as carriers for vitamins and as an ingredient in emulsifiers and stabilizers:

2. Coffee based products where coffee or water is the primary ingredient as indicated in the ingredient statement;

3. Tea based products where tea or water is the primary ingredient as indicated in the ingredient statement;

4. Dietary products (except as defined in 21 CFR 130.10);

5. Infant formula;

6. Ice cream or other frozen desserts;

7. Butter;

8. Standardized cheese with the exception of cottage cheese as defined under 21 CFR 133.128 and dry curd cottage cheese as defined under 21 CFR 131.129 and nonstandardized cheese; or

9. Puddings.

E. Milk and milk products which have been retort processed after packaging, or which have been concentrated (condensed) or dried shall conform to the requirements of 2VAC5-490-15 A and 2VAC5-490-15 B if they are utilized as an ingredient in any grade A milk or milk product or if they are labeled as grade A under 2VAC5-490-15 A 4.

F. Powdered dairy blends may be labeled grade A and used as ingredients in grade A milk and milk products, such as cottage cheese dressing mixes or starter media for cultures used to produce various grade A cultured milk and milk products, if they meet the requirements of this chapter. If powdered dairy blends are used as an ingredient in grade A milk and milk products, blends of dairy powders must be blended under conditions which meet all applicable grade A powdered dairy blends requirements. Grade A powder blends must be made from grade A powdered milk and milk products, except that small amounts of functional ingredients not to exceed 10% by weight of the finished blend which are not grade A are allowed in grade A blends when the finished ingredient is not available in grade A form (e.g., sodium caseinate).

G. Grade A milk and milk products~~, and condensed and dry milk products~~ include: ~~(i) (a)~~ acidified lowfat milk, acidified nonfat milk, acidified milk, acidified milk product, acidified reduced fat milk, acidified skim milk, acidified sour cream, acidified sour half-and-half, aseptically processed milk, aseptically processed milk product, boiled custard, buttermilk, coffee cream, concentrated milk, concentrated milk product, condensed buttermilk, cottage cheese, cottage cheese dry curd, cream, cultured half-and-half, cultured milk, cultured lowfat milk, cultured nonfat milk, cultured reduced fat milk, cultured skim milk, cultured sour cream, cultured sour half-and-half, dry buttermilk, dry buttermilk product, dry cream, dry curd cottage cheese, dry whole milk, eggnog, eggnog-flavored milk, flavored milk, flavored milk product, fortified milk, fortified milk product, frozen milk concentrate, goat milk, half-and-half, heavy cream, heavy whipping cream, lactose-reduced lowfat milk, lactose-reduced nonfat milk, lactose-reduced milk, lactose-reduced reduced fat milk, lactose-reduced skim milk, light cream, light whipping cream, lowfat cottage cheese, lowfat dry milk, lowfat milk, lowfat yogurt, low-sodium lowfat milk, low-sodium nonfat milk, low-sodium milk, low-sodium reduced fat milk, low-sodium skim milk, milk, nonfat milk, nonfat dry milk, nonfat dry milk fortified with vitamins A and D, nonfat yogurt, recombined milk, recombined milk product, reconstituted milk, reconstituted milk product, reduced lactose whey, reduced fat milk, reduced minerals whey, sheep milk, skim milk, sour cream, sour half-and-half, table cream, vitamin A milk, vitamin A milk product, vitamin D milk, vitamin D milk product, whipped cream, whipped light cream, whipping cream, ~~or~~ and yogurt~~; (b) any of the following foods: milk, lowfat milk, or skim milk with added safe and suitable microbial organisms; or (c) any food made with a food specified in clause (i) (a) of this definition by the addition or subtraction of milkfat or addition of safe and suitable optional ingredients for protein, vitamin, or mineral fortification; and (ii) grade A condensed milk, grade A condensed whey, grade A dry whey, grade A dry milk product, grade A dry milk and grade A dry whey product. Nothing in this section shall be deemed to include any evaporated milk, evaporated skim milk, condensed milk (sweetened or unsweetened), infant formula, ice cream or other dessert, dietary product, dry milk product (except as defined herein), canned eggnog in a rigid metal container, or butter or cheese, except when butter or cheese is combined with other substances to produce any pasteurized or aseptically processed food as specified in this definition~~.

H. Persons holding a valid permit on January 1, 2011, to receive and process milk for manufacturing purposes pursuant to 2VAC5-531-50 of the Regulations Governing Milk for Manufacturing Purposes and who have manufactured dairy products not previously considered to be grade A dairy products prior to January 1, 2011, may continue to manufacture and sell those specific dairy products they produced prior to January 1, 2011, after [~~[the effective date~~

~~of these regulations]~~ December 10, 2010]; however, this limited exemption shall not apply to any new or revised dairy products the permit holder wishes to manufacture if the new or revised dairy product is considered to be grade A.

2VAC5-490-30.1. Permit exemption for restaurants making yogurt.

Restaurants as defined in § 35.1-1 of the Code of Virginia shall be exempt from the requirements of this chapter for the manufacturer of yogurt provided (i) the restaurant manufactures the yogurt from pasteurized milk and milk products and cultures obtained from an approved source; and (ii) all of the yogurt is utilized by the restaurant or sold on site to the final consumer either as an ingredient in other foods or as yogurt.

2VAC5-490-32. Authority to impound milk and milk products.

The State Regulatory Authority may impound any condensed milk, condensed milk product, dry milk, dry milk product, milk, or milk product ~~if the condensed milk, condensed milk product, dry milk, dry milk product, milk or milk product~~ if it is in violation of any requirement of this chapter.

2VAC5-490-35. The examination of milk and milk products.

A. The State Regulatory Authority shall collect during any consecutive six months at least four samples of raw milk, collected in at least four separate months, except when three months show a month containing two sampling dates separated by at least 20 days for pasteurization, ultra-pasteurization, or aseptic processing from each dairy farm that holds a grade A permit.

B. After receipt of the milk by the milk plant and prior to pasteurization, ultra-pasteurization or aseptic processing the State Regulatory Authority shall collect during any consecutive six months at least four samples of raw milk, collected in at least four separate months, except when three months show a month containing two sampling dates separated by at least 20 days for pasteurization, ultra-pasteurization, or aseptic processing from each milk plant located within the Commonwealth that holds a grade A permit.

C. The State Regulatory Authority shall collect during any consecutive six-month period at least four samples of each heat-treated, pasteurized, ultra-pasteurized, and aseptically processed milk product, collected in at least four separate months, except when three months show a month containing two sampling dates separated by at least 20 days, from each milk plant located in the Commonwealth and holding a grade A permit.

D. The State Regulatory Authority shall, except when the production is not on a yearly basis, during each month collect from each milk condensing plant, milk drying plant, whey condensing plant or whey drying plant holding a grade A permit at least one sample of raw milk for pasteurization, after receipt of the milk by the plant and before pasteurization, and at least one sample of each grade A condensed milk product, grade A dry milk product, grade A condensed whey, and grade A dry whey manufactured. If the production of grade A dry milk products or grade A dry whey is not on a yearly basis, the State Regulatory Authority [~~the~~] shall collect at least five samples within a continuous production period.

E. The State Regulatory Authority may collect samples of milk and milk products as it deems necessary from retail establishments selling milk or milk products to determine compliance with 2VAC5-490-20, 2VAC5-490-40, 2VAC5-490-50 and 2VAC5-490-80. Each person who operates the retail establishment shall furnish the State Regulatory Authority, upon the request of the State Regulatory Authority, with the names of all distributors from whom the person has obtained milk or milk products.

F. The State Regulatory Authority shall provide the remaining portion of the original raw milk sample from each grade A dairy farm which has been screened positive for animal drug residues by a milk plant, receiving station, or transfer station to the grade A dairy farms' milk marketing organization upon request.

G. Each grade A permit holder operating a milk plant within the Commonwealth shall provide to the State Regulatory Authority laboratory determinations of the quantity of vitamin A and vitamin D present in each of the milk plant's milk and milk products to which vitamin A or vitamin D has been added. Each grade A permit holder who operates a milk plant shall provide these laboratory determinations at least annually from a laboratory certified to determine the amount of vitamin A and vitamin D in milk and milk products under the requirements established in "Evaluation of Milk Laboratories," ~~2005~~ [~~2007~~ 2009] revision, available from the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Field Programs, Division of HACCP, Laboratory Quality Assurance Branch, HFH-450, 6502 South Archer Road, Summit-Argo, Illinois 60501, USA. Each grade A permit holder who operates a milk plant shall pay for the cost of the laboratory determinations.

2VAC5-490-36. Drug residue monitoring, farm surveillance and follow up.

A. Each grade A permit holder operating a milk plant, receiving station, or transfer station shall:

1. Prior to processing any raw milk from bulk tanks on farms, test for residues of beta lactam drugs all raw milk that the milk plant, receiving station, or transfer station receives for pasteurization, ultra-pasteurization, or aseptic processing;

2. Test each shipment of bulk tank raw milk received for pasteurization, ultra-pasteurization, or aseptic processing by screening tests methods which have been Association of Official Analytical [~~Chemists (AOAC) reviewed~~ Chemists (AOAC) reviewed] and Food and Drug [~~Administration (FDA) accepted~~ Administration (FDA) accepted]. In lieu of any test specified in this subdivision a grade A permit holder may use AOAC first-action and AOAC final-action tests methods. Nothing in this subdivision shall be deemed to require the testing of individual raw milk samples prior to processing collected from each grade A dairy farm included in any shipment of bulk tank raw milk for pasteurization, ultra-pasteurization, or aseptic processing;

3. Implement a random-sampling program when the Commissioner of the Food and Drug Administration determines that a potential problem exists with animal drug residues or other contaminants in the milk supply. Each grade A permit holder operating a milk plant, receiving station, or transfer station shall analyze the samples for the contaminant by a method determined by FDA to be effective in determining compliance with actionable levels or established tolerances. Each grade A permit holder operating a milk plant, receiving station, or transfer station shall continue the random-sampling program until such time that the Commissioner of the Food and Drug Administration is reasonably assured that the problem has been corrected. The sampling program shall represent and include during any consecutive six months, at least four samples collected in at least four separate months, except when three months show a month containing two sampling dates separated by at least 20 days.

4. Retain each sample found to be positive for drug residues for a period of 120 hours after the sample test result is positive for drug residues for the use of the State Regulatory Authority unless directed otherwise by a representative of the State Regulatory Authority;

5. Abstain from selling or offering for sale any pasteurized, ultra-pasteurized, or aseptically processed milk, milk product, or condensed and dry milk product processed from raw milk for pasteurization, ultra-pasteurization, or aseptic processing before results of drug screening tests are available and which raw milk later tests positive for drug residues. All of the grade A permit holder's milk commingled with any raw milk which tests positive for drug residues shall be deemed adulterated. Any grade A permit holder operating a milk plant, receiving station, or transfer station shall report to the State Regulatory Authority instances of adulteration immediately;

6. Record the results of tests on samples of raw milk and retain such records for a period of six months; report records of all results of tests on samples of raw milk to the State Regulatory Authority by the fifteenth day of each month for the preceding month; and maintain and make available to the State Regulatory Authority for inspection and review at the permitted facility records of results of tests on samples of raw milk. Each record of results of tests on samples of raw milk required by this subdivision shall include:

a. The analyst's signature, date, time, and place where the test was performed;

b. The registration identification of each pickup tanker of bulk raw milk or raw milk sampled;

c. The test method used;

d. The Interstate Milk Shipper Bulk Tank Unit identification number of each grade A milk supply included on each pickup tanker of bulk raw milk tested; and

e. A statement as to whether the test results were positive or negative. If the results were positive, the grade A permit holder shall also record:

(1) The identity of each producer contributing to the load from which the positive sample of raw milk was taken;

(2) The name of the person notified at the State Regulatory Authority of the positive test results;

(3) The date and time of day the person at the State Regulatory Authority was notified of the positive test results; and

(4) The method of notification of the State Regulatory Authority;

7. Immediately notify the State Regulatory Authority and the milk marketing cooperative or broker of any shipment of bulk tank raw milk for pasteurization, ultra-pasteurization, or aseptic processing when the shipment of bulk tank raw milk is found to be positive for drug residues. Nothing in this subdivision shall be deemed to include individual raw milk samples collected from each grade A dairy farm included in any shipment of bulk tank raw milk for pasteurization, ultra-pasteurization, or aseptic processing;

8. Test each producer sample of raw milk to determine the farm of origin represented by any sample of raw milk which tests positive for drug residues and immediately report to the State Regulatory Authority the result of each producer sample representing the raw milk for pasteurization, ultra-pasteurization, or aseptic processing found to be positive for drug residues;

9. Provide by facsimile machine or other electronic means to the Virginia Department of Agriculture and Consumer Services copies of load manifests, producer weight tickets, laboratory worksheets where the results of laboratory tests are originally recorded, and records from electronic readers

documenting the results for samples tested for all positive loads; and

10. Immediately discontinue receiving shipments of raw milk from the grade A permit holder whose milk tests positive for drug residues, until subsequent tests are no longer positive for drug residues.

B. Each grade A dairy farm permit holder's milk marketing cooperative or milk marketing agent shall be responsible for the collection and testing of follow-up milk samples for animal drug residues required for permit reinstatement and resumption of milk shipment from the dairy farm each time the grade A dairy farm permit holder's milk test positive for animal drug residues.

C. Each grade A dairy farm permit holder's milk marketing cooperative or milk marketing agent shall comply with the following when following up on a producer's dairy farm after a positive animal drug residue:

1. Only person's who hold valid permits to weigh, sample and collect milk issued by the Virginia Department of Agriculture and Consumer Services shall collect and deliver follow-up milk samples to laboratories for official testing for the purpose of permit reinstatement and the resumption of milk shipments from the dairy farm;

2. Reports of laboratory testing shall be provided from officially designated laboratories for each milk sample tested for animal drug residues and shall include the following information:

a. The name of the grade A dairy farm permit holder;

b. The patron number of the grade A dairy farm permit holder;

c. The date, time and temperature of the milk sample when collected;

d. The name of the person who collected the milk sample;

e. The name of the test method used to test the milk sample; and

f. The test result for the milk sample; and

3. Only confirmation test methods approved under M-I-96-10 (Revision ~~#5)~~ #7) dated ~~March 10, 2004~~ January 4, 2010, and titled "Drug Residue Test Methods for Confirmation of Presumptive Positive Results and Initial Producer [~~Traceback"~~ Trace Back"] may be used for follow-up milk sample testing.

2VAC5-490-37. Laboratory certification.

A. Each grade A permit holder operating a dairy plant that receives any milk that could require load confirmation or producer trace-back as a result of a positive animal drug residue on a load of milk delivered at the plant shall provide to the Virginia Department of Agriculture and Consumer Services results of animal drug residue tests from an officially designated laboratory. Each officially designated laboratory shall maintain a listing in the IMS List – Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers as an approved milk laboratory certified to test load and producer samples. All laboratory results from officially designated laboratories shall be reported to the Virginia Department of Agriculture and Consumer Services within six hours of the initial presumptive positive result at the plant. ~~Existing dairy plants holding permits on May 23, 2007, shall have until December 31, 2007, to comply with this section.~~

B. Each officially designated laboratory shall comply with the requirements contained in the "Evaluation of Milk Laboratories, ~~2005~~ [~~2007~~ 2009] revision" for certification and listing in the "IMS List – Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers."

Part V
Labeling

2VAC5-490-40. Labeling.

No person may produce, provide, manufacture, sell, offer for sale, or store in the Commonwealth or, bring, send into, or receive into the Commonwealth any milk, milk product, or condensed and dry milk product for use in the commercial preparation of grade A pasteurized, ultra-pasteurized, or aseptically processed milk or milk products which are not labeled in compliance with the following:

1. Each grade A permit holder's bottles, containers, and packages enclosing any milk or milk products shall be labeled in accordance with the requirements of the Federal Food, Drug and Cosmetic Act, as amended, the Nutrition Labeling and Education Act (NLEA) of 1990, and regulations developed thereunder;

2. The grade A permit holder shall label or mark all bottles, containers, and packages enclosing any milk or milk products with:

a. The name of a defined milk product, if there is a definition, and if there is no definition, a name that is not false or misleading;

b. The word "reconstituted" or "recombined" if the milk product is made by reconstitution or recombination;

c. The term "grade A" located on the exterior of the package on the principal display panel, the secondary or informational panel, or the cap or cover;

d. The identity of the plant where the grade A permit holder's milk or milk product is pasteurized, ultra-pasteurized, or aseptically processed by specifying:

(1) The street address, city, state, and zip code of the plant; or

(2) The code assigned the plant under the National Uniform Coding System for Packaging Identification of Milk and Milk Product Processing Plants.

e. In the case of concentrated milk or concentrated milk products the volume or proportion of water to be added for recombining;

f. The name of the milk product that the concentrated milk product will produce, which name shall be preceded by the term "concentrated." In the case of flavored milk or flavored reconstituted milk, the grade A permit holder shall substitute the name of the principal flavor for the word "flavored";

g. In the case of aseptically processed milk and milk products the words "keep refrigerated after opening;"

h. In the case of aseptically processed and packaged milk or milk products, the term "UHT" ultra-high-temperature;

i. The term "ultra-pasteurized" if the milk or milk product has been ultra-pasteurized;

j. The term "goat" preceding the name of the milk or milk product when the milk or milk product is goat milk or is made from goat milk;

k. The term "sheep" preceding the name of the milk or milk product when the milk or milk product is sheep milk or is made from sheep milk;

l. The term "water buffalo" preceding the name of the milk or milk product when the milk or milk product is water buffalo milk or is made from water buffalo milk;

m. As in the case of cow's milk, goat's milk, sheep's milk, and water buffalo's milk, the common or usual name of the mammal from which the milk was obtained shall precede the name of the milk, milk product, condensed milk, condensed milk product, dry milk or dry milk product;

n. The information appearing on the label of any bottle, container, or package of milk or milk product shall contain no marks, pictures, graphics, or words which are misleading;

o. The "pull date" which shall not interfere with the legibility of other labeling required for the milk or milk product and shall be expressed by: the first three letters in the name of the month, followed by or preceded by the numeral or numerals constituting the calendar date after which the product shall not be sold or expressed numerically by the number of the month followed by the number of the day. For example, June 1 shall be expressed "JUN 1," "1 JUN," "06 01," or "06-01";

p. The grade A permit holder who operates a milk plant and offers for sale milk or milk product within the Commonwealth shall file and certify with the State Regulatory Authority the maximum number of days after manufacturing or processing the grade A permit holder's milk or milk products which will be used to determine the "pull date." The grade A permit holder shall establish a "pull date" that under normal storage the milk or milk product meets for a minimum of 96 hours after the "pull date," standards set by this chapter;

q. No person may sell or offer for sale any packaged grade A pasteurized milk, grade A pasteurized milk product, or milk product after the date of the "pull date" on the package;

r. No person may sell or offer for sale any grade A pasteurized milk, grade A pasteurized milk product, or milk product in a package that does not bear the "pull date"; ~~and~~

s. Nothing in this chapter shall apply to containers of grade A pasteurized milk, grade A milk products, or milk products which are not to be sold in the Commonwealth~~.~~; and

t. In the case of condensed or dry milk products the label shall also contain (i) the identity of the State Regulatory Authority issuing the processing plant's permit; (ii) the identity of the distributor if the condensed or dry milk products are distributed by a party other than the processing plant; (iii) the code or lot number identifying the contents with a specific date, run, or batch of the product; and (iv) a statement of the quantity of the contents of the container.

Part VI
Standards for Milk and Milk Products

2VAC5-490-50. Quality standards for milk and milk products.

A. No person may produce, provide, manufacture, sell, offer for sale, or store in the Commonwealth, or, bring, send, or receive into the Commonwealth, any milk, milk product, condensed milk product or dry milk product for use in the commercial preparation of grade A pasteurized, ultra-pasteurized, or aseptically processed milk or milk products which do not comply with the following:

1. Grade A raw milk for pasteurization or ultra-pasteurization or aseptic processing and all grade A pasteurized, ultra-pasteurized, or aseptically processed milk or milk products shall be produced, processed, and pasteurized or ultra-pasteurized, or aseptically processed to conform with the following chemical, bacteriological, somatic cell, cryoscope, and temperature standards, and with the requirements of this chapter;

2. No process or manipulation other than (i) pasteurization; (ii) ultra-pasteurization; (iii) aseptic processing; or (iv) processing methods integral with pasteurization, ultra-

pasteurization, or aseptic processing; and refrigeration may be applied to milk or milk products for the purpose of removing or deactivating microorganisms provided that filtration, bactofugation, or filtration and bactofugation may be performed in the plant in which the milk or milk product is pasteurized, ultra-pasteurized, or aseptically processed. Nothing in this chapter is deemed to prohibit any grade A permit holder who operates a milk plant from preparing bulk shipments of cream, skim milk, or lowfat milk labeled as "heat treated"; if the raw milk, raw cream, skim milk, or lowfat milk is heated, one time, to a temperature warmer than 125°F but cooler than 161°F for separation purposes;

3. Grade A raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall comply with the following standards:

a. The temperature of the raw milk shall be cooled to 40°F or cooler, but not frozen, within two hours after milking and the temperature after the first or any subsequent milking shall not be warmer than 50°F;

b. The bacteria count of the raw milk shall not exceed 100,000 bacteria per milliliter prior to commingling with any other milk; and the bacteria count of the raw milk that is commingled shall not exceed 300,000 bacteria per milliliter prior to pasteurization;

c. Raw milk shall freeze at or below -0.530° Hortvet;

d. Raw milk shall have no positive results of tests for drug residues by detection methods reported to the State Regulatory Authority by official laboratories, officially designated laboratories, milk plants, receiving stations, or transfer stations;

e. The somatic cell count of raw cow's milk, water buffalo's milk or raw sheep's milk shall not exceed 750,000 somatic cells per milliliter. The somatic cell count of raw goat's milk shall not exceed ~~1,000,000~~ 1,500,000 somatic cells per milliliter;

f. Raw milk shall not exceed the actionable level, tolerance level, or safe level for any chemical residue or pesticide residue specified in: 40 CFR Part 180 and 21 CFR Parts 70, 71, 73, 74, 80, 82, 130, 131, 133, 170, 172, 173, 174, 175, 176, 177, 178, 189, 556, 570, 573, 589. In the event that no actionable level, tolerance level, or safe level for a chemical residue or pesticides residue has been established in 40 CFR Part 180 and 21 CFR Parts 70, 71, 73, 74, 80, 82, 130, 131, 133, 170, 172, 173, 174, 175, 176, 177, 178, 189, 556, 570, 573, 589, the tolerance level shall be deemed to be zero; and

g. Raw milk shall not contain aflatoxin residues equal to or greater than 0.50 parts per billion as determined by the Charm II aflatoxin test or other equivalent method.

4. Grade A pasteurized or ultra-pasteurized, milk and milk products shall comply with the following standards:

a. The temperature of milk products shall be cooled to 45°F or cooler (but not frozen) and maintained at that temperature;

b. The bacteria count for any milk or milk products (except cultured products) shall not exceed 20,000 bacteria per milliliter;

c. Except for commingled milk shipped in a transport tank the coliform count for any milk or milk products shall not exceed 10 coliform organisms per milliliter. Commingled milk shipped in a transport tank shall not exceed 100 coliform organisms per milliliter;

d. The phenol value of test samples of pasteurized finished product shall be no greater than the maximum specified for the particular product as determined and specified by: (i) any phosphatase test method prescribed in the Official Methods of Analysis, 18th Edition, 2005, published by the Association of Official Analytical Chemists; (ii) the Fluorometer test method; (iii) the Charm ALP test method; or (iv) other equivalent method as determined by the Virginia Department of Agriculture and Consumer Services. A phenol value greater than the maximum specified for the particular product shall mean that the product was not properly pasteurized. A phenol value less than the maximum specified for the particular product shall not be deemed to mean that the product was properly pasteurized, unless there is evidence of proper pasteurization equipment in conformance with this chapter and records to determine an adequate pasteurization process has been completed for each separate batch or lot of milk, milk product, condensed milk, condensed milk product, dry milk, or dry milk product;

e. Milk or milk products shall have no positive results of tests for drug residues by detection methods reported to the State Regulatory Authority by official laboratories, officially designated laboratories, milk plants, receiving stations, or transfer stations;

f. Milk or milk products shall not exceed the actionable level, tolerance level, or safe level for any chemical residue or pesticide residue specified in: 40 CFR Part 180 and 21 CFR Parts 70, 71, 73, 74, 80, 82, 130, 131, 133, 170, 172, 173, 174, 175, 176, 177, 178, 189, 556, 570, 573, 589. In the event that no actionable level, tolerance level, or safe level for a chemical residue or pesticides residue has been established in 40 CFR Part 180 and 21 CFR Parts 70, 71, 73, 74, 80, 82, 130, 131, 133, 170, 172, 173, 174, 175, 176, 177, 178, 189, 556, 570, 573, 589, the tolerance level shall be deemed to be zero; and

g. Milk or milk products shall not contain aflatoxin residues equal to or greater than 0.50 parts per billion as

determined by the Charm II aflatoxin test or other equivalent method.

5. Grade A aseptically processed milk and milk products shall comply with the following standards:

a. Aseptically processed milk and milk products shall be commercially sterile;

b. Aseptically processed milk and milk products shall have no positive results of tests for drug residues by detection methods reported to the State Regulatory Authority by official laboratories, officially designated laboratories, milk plants, receiving stations, or transfer stations;

c. Aseptically processed milk and milk products shall not exceed the actionable level, tolerance level, or safe level for any chemical residue or pesticide residue specified in 40 CFR Part 180 and 21 CFR Parts 70, 71, 73, 74, 80, 82, 130, 131, 133, 170, 172, 173, 174, 175, 176, 177, 178, 189, 556, 570, 573, 589. In the event that no actionable level, tolerance level, or safe level for a chemical residue or pesticides residue has been established in 40 CFR Part 180 and 21 CFR Parts 70, 71, 73, 74, 80, 82, 130, 131, 133, 170, 172, 173, 174, 175, 176, 177, 178, 189, 556, 570, 573, 589, the tolerance level shall be deemed to be zero; and

d. Aseptically processed milk and milk products milk shall not contain aflatoxin residues equal to or greater than 0.05 parts per billion.

6. Grade A nonfat dry milk shall comply with the following standards:

a. The butterfat content shall not be greater than 1-1/4%;

b. The moisture content shall not be greater than 4.0%;

c. The titratable acidity shall not exceed 0.15%;

d. The solubility index shall not exceed 1-1/4 milliliters;

e. The bacteria count shall not exceed 30,000 bacteria per gram;

f. The coliform count shall not exceed 10 coliform organisms per gram; and

g. The amount of scorched particles shall not exceed 15 particles per gram.

7. Grade A whey for condensing or drying shall be maintained at a temperature of 45°F (7°C) or less, or 135°F (57°C) or greater; provided that, acid-type whey with a titratable acidity of 0.40% or above or a pH of 4.6 or below shall be exempt for the requirements of this subdivision;

8. Grade A pasteurized condensed whey and whey products shall be cooled to 50°F (10°C) or less during crystallization and within 72 hours of condensing. The coliform count of grade A pasteurized condensed whey and whey products shall not exceed 10 coliform organisms per gram; and

9. The coliform count of grade A dry whey, grade A dry whey products, grade A dry buttermilk, and grade A dry buttermilk products shall not exceed 10 coliform organisms per gram.

B. Sanitation requirements for grade A raw milk.

1. Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall comply with:

a. The following administrative procedures contained in the "Grade [~~A~~ "A"] Pasteurized Milk Ordinance ~~2005~~ [,] 2009 Revision": Section 4. – Labeling~~.~~; Section 7. - Standards for Grade "A" Raw Milk for Pasteurization, Ultra-Pasteurization or Aseptic Processing, Items 1r, 2r, 3r, 4r, 5r, 6r, 7r, 8r, 9r, 10r, 11r, 12r, 13r(1), 13r(2), 13r(4), 13r(5), 14r, 15r, 16r, 17r, 18r(2), 19r~~.~~; Section 8. – Animal Health; Section 10. – Transferring; Delivery Containers; Cooling; and Section 13. – Personnel Health;

b. The following appendices contained in the "Grade [~~A~~ "A"] Pasteurized Milk Ordinance ~~2005~~ [,] 2009 Revision": Appendices A, B, C, D, F, G, N, Q and R; and

c. Item 1r. Abnormal milk. Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:

(1) Milk last or with separate equipment cows, sheep, goats, water buffalo, or other mammals which show evidence of the secretion of abnormal milk in one or more quarters (based upon bacteriological, chemical, or physical examination) and discard the milk obtained from cows, sheep, goats, water buffalo, or other mammals which show evidence of the secretion of abnormal milk in one or more quarters based upon bacteriological, chemical, or physical examination; and

(2) Milk last or with separate equipment cows, sheep, goats, water buffalo, or other mammals treated with, or which have consumed, chemical, medicinal, or radioactive agents which are capable of being secreted in the milk and which may be deleterious to human health; and dispose of in a manner which will not pollute the environment or any human food the milk obtained from cows, sheep, goats, water buffalo, or other mammals treated with, or which have consumed, chemical, medicinal, or radioactive agents which are capable of being secreted in the milk and which may be deleterious to human health;

d. Item 2r. Milking barn, stable, or parlor-construction. Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:

(1) Provide on the person's dairy farm a milking barn, stable, or parlor in which the milking herd shall be housed during milking time;

(2) Provide on the grade A permit holder's dairy farm a milking barn, stable, or parlor which, milking barn, stable, or parlor shall:

(a) Have floors constructed of concrete or equally impervious material;

(b) Have walls and ceiling which are smooth, painted, or finished in an approved manner, and in good repair and have a ceiling which is dust tight;

(c) Have separate stalls or pens for horses, calves, and bulls;

(d) Have natural or artificial light, well distributed for day or night milking;

(e) Have sufficient air space and air circulation to prevent condensation and excessive odors;

(f) Have dust-tight covered boxes or bins, or separate storage facilities for ground, chopped, or concentrated feed; and

(g) Not be overcrowded; and

(3) Provide and use only an "automatic milking installation" that complies with the requirements of Appendix Q of the "Grade [~~A~~ "A"] Pasteurized Milk Ordinance [, 2009 Revision]" if the person milks any cows, goats, sheep, water buffalo, or other mammals (except humans) using robots or other automated means in the absence of any human;

e. Item 3r. Milking barn, stable, or parlor-cleanliness. Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:

(1) Keep the interior of the milking barn, stable, or parlor clean;

(2) Keep the floors, walls, windows, pipelines, and equipment in the milking barn, stable, or parlor free of filth or litter and clean;

(3) Keep swine and fowl out of the milking barn, stable, and parlor; and

(4) Keep surcingles, belly straps, milk stools and antikickers clean and stored above the floor;

f. Item 4r. Cow yard, sheep yard, goat yard, water buffalo yard or other milking mammal yard. Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:

(1) Provide and maintain the cow yard, sheep yard, goat yard, water buffalo yard or other milking mammal yard, to be graded and drained, and to have no standing pools of water or accumulations of organic wastes;

(2) In the cow loafing, goat loafing, sheep loafing, water buffalo loafing or other milking mammal loafing, cattle-housing, sheep-housing, goat-housing, water buffalo-housing, or other milking mammal-housing areas remove cow droppings, sheep droppings, goat droppings, water buffalo droppings, and other milking mammal droppings and remove soiled bedding or add clean bedding at sufficiently frequent intervals to prevent the soiling of the cow's, sheep's, goat's, water buffalo's, or other milking mammal's udder and flanks;

(3) Assure that waste feed does not accumulate in the goat yard, cow yard, sheep yard, water buffalo yard, other milking mammal yard, cow loafing, sheep loafing, goat loafing, water buffalo loafing, other milking mammal loafing, cattle-housing, sheep-housing, goat-housing, water buffalo-housing, or other milking mammal-housing area;

(4) Maintain any manure packs so as to be properly drained and so as to provide a reasonably firm footing; and

(5) Keep swine and fowl out of the cow yard, sheep yard, goat yard, water buffalo yard, other milking mammal yard, cow loafing, sheep loafing, goat loafing, water buffalo loafing, other milking mammal loafing, cattle-housing, sheep-housing, goat-housing, water buffalo-housing, or other milking mammal-housing area.

g. Item 5r. Milkhouse or room-construction and facilities. Each who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:

(1) Provide a milkhouse or milkroom of sufficient size in which the cooling, handling, and storing of milk and the washing, sanitizing, and storing of milk containers and utensils shall be conducted except as provided under subdivision 1 n of this subsection;

(2) Provide a milkhouse with a smooth floor, constructed of concrete or equally impervious material graded to drain, and maintained in good repair;

(3) Dispose of in a sanitary manner all liquid waste generated in the milkhouse;

(4) Provide one or more floor drains in the milkhouse, which floor drains shall be accessible, and if connected to a sanitary sewer system trapped;

(5) Provide in the milkhouse walls and ceilings constructed of a smooth material, in good repair, well painted, or finished in an equally suitable manner;

(6) Provide adequate natural or artificial light and ventilation in the milkhouse;

(7) Use the milkhouse for no other purpose than milkhouse operations;

(8) Provide no direct opening from the milkhouse into any barn, stable, or into any room used for domestic purposes, other than a direct opening between the milkhouse and milking barn, stable, or parlor provided with a tight-fitting, self-closing, solid door, which door has been hinged to be single or double acting;

(9) Provide in the milkhouse water under pressure which has been piped into the milkhouse;

(10) Provide in the milkhouse a two-compartment wash vat and adequate hot water heating facilities;

(11) Except as provided for under subdivision 1 g (12) of this subsection provide a suitable shelter for the receipt of milk when the grade A permit holder uses a transportation tank for the cooling or storage of milk on the grade A permit holder's dairy farm, which shelter adjacent to, but not a part of, the milkroom; and with the requirements of the milkroom shall comply with respect to construction, light, drainage, insect and rodent control, and general maintenance. In addition to providing a suitable shelter as required by this subsection, the grade A permit holder shall:

(a) Install an accurate, accessible temperature-recording device in the milk line used to fill the transportation tank downstream from an effective cooling device capable of cooling the milk to 40°F or less before the milk enters the transportation tank;

(b) Install an indicating thermometer as close as possible to the temperature-recording device in the milk line used to fill the transportation tank to be used for verification of recording temperatures, which indicating thermometer shall:

(i) Have a temperature span of not less than 50°F including normal storage temperatures plus or minus 5°F, with an extension of the scale on either side permitted and graduated in not more that 2°F divisions;

(ii) Have temperature scale divisions spaced not less that 0.0625 inches apart between 35°F and 55°F;

(iii) Have an accuracy within plus or minus 2°F throughout the scale range; and

(iv) Have the stem fitting installed in a pressure-tight seat or other sanitary fitting with no threads exposed;

(c) Provide an effective means to agitate the transport tank or an approved in-line sampling device in order to collect a representative milk sample;

(12) If the State Regulatory Authority determines conditions exist whereby the milk transport tank may be adequately protected and sampled without contamination, a shelter need not be provided if the grade A permit holder:

(a) Provides a means to make all milk hose connections to the transport tank accessible from within the milkhouse;

(b) Provides a means to completely protect the milk hose connection to the transport tank from the outside environment;

(c) Ensures he utilizes only milk transport tanks the manholes of which have been sealed after cleaning and sanitizing;

(d) Ensures he utilizes only milk transport tanks that have been washed and sanitized at permitted dairy plants or a permitted milk tank truck cleaning facilities acceptable to the State Regulatory Agency;

(e) Installs an accurate, accessible temperature-recording device in the milk line used to fill the transportation tank downstream from an effective cooling device capable of cooling the milk to 40°F or less before the milk enters the transportation tank;

(f) Installs an indicating thermometer as close as possible to the temperature-recording device in the milk line used to fill the transportation tank to be used for verification of recording temperatures, which indicating thermometer shall:

(i) Have a temperature span of not less than 50°F including normal storage temperatures plus or minus 5°F, with an extension of the scale on either side permitted and graduated in not more that 2°F divisions;

(ii) Have temperature scale divisions spaced not less that 0.0625 inches apart between 35°F and 55°F;

(iii) Have an accuracy within plus or minus 2°F throughout the scale range; and

(iv) Have the stem fitting installed in a pressure-tight seat or other sanitary fitting with no threads exposed;

(g) Provides an effective means to agitate the transport tank or an approved in-line sampling device in order to collect a representative milk sample; and

(h) Provides a self-draining concrete or equally impervious surface on which the transport tank can be parked during filling and storage;

h. Item 6r. Milkhouse or milkroom-cleanliness. Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:

(1) Keep clean the floors, walls, ceilings, windows, tables, shelves, cabinets, wash vats, nonproduct contact surfaces of milk containers, utensils, equipment, and other milkroom equipment in the milkroom;

(2) Place in the milkroom only those articles directly related to milkroom activities; and

(3) Keep the milkroom free of trash, animals, and fowl;

i. Item 7r. Toilets. Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:

(1) Provide on the person's grade A dairy farm one or more toilets, which shall be conveniently located and properly constructed, and operated, and maintained in a sanitary manner;

(2) Prevent the access of flies to the waste contained in or from the toilet;

(3) Prevent the waste contained in or from the toilet from polluting the soil surface or contaminating any water supply; and

(4) Assure that there is no direct opening from the toilet into any milkroom;

j. Item 8r. Water supply. Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:

(1) Provide water for milkhouse and milking operations from a water supply properly located, protected, and operated. The water supply shall be easily accessible, adequate, and of a safe, sanitary quality;

(2) Assure that any well casing which is part of a water supply that provides water for any milkhouse or milking operation is not located closer to any source of contamination which may contaminate the water supply than is specified as follows:

(a) No grade A permit holder may locate a well casing closer than 10 feet to a pit;

(b) No grade A permit holder may locate a well casing closer than 10 feet to any sewer pipe, floor drain, or other pipe which may back up;

(c) No grade A permit holder may locate a well casing closer than 50 feet to any above-ground gas, oil, petroleum, or chemical storage tank;

(d) No grade A permit holder may locate a well casing closer than 50 feet to any accumulated animal manure;

(e) No grade A permit holder may locate a well casing closer than 50 feet to any area to which livestock has access; or animal-holding area, feedlot, or loafing area on dirt;

(f) No grade A permit holder may locate a well casing closer than 50 feet to any pit not drained to the surface of the ground. Nothing in this requirement shall apply to a residential basement;

(g) No grade A permit holder may locate a well casing closer than 100 feet to any pit privy. Existing well casings located on grade A dairy farms holding valid permits issued by the State Regulatory Authority on September 1, 1993, shall be exempt from the 100 foot distance requirement of this subdivision until the existing permit is canceled or revoked;

(h) No grade A permit holder may locate a well casing closer than 100 feet to any animal-manure disposal area;

(i) No grade A permit holder may locate a well casing closer than 100 feet to any cess pool;

(j) No grade A permit holder may locate a well casing closer than 100 feet to any dry well;

(k) No grade A permit holder may locate a well casing closer than 100 feet to any structure which stores animal manure;

(l) No grade A permit holder may locate a well casing closer than 100 feet to any septic tank or drain field; and

(m) No grade A permit holder may locate a well casing closer than 100 feet to any underground or partially-buried gas, oil, petroleum, or chemical storage tank;

(3) Construct the water supply so that the well casing terminates at least two feet above the highest-known flood plane for the location in which the water supply is located; and

(4) Construct the water supply so that no potable water supply pipe attached to the water supply is located closer than 10 feet measured horizontally to any sewer pipe, soil pipe, or drain;

k. Item 9r. Utensils and equipment-construction. Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:

(1) Provide multiuse containers, equipment, and utensils for use in the handling, storage, or transportation of any milk, which multiuse containers, equipment, and utensils, shall be made of smooth, nonabsorbent, corrosion-resistant, and nontoxic materials; constructed as to be easily cleaned; and in good repair;

(2) Provide milk pails which are constructed to be seamless and of the hooded type if the grade A permit holder does hand milking and stripping;

(3) Abstain from using multiple-use woven material for straining any milk;

(4) Use only single-service articles which have been manufactured, packaged, transported, stored, and handled in a sanitary manner and that comply with the requirements of subdivision C 1 of this section;

(5) Abstain from reusing any article intended for single-service use; and

(6) Provide farm holding or cooling tanks, welded sanitary piping, and transportation tanks which comply with the requirements of subdivisions C 1 l and C 1 m of this section on any grade A dairy farm;

l. Item 10r. Utensils and equipment; cleaning. Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:

(1) Clean after each use the product-contact surfaces of all multiuse containers, multiuse equipment, and multiuse utensils used in the handling, storage, or transportation of any milk; and

(2) Offer for sale or sell no milk which has passed through any equipment, if the milk-contact surfaces of the equipment are no longer visible, or are covered or partially covered by an accumulation of milk solids, milk fat, cleaning compounds or other soils. Any milk which passes through equipment, the milk-contact surfaces of which are no longer visible, or are covered or partially covered by an accumulation of milk solids, milk fat, cleaning compounds, or other soils shall be deemed adulterated;

m. Item 11r. Utensils and equipment; sanitization. Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall sanitize before each use the product-contact surfaces of all multiuse containers, equipment, and utensils used in the handling, storage, or transportation of any milk;

n. Item 12r. Utensils and equipment; storage. Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall store containers, utensils, and equipment used in the handling, storage, or transportation of any milk in a sanitizing solution or store the containers, utensils, and equipment used in the handling, storage, or transportation of any milk to assure complete drainage, and protected from contamination prior to use. Nothing in this requirement shall be deemed to prohibit a grade A permit holder from storing in a milking barn or milking parlor a milk pipeline, or the following pipeline milking equipment: milker claw, inflation, weigh jar, meter, milk hose, milk receiver, tubular cooler, plate cooler, or milk pump; if the milk pipeline or pipeline milking equipment specified in this subdivision is designed for mechanical cleaning; and designed, installed, and operated to protect the milk product and solution-contact surfaces from contamination at all times;

o. Item 13r. Milking; flanks, udders, and teats. Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:

(1) Milk all cows, sheep, goats, water buffalo, and other mammals in a milking barn, stable, or parlor;

(2) Trim the hair from the udder and tail of all milking cows, sheep, goats, water buffalo, and other mammals to facilitate cleaning of the udder and tail;

(3) Keep the flanks, udders, bellies, and tails of all milking cows, sheep, goats, water buffalo, and other mammals free of visible dirt;

(4) Keep the hair on the udders of all milking cows, sheep, goats, water buffalo and other mammals to a length that the hair on the udder of any cow, sheep, goat, water buffalo, or other mammal cannot be incorporated with the teat in the inflation during milking;

(5) Abstain from milking any cow, sheep, goat, water buffalo, or other mammal whose udder or teats is not clean and dry;

(6) Treat with a sanitizing solution, just prior to milking, the teats of each milking cow, sheep, goat, water buffalo, and other mammal and dry the teats of each milking cow, sheep, goat, water buffalo, and other mammal before milking; and

(7) Milk all cows, sheep, goats, water buffalo, and other mammal with dry hands;

p. Item 14r. Protection from contamination. Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:

(1) Locate and operate the milking and milk house operations, equipment, and facilities to prevent any contamination of the milk, equipment, containers, or utensils;

(2) Transfer immediately from the milking barn, stable, or parlor to the milkhouse each pail or container of milk;

(3) Strain, pour, transfer, or store any milk unless it is protected from contamination;

(4) Handle all containers, utensils and equipment that have been sanitized in such a manner as to prevent contamination of any product-contact surfaces;

(5) Transport from the grade A permit holder's dairy farm to a milk plant or receiving station all milk in cans, using vehicles which are constructed and operated to protect the milk from sun, freezing, and contamination;

(6) Keep clean the inside and outside of each vehicle used to transport from the grade A permit holder's dairy farm to a milk plant or receiving station any milk in cans; and

(7) Transport no substance capable of contaminating the milk when transporting milk;

q. Item 15r. Drug and chemical control. Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:

(1) Store all drugs and medicinals in such a manner that neither the drugs nor the medicinals can contaminate any milk or the milk product-contact surface of any equipment, containers or utensils;

(2) Abstain from using unapproved or improperly labeled medicinals or drugs to treat any dairy animals or store unapproved or improperly labeled medicinals or drugs in the milkhouse, milking barn, stable or parlor. Except for topical antiseptics, wound dressings (unless intended for direct injection into the teat), vaccines and other biologics, and dosage form vitamins and mineral products a drug or medicinal is properly labeled only if the drug or medicinal is labeled with the following:

(a) For over-the-counter medicinals or drugs, the name and address of the manufacturer or distributor, or for prescription and extra-label use medicinals or drugs, the name of the veterinary practitioner dispensing the product;

(b) Directions for use of the drug or medicinal and the prescribed holding time;

(c) Any cautionary statement for the drug or medicinal, if needed; and

(d) The active ingredient or ingredients in the drug or medicinal;

(3) Except for topical antiseptics, wound dressings (unless intended for direct injection into the teat), vaccines and other biologics, and dosage form vitamins and mineral products, segregate all medicinals and drugs used for lactating dairy animals from any medicinals and drugs used for nonlactating dairy animals;

(4) Except for topical antiseptics, wound dressings (unless intended for direct injection into the teat), vaccines and other biologics, and dosage form vitamins and mineral products, provide separate shelves in a cabinet, refrigerator, or other storage facility for the storage of all medicinals and drugs for treatment of nonlactating dairy animals separate from those medicinals or drugs used for lactating dairy animals; and

(5) Store topical antiseptics, wound dressings (unless intended for direct injection into the teat), vaccines and other biologics, and dosage-form vitamins and mineral products in a manner that does not contaminate any milk or the milk-product surfaces of any containers or utensils;

r. Item 16r. Personnel; hand-washing facilities. Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall provide hand-washing facilities that are convenient to the milkhouse, milking barn, stable, or parlor, and flush toilet and that include separate hot and cold running water; soap or detergent; and individual sanitary towels;

s. Item 17r. Personnel; cleanliness. Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:

(1) Wash clean and dry with an individual sanitary towel the person's hands immediately before milking, before performing any milkhouse function, and immediately after the interruption of milking or performing any milkhouse function; and

(2) Wear clean outer garments while milking or handling any milk, milk containers, utensils, or equipment. Bulk milk haulers shall wear clean outer garments while handling any milk, milk containers, utensils, or equipment;

t. Item 18r. Cooling. Each person who holds a grade A permit to produce raw milk for pasteurization, ultra-pasteurization, or aseptic processing shall:

(1) Cool to 40°F or cooler (but not freeze), all raw milk for pasteurization, ultra-pasteurization, or aseptic processing, within two hours after the grade A permit holder completes milking; and assure that the temperature of the grade A permit holder's raw milk is not warmer than 50°F after the first milking or any subsequent milking. Raw milk for pasteurization which is warmer than a temperature of 50°F after the first milking or any subsequent milking shall be deemed a public health hazard and shall not be offered for sale or sold; and

(2) Agitate all raw milk for pasteurization for not less than five minutes at least once every hour; assure that the milk in the farm's bulk milk cooling or holding tank covers the agitator paddle sufficiently to facilitate proper cooling and sampling after the completion of the first milking; and abstain from selling or offering for sale milk which does not cover the agitator paddle sufficiently to facilitate proper cooling and sampling after the completion of the first milking;

u. Item 19r. Insect and rodent control. Each person who holds a grade A permit to produce raw milk for

pasteurization, ultra-pasteurization, or aseptic processing shall:

(1) Take effective measures to prevent the contamination of any milk, containers, equipment, and utensils by insects, rodents, and other animals, and by chemicals used to control insects, rodents, and other animals;

(2) Maintain the milkroom free of insects, rodents and other animals;

(3) Keep the areas surrounding the: milkhouse; milking barn; milking stable; milking parlor; cattle, sheep, water buffalo, other mammal, or goat housing; cattle, sheep, water buffalo, other mammal, or goat loafing; water supply; or other facilities on the grade A permit holder's dairy farm neat, clean, and free of conditions which might harbor or be conducive to the breeding of insects and rodents; and

(4) Store all feed in such a manner that the feed will not attract birds, rodents or insects.

C. Sanitation requirements for grade A pasteurized, ultra-pasteurized, or aseptically processed milk or milk products.

1. Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk or milk products shall comply with:

a. The following administrative procedures contained in the "Grade [~~A~~ "A"] Pasteurized Milk Ordinance ~~2005~~ [,] 2009 Revision": Section 7. Standards for Grade "A" Pasteurized, Ultra-pasteurized and Aseptically Processed Milk and Milk Products, Items 1p, 2p, 3p, 4p, 5p, 6p, 7p, 8p, 9p, 10p, 11p, 12p, 13p, 14p, 15p, 16p, 17p, 18p, 19p, 20p, 21p, and 22p;

b. The following appendices contained in the "Grade [~~A~~ "A"] Pasteurized Milk [~~Ordinance~~] ~~2005~~ [Ordinance,] 2009 Revision:" Appendices D, F, G, H, I, J, K, L, N, O and R;

c. Item 1p. Floors; construction. Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall:

(1) Except as specified in subdivision C 1 c (2) of this section, provide floors, for all rooms in which milk or milk products are processed, handled, or stored, or in which milk containers, equipment, or utensils are washed constructed of concrete or other equally impervious and easily cleaned material and which are smooth, properly sloped, provided with trapped drains, and kept in good repair;

(2) The floor in any cold-storage room used for storing milk and milk products need not be provided with floor drains if the floors are sloped to drain to one or more exits from the cold-storage room. The floor in any storage room used for storing dry ingredients or packaging materials need not be provided with drains and the floor in any storage room used for storing dry ingredients or packaging materials may be constructed of tightly joined wood;

d. Item 2p. Walls and ceilings; construction. Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall provide walls and ceilings of rooms in which milk or milk products are handled, processed, or stored, or in which milk containers, utensils, or equipment are washed, that have a smooth, washable, light-colored surface, and that are in good repair;

e. Item 3p. Doors and windows. Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall provide:

(1) Effective means to prevent the access of flies and rodents to any part of a milk plant, receiving station, or transfer station; and

(2) Solid doors or glazed windows for all openings to the outside of any milk plant, receiving station, or transfer station and keep the doors and windows closed during dusty weather;

f. Item 4p. Lighting and ventilation. Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall provide rooms in which any milk or milk products are handled, processed, or stored or in which any milk containers, equipment, or utensils are washed, that are well lighted and well ventilated;

g. Item 5p. Separate rooms. Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall:

(1) Provide separate rooms for: (i) pasteurizing, processing, cooling, and packaging milk and milk products; (ii) cleaning milk cans, bottles, and cases; (iii) the fabrication of containers and closures for milk and milk products; (iv) cleaning and sanitizing facilities for bulk milk transport tanks if the grade A permit holder receives any milk or milk product in bulk milk transport tanks; and (v) receiving cans of milk and milk products separate from clauses (i), (ii) and (iii) of this subdivision, unless all of the grade A permit holder's milk or milk products are received in bulk milk transport tanks;

(2) Not use any room with a direct opening into any stable or room used for domestic purposes to handle, process, or store any milk or milk products or; wash or store any milk containers, utensils, or equipment;

(3) Use rooms of sufficient size so as not to be crowded to handle, process, or store any milk or milk products or wash or store any milk containers, utensils, or equipment; and

(4) Provide designated areas or rooms for the receiving, handling and storage of returned packaged milk and milk products if the permit holder receives any returned packaged milk or milk products;

h. Item 6p. Toilet-sewage disposal facilities. Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall provide each milk plant with toilet facilities conforming with the regulations of the Commonwealth and the following requirements: no toilet room may open directly into any room in which milk or milk products are processed; the toilet room shall be completely enclosed and shall have tight-fitting, self closing doors; the dressing room, toilet room, and fixtures shall be kept in a clean condition, in good repair, and shall be well ventilated and well lighted; and sewage and other liquid wastes from the toilet room shall be disposed of in a sanitary manner;

i. Item 7p. Water supply. Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall:

(1) Provide water for each milk plant from a supply which is properly located, protected, and operated; and

(2) Provide water from a supply which is easily accessible for inspection by the State Regulatory Authority, adequate, and of a safe, sanitary quality;

j. Item 8p. Hand-washing facilities. Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall:

(1) Provide hand-washing facilities, including separate hot and cold running water, mix valve, soap, and individual sanitary towels or other approved hand-drying devices, convenient in any area where milk or milk products are handled, processed, or stored, and any area where containers, utensils, or equipment, are washed or stored; and

(2) Keep the hand-washing facilities clean and in good repair;

k. Item 9p. Milk plant cleanliness. Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall:

(1) Keep clean, neat, and free of any evidence of animals, insects or rodents, all rooms in which milk or milk products are handled, processed, or stored or in which containers, utensils, or equipment are washed or stored; and

(2) Permit only equipment directly related to processing operations or to the handling of containers, utensils, and equipment, in pasteurizing, processing, cooling, packaging, or bulk milk storage rooms;

l. Item 10p. Sanitary piping. Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall:

(1) Use only sanitary piping, fittings, and connections consisting of smooth, impervious corrosion-resistant, nontoxic, easily cleanable materials that are exposed to any milk or milk products, or from which liquids may drip, drain, or be drawn into any milk or milk products;

(2) Keep all piping in good repair;

(3) Except as specified in subdivision 1 l of this subsection, use only sanitary piping to transfer any pasteurized or ultra-pasteurized milk or milk products from one piece of equipment to another piece of equipment; and

(4) Transport cottage cheese, cheese dressings, or cheese ingredients by methods which protect the product from contamination;

m. Item 11p. Construction and repair of containers and equipment. Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall:

(1) Use only multiuse containers and equipment, that may come in contact with any milk or milk products constructed of smooth, impervious, corrosion-resistant, and nontoxic materials; constructed for ease of cleaning; and kept in good repair;

(2) Use only single-service containers, closures, gaskets, and other articles, that may come in contact with any milk or milk products, that are nontoxic and have been manufactured, packaged, transported, and handled in a sanitary manner;

(3) Abstain from using more than once any articles intended for single-service use; and

(4) Use only single-service containers, closures, caps, gaskets, and similar articles manufactured, packed, transported, and handled in a manner which complies with the requirements of Appendix J, "Standards for the Fabrication of Single-Service Containers and Closures for Milk and Milk Products"; contained in the "Grade [~~A~~ "A"] Pasteurized Milk Ordinance, ~~2005~~ 2009 [~~revision"~~ Revision"];

n. Item 12p. Cleaning and sanitizing of containers and equipment. Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall:

(1) Effectively clean and sanitize before each use the product-contact surfaces of all multiuse containers and equipment, utensils, and equipment used in the transportation, processing, handling, and storage of any milk or milk products;

(2) Use only multi-use containers for packaging pasteurized milk and milk products that comply with the following: (i) the residual bacteria count on multi-use containers may not exceed one per milliliter of capacity when the rinse test is used, or the residual bacteria count on multi-use containers shall not exceed 50 colonies per eight square inches (one per square centimeter) of product-contact surface, when the swab test is used; in three-out-of-four samples taken at random on a given day; and (ii) all multi-use containers shall be free of coliform organisms; and

(3) Use only single-service containers for packaging pasteurized milk and milk products that comply with the following: (i) the residual bacteria count of single-service containers shall not exceed 50 per container, when the rinse test is used, except that in containers less than 100 milliliters, the count shall not exceed 10, or the residual bacteria count of single-service containers shall not exceed 50 colonies per eight square inches (one per square centimeter) of product contact surface, when the swab test is used; in three-out-of-four samples taken at random on a given day; and (ii) all single-service containers shall be free of coliform organisms;

o. Item 13p. Storage of cleaned containers and equipment. Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products, shall after cleaning any multiuse milk or milk product containers, utensils, or equipment, transport or store the multiuse milk or milk product containers, utensils, or equipment in a manner that assures complete drainage and in a manner that protects the multiuse milk or milk product containers, utensils, or equipment from contamination before use;

p. Item 14p. Storage of single-service containers, utensils, and materials. Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall:

(1) Purchase all single-service caps, cap stock, parchment paper, containers, gaskets, and other single-service articles for use in contact with milk or milk products, in sanitary tubes, wrappings, or cartons;

(2) Store in a clean dry place until used, single-service caps, cap stock, parchment paper, containers, gaskets, and other single-service articles for use in contact with milk or milk products;

(3) Store single-service caps, cap stock, parchment paper, containers, gaskets, and other single-service articles for use in contact with milk or milk products in sanitary tubes, wrappings, or cartons; and

(4) Handle single-service caps, cap stock, parchment paper, containers, gaskets, and other single-service articles for use in contact with milk or milk products in a sanitary manner;

q. Item 15p. Protection from contamination. Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall:

(1) Locate the person's equipment and facilities and conduct milk plant operations to prevent any contamination of any milk or milk products, ingredients, equipment, containers, or utensils;

(2) Discard all milk, milk products, or ingredients which have been spilled, overflowed, or leaked;

(3) Perform the processing and handling of products other than milk and milk products in the person's milk plant to preclude the contamination of any milk or milk products;

(4) Store, handle, or use any toxic material to preclude the contamination of any milk, milk product, or ingredient, and the milk product contact surfaces of all equipment, containers, or utensils; and

(5) Clean, prior to use, all multi-use cases used to encase packaged milk or milk product containers;

r. Item 16p. Pasteurization and ultra-pasteurization. Each person who holds a grade A permit to produce grade A pasteurized, ultra- pasteurized, or aseptically processed milk, or milk products shall:

(1) Perform pasteurization or ultra-pasteurization as defined in 2VAC5-490-10; and

(2) Perform aseptic processing in compliance with the provisions of 21 CFR Part 113, 21 CFR Part 108, and the Administrative Procedures of Item 16p, 16p(C), 16p(D), and 16p(E) of the "Grade [~~A~~ "A"] Pasteurized Milk Ordinance, ~~2005~~ 2009 [~~revision"~~ Revision"];

s. Item 17p. Cooling of milk. Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall:

(1) Maintain all raw milk and milk products at a temperature of 45°F or cooler, but not frozen, until processed;

(2) Maintain all whey and whey products for condensing, drying, or condensing and drying at a temperature of 45°F (7°C) or cooler; or 135°F (57°C) or greater until processed, except that acid-type whey with a titratable acidity of 0.40% or above, or a pH of 4.6 or below, is exempted from these temperature requirements;

~~(2)~~ (3) Immediately cool, except for the following milk or milk products ~~to be cultured~~, all pasteurized or ultra-pasteurized milk or milk products prior to filling or packaging in approved cooling equipment to a temperature of 45°F or cooler, but not frozen unless drying is commenced immediately after condensing:

(a) Those milk or milk products to be cultured;

(b) Cultured sour cream at all milkfat levels with a pH of 4.70 or below:

(c) Acidified sour cream at all milkfat levels with a pH of 4.60 or below;

(d) All yogurt products at all milkfat levels with an initial pH of 4.80 or below at filling;

(e) Cultured buttermilk at all milkfat levels with a pH of 4.60 or below; and

(f) All condensed whey and whey products shall be cooled during the crystallization process to 50°F (10°C) or less within 72 hours of condensing, including the filling and emptying time, unless filling occurs above 135°F (57°C), in which case, the 72 hour time period begins when cooling started;

~~(3)~~ (4) Store, transport, and deliver at a temperature of 45°F or cooler, but not frozen, all pasteurized or ultra-pasteurized milk or milk products with the following exceptions:

(a) Cultured sour cream at all milkfat levels with a pH of 4.70 or below shall be cooled to 45°F (7°C) or cooler within 168 hours of filling;

(b) Acidified sour cream at all milkfat levels with a pH of 4.60 or below shall be cooled to 45°F (7°C) or cooler within 168 hours of filling;

(c) All yogurt products at all milkfat levels with an initial pH of 4.80 or below at filling and with a subsequent pH of 4.60 or below within 24 hours after filling shall be cooled to 45°F (7°C) or cooler within 96 hours after filling; and

(d) Cultured buttermilk at all milkfat levels with a pH of 4.60 or below shall be cooled to 45°F (7°C) or cooler within 24 hours after filling; ~~and~~

(5) Store all pasteurized milk and milk products to be condensed, dried, or condensed and dried at a temperature of 50°F (10°C) or cooler until further processed;

~~(4)~~ (6) Equip with an accurate indicating thermometer each of the rooms or tanks in which any milk, ~~or~~ milk products, whey, or whey products are stored; and

(7) Provide ready access at the plant to cleaning records and product storage temperature records stored electronically for review by the State Regulatory Authority. Electronic records of cleaning shall comply with the applicable provisions of Appendix H, Sections IV and V of the "Grade [~~A~~ "A"] Pasteurized Milk Ordinance, 2009 [~~revision"~~ Revision"];

t. Item 18p. Bottling and packaging. Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall:

(1) Bottle or package all milk or milk products ~~(except for cottage cheese, dry curd cottage cheese and lowfat cottage cheese)~~ at the place of pasteurization in the grade A permit holder's milk plant and in approved mechanical equipment; ~~and~~

(2) ~~Transport all cottage cheese, dry curd cottage cheese, or lowfat cottage cheese not creamed or packaged in the grade A permit holder's milk plant in sealed containers and in a protected, sanitary manner from the grade A permit holder's milk plant to another grade A permit holder's milk plant for creaming or packaging;~~ Package and store in a sanitary manner all dry milk products in new containers, which protect the contents from contamination; and

(3) Transport and store in a sanitary manner all condensed and dry milk products in sealed containers from one milk plant to another milk plant for further processing or packaging;

u. Item 19p. Capping. Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall:

(1) Cap or close all milk or milk product containers in a sanitary manner by use of approved mechanical capping or closing equipment; and

(2) Use only caps or closures for all milk or milk products, which protect the pouring lip of a milk or milk product container to at least its largest diameter and, use with respect to fluid product containers, only caps or closures that the removal of the cap or closure cannot be made without detection;

v. Item 20p. Personnel; cleanliness. No person who holds a grade A permit to produce grade A pasteurized, ultra-

pasteurized, or aseptically processed milk, or milk products shall:

(1) Permit any person in a milk plant to commence any plant function before the person has thoroughly washed the person's hands to remove soil and contamination or to permit any person in a milk plant to continue any plant function if the person's hands are not clean;

(2) Permit any person in a milk plant to resume work after the person has visited the toilet room before the person has thoroughly washed the person's hands;

(3) Permit any person in a milk plant to engage in the processing, pasteurization, handling, storage, or transportation of any milk, milk products, containers, equipment or utensils, unless the person is wearing clean outer garments;

(4) Permit any person in a milk plant, to engage in the processing of any milk or milk products unless the person wears adequate hair covering; or

(5) Permit any person in a milk plant, to engage in the processing of any milk or milk products if the person is using tobacco;

w. Item 21p. Vehicles. Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall use vehicles to transport pasteurized and ultra-pasteurized milk and milk products that are constructed and operated so that the milk or milk products are maintained at a temperature of 45°F or cooler, but not frozen and protected from sunlight, from freezing, and from contamination;

x. Item 22p. Surroundings. Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk, or milk products shall keep neat, clean, and free from conditions which might attract or harbor flies, other insects, rodents, or which otherwise constitute a nuisance, the area surrounding any milk plant;

y. Each grade A permit holder's receiving station shall comply with subdivisions C 1 a through q of this section, inclusive, and subdivisions C 1, s, v, and x of this section, except that the partitioning requirement of subdivision C 1 g of this section shall not be deemed to apply;

z. Each grade A permit holder's transfer station shall comply with subdivisions C 1 c, f, h through n, p, q, s, v, and x of this section; and as climatic and operating conditions require, the provisions of subdivisions C 1 d and e of this section; except that each person shall provide overhead protection for a transfer station; and

a1. Each grade A permit holder's facilities for the cleaning and sanitizing of bulk tanks which transport milk and milk products shall comply with subdivisions C 1 a, f, h through n, p, q, v, and x of this section; and as climatic and operating conditions require, the provisions of subdivisions C 1 d and e of this section except that each grade A permit holder shall provide overhead protection for facilities for the cleaning and sanitizing of bulk tanks which transport milk and milk products in the grade A permit holder's milk plant, receiving station, or transfer station.

D. Minimum facilities requirements for milk processing plant. Each person who holds a grade A permit to produce grade A pasteurized, ultra-pasteurized, or aseptically processed milk or milk products shall:

1. Provide a separate receiving room meeting the requirements of subdivision C 1 y of this section from any other area of the plant for the receipt of milk or milk products in bulk if the plant receives any milk or milk products in bulk;

2. Provide cleaning and sanitizing facilities for milk tank trucks as part of the plant's receiving room facilities if the plant receives any milk or milk products in bulk;

3. Provide a separate receiving room from any other area of the plant for the receipt of milk or milk product in cans or other containers if the plant receives any milk or milk product in cans or other containers;

4. Provide a separate room from any other area of the plant for the cleaning of milk cans or containers, bottles, milk cases, and dry milk or milk product containers if the plant receives any milk in cans or containers or washes any bottles, milk cases, or dry milk or milk product containers;

5. Provide a separate room for the fabrication of containers and closures for milk and milk products if the plant fabricates any containers or closures;

6. Provide a separate room for the packaging of dry milk or milk products if the plant packages any dry milk or milk product; and

7. Provide separate rooms from any other area of the plant for each of the following operations performed on any milk, milk product, or condensed and dry milk product: (i) pasteurization; (ii) processing; (iii) cooling; (iv) reconstitution; (v) condensing; (vi) drying; and (vii) packaging, if the operation is performed in the plant.

2VAC5-490-73. Mandatory pasteurization for all milk, milk products, condensed milk, condensed milk products, dry milk, and dry milk products in final package form intended for direct human consumption.

No person shall ~~cause to be delivered into intrastate commerce or shall~~ sell~~, otherwise distribute,~~ or hold ~~for sale~~

with intent to sell or ~~other distribution after shipment~~ offer to sell in intrastate commerce any milk, milk product, condensed milk, condensed milk product, dry milk, or dry milk product in final package form for direct human consumption unless the product has been pasteurized or is made from milk, milk product, condensed milk, condensed milk product, dry milk, or dry milk product that has all been pasteurized, except where alternative procedures to pasteurization are provided for under 21 CFR Part 133 for curing of certain cheese varieties.

2VAC5-490-105. New or test facilities and equipment; equipment design, construction and approval process.

A. At the request of any grade A permit holder, the State Regulatory Authority may allow the temporary installation of equipment or the temporary construction of dairy facilities that the State Regulatory Authority has no or limited regulatory experience with, on a trial basis, to determine if the equipment or dairy facilities can comply with the requirements of this chapter under normal conditions of use. The State Regulatory Authority will at a minimum evaluate the equipment or facilities for compliance with the requirements of this chapter when newly installed, as well as, complete a separate evaluation of the inspection record during the trial of the equipment or facilities to comply with the requirements of this chapter over time under normal conditions of use.

B. At the conclusion of each trial, the State Regulatory Authority shall inform the grade A permit holder in writing if the equipment or facilities or both the equipment and facilities comply with the requirements of this chapter. If the equipment or facilities do not comply or both the equipment and facilities do not comply with the requirements of this chapter, the State Regulatory Authority shall inform the grade A permit holder in writing to alter or remove his equipment or facilities or to alter or remove both his equipment and facilities within a maximum of six months from the date of receipt of the written decision by the permit holder.

C. The State Regulatory Authority ~~shall not~~ may renew or extend any temporary installation of equipment or the temporary construction of dairy facilities beyond the time specified in the written agreement between the grade A permit holder and the State Regulatory Authority ~~for more than one year after the time specified in the written agreement for any reason. The State Regulatory Authority shall not accept any agreement between the grade A permit holder and the State Regulatory Authority for the temporary installation of equipment or the temporary construction of dairy facilities that proposes to be evaluated for a period longer than one year~~.

D. If the State Regulatory Authority agrees to allow the temporary installation of equipment or the temporary construction of dairy facilities, the State Regulatory Authority and the grade A permit holder installing the equipment or constructing the facilities shall each sign a written agreement that at a minimum includes:

1. A description of the equipment or facilities and detailed plans for their installation acceptable to the State Regulatory Authority;

2. The name of the grade A permit holder and the physical address where the equipment or facilities will be installed;

3. The name and contact information for the person or persons who will be installing the equipment or constructing the facilities;

4. A detailed plan including:

a. A description of the items to be evaluated by the State Regulatory Authority;

b. Criteria to judge the acceptability of performance by which each item being evaluated will be measured by the State Regulatory Authority;

c. A time table specifying the length of the trial, the minimum number of inspections and time periods between inspections;

d. How inspection findings will be documented and reviewed with the permit holder and at what frequency;

e. A provision for the State Regulatory Authority to end the temporary installation agreement before the completion of the timeline and reject the equipment or facilities as not complying with the requirements of this chapter if continuation of the trial will not substantially affect the decision of the State Regulatory Authority;

f. A provision that at the end of the timeline specified in the agreement, the permit holder will remove or alter the equipment or facilities within a maximum of six months from the date he receives written instruction to do so from the State Regulatory Authority to comply with the requirements of this chapter if the State Regulatory Authority does not approve the equipment or facilities; and

g. A provision that the permit holder's failure to remove or alter the equipment or facilities to comply with the requirements of this chapter within six months after receipt of written instructions from the State Regulatory Authority shall be considered sufficient cause for permit suspension.

Part XI
Voluntary HACCP Program

Article 1
Program Participation

2VAC5-490-131. HACCP program participation voluntary.

A. Participation in the HACCP program is voluntary for each person who operates a dairy plant, receiving station or transfer station and the State Regulatory Authority responsible for the permitting and auditing of each person's dairy plant, receiving station or transfer station. No person operating a milk plant, receiving station or transfer station may participate in the voluntary HACCP program unless the State Regulatory Agency responsible for the permitting and auditing of each person's dairy plant agrees to participate in the voluntary HACCP program, also.

B. Each person volunteering to operate his milk plant, receiving station or transfer station under the voluntary HACCP program shall provide a written commitment to the State Regulatory Authority responsible for his milk plant, receiving station or transfer station that he will supply the necessary resources to support participation in the voluntary HACCP program.

C. Each State Regulatory Authority volunteering to participate in the voluntary HACCP program shall provide a written commitment to the person requesting to operate a milk plant, receiving station or transfer station under the voluntary HACCP program that the State Regulatory Authority will supply the necessary resources to support participation in the voluntary HACCP program.

D. Each person operating a milk plant, receiving station or transfer station and participating in the voluntary HACCP program shall have a minimum of 60 days of HACCP System records prior to a HACCP listing audit. Each milk plant, receiving station or transfer station shall be inspected and permitted initially by the State Regulatory Authority and shall be regulated initially under the requirements of this chapter without taking into consideration the provisions of this part until the State Regulatory Authority conducts an acceptable HACCP listing audit documenting the successful implementation of a fully functioning HACCP System in the person's milk plant, receiving station or transfer station.

E. Each person operating a milk plant, receiving station or transfer station and participating in the voluntary HACCP program shall:

1. Comply with all of the provisions applicable to the voluntary HACCP program contained in:

a. Section 7, Standards for grade "A" milk and milk products;

b. Item 16p, Pasteurization and aseptic processing;

c. Item 16p(E), Pasteurization and aseptic processing records, equipment tests and examinations;

d. Section 13, Personnel health;

e. Section 14, Procedure when infection or high risk of personnel health;

f. Appendix H, Pasteurization Equipment and procedures;

g. Appendix I, Pasteurization equipment and controls tests;

h. Appendix K, HACCP Program; and

i. Appendix R, Determination of Time/Temperature Control for Safety of Milk and Milk Products contained in the "Grade [~~A~~ "A"] Pasteurized Milk Ordinance, ~~2005~~ 2009 [~~revision"~~ Revision"];

2. Prepare their HACCP Plan based on the following HACCP principles:

a. Conduct a hazard analysis;

b. Determine the critical control points;

c. Establish critical limits;

d. Establish monitoring procedures;

e. Establish corrective actions;

f. Establish verification procedures; and

g. Establish recordkeeping and documentation procedures;

3. Prior to the implementation of a HACCP Plan develop, document and successfully implement written prerequisite programs which provide the basic environment and operating conditions that are necessary for the production of safe, wholesome food.

2VAC5-490-138. Training.

Each person operating a milk plant, receiving station or transfer station and participating in the voluntary HACCP program shall ensure that each person who is responsible for: (i) developing a hazard analysis; (ii) delineating control measures; (iii) developing a HACCP plan that is appropriate for the specific milk plant, receiving station or transfer station; (iv) validating and modifying the HACCP plan; or (v) performing required HACCP plan record reviews has received basic HACCP training and an orientation to the HACCP requirements contained in Appendix K of the "Grade [~~A~~ "A"] Pasteurized Milk Ordinance, ~~2005~~ 2009 [~~revision"~~ Revision"].

Part XII
Interpretation and Enforcement

2VAC5-490-140. Interpretation and enforcement.

A. This chapter is based on the "Grade [~~A~~ "A"] Pasteurized Milk [~~Ordinance~~] ~~2005~~ [Ordinance,] 2009 [~~recommendations~~ Revision]." Except as otherwise provided in this chapter, the provisions of this chapter shall be interpreted in a manner consistent with interpretations accorded the "Grade [~~A~~ "A"] Pasteurized Milk [~~Ordinance~~] ~~2005~~ [Ordinance,] 2009 [~~recommendations~~ Revision]."

B. The administrative procedures used to conduct case decisions under this chapter shall conform to the provisions of the Virginia Administrative Process Act.

C. The State Regulatory Authority shall comply with the following administrative procedures when summarily suspending a grade A permit as specified in 2VAC5-490-31 B:

1. The State Regulatory Authority shall serve upon the grade A permit holder a written notice of suspension. The written notice of suspension shall specify the violations in question and inform the grade A permit holder of the right to appear before the State Regulatory Authority in person, by counsel, or by other qualified representative at a fact-finding conference for the informal presentation of factual data, arguments, and proof to appeal this determination of violation;

2. Upon receipt of written application from any person whose grade A permit has been summarily suspended (within 30 days after the effective date of the summary suspension) the State Regulatory Authority shall within seven days after the date of receipt by the State Regulatory Authority of a written application from any person whose grade A permit has been summarily suspended proceed to hold an informal fact-finding conference to ascertain the facts of the violations in question and upon evidence presented at the informal fact-finding conference shall affirm, modify, or rescind the summary suspension;

3. The State Regulatory Authority shall, unless the parties consent, ascertain the fact basis for their decisions of cases through informal conference proceedings. Such conference proceedings include the rights of parties to the case to have reasonable notice thereof, to appear in person or by counsel or other qualified representative before the State Regulatory Authority for the informal presentation of factual data, argument, or proof in connection with any case, to have notice of any contrary fact basis or information in the possession of the agency which can be relied upon in making an adverse decision, to receive a prompt decision of any application for license, benefit, or renewal thereof, and to be informed, briefly and generally in writing, of the factual or procedural basis for an adverse decision in any case;

4. No person whose grade A permit has been summarily suspended may be granted an informal fact-finding conference by the State Regulatory Authority unless the State Regulatory Authority receives the person's written application within 30 days after the effective date of the summary suspension;

5. From any adverse decision of an informal fact-finding conference, the grade A permit holder may request a formal hearing under § 2.2-4020 of the Code of Virginia by writing the Program Manager of the Office of Dairy and Foods within 30 days stating the request and by providing the State Regulatory Authority with a statement of the issues in dispute. If the request for a formal conference is denied, the State Regulatory Authority shall notify the grade A permit holder in writing and further may affirm or modify the decision of the informal fact-finding conference; and

6. If a formal fact-finding conference is denied, the State Regulatory Authority shall notify the grade A permit holder of the right to file an appeal in the circuit court.

DOCUMENTS INCORPORATED BY REFERENCE (2VAC5-490)

[~~Drug Residue Test Methods for Confirmation of Presumptive Positive Results and Initial Producer Traceback, M-I-96-10 (Revision #5) #7), March 10, 2004 January 4, 2010, published by the Food and Drug Administration, Milk Safety Branch (HFS-626), 5100 Paint Branch Parkway, College Park, MD 20740-3835.~~

~~Evaluation of Milk Laboratories, 2005 2007 Revision, published by the Food and Drug Administration Laboratory Quality Assurance Team, HFH-450, 6502 South Archer Road, Summit-Argo, Illinois 60501.~~

~~Grade "A" Pasteurized Milk Ordinance, 2005 2009 Revision, published by the Food and Drug Administration, Milk Safety Branch (HFS-626), 5100 Paint Branch Parkway, College Park, MD 20740-3835.~~

Drug Residue Test Methods for Confirmation of Presumptive Positive Results and Initial Producer Trace Back, M-I-96-10 (Revision #7), January 4, 2010, published by the Food and Drug Administration, Dairy and Egg Branch (HFS 316), 5100 Paint Branch Parkway, College Park, MD 20740-3835.

Evaluation of Milk Laboratories, 2009 Revision, published by the Food and Drug Administration Laboratory Proficiency and Evaluation Team, HFH-450, 6502 South Archer Road, Summit-Argo, Illinois 60501.

Grade "A" Pasteurized Milk Ordinance, 2009 Revision, published by the Food and Drug Administration, Milk Safety Branch (HFS-626), 5100 Paint Branch Parkway, College Park, MD 20740-3835.]

Official Methods of Analysis of the Association of AOAC International, 18th Edition, 2005, published by the Association of Official Analytical Chemists International, 481 North Frederick Avenue, Suite 500, Gaithersburg, Maryland 20877-2417.

Uniform Methods and Rules: Brucellosis Eradication - effective October 1, 2003, available from U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, Federal center Building, Hyattsville, Maryland 20782 or Federal Veterinarian in Charge, USDA/APHIS-VS, Virginia Area Office, 7th Floor, Federal Building, 400 N. 8th Street, Richmond, Virginia 23240.

Uniform Methods and Rules: Bovine Tuberculosis Eradication - effective January 1, 2005, available from U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, federal Center Building, Hyattsville, Maryland 20782 or Federal Veterinarian in Charge, USDA/APHIS-VS, Virginia Area Office, 7th Floor, Federal Building, 400 N. 8th Street, Richmond, Virginia 23240.

VA.R. Doc. No. R10-2395; Filed December 10, 2010, 2:29 p.m.

TITLE 12. HEALTH

DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

Fast-Track Regulation

Titles of Regulations: **12VAC30-40. Eligibility Conditions and Requirements (amending 12VAC30-40-10).**

12VAC30-110. Eligibility and Appeals (amending 12VAC30-110-1300, 12VAC30-110-1350).

Statutory Authority: §§ 32.1-324 and 32.1-325 of the Code of Virginia.

Public Hearing Information: No public hearings are scheduled.

Public Comment Deadline: February 2, 2011.

Effective Date: February 2, 2011.

Agency Contact: Brian McCormick, Regulatory Supervisor, Department of Medical Assistance Services, 600 East Broad Street, Suite 1300, Richmond, VA 23219, telephone (804) 371-8856, FAX (804) 786-1680, or email brian.mccormick@dmas.virginia.gov.

Basis: 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 (Plan). Section 32.1-324 of the Code of Virginia authorizes the Director of DMAS to administer and amend the Plan 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.

Purpose: The purpose of this action is to promulgate state Plan regulations that will provide for continued Medicaid coverage of lawfully residing noncitizen children (legal immigrant children) under the age of 19 and enable the Commonwealth to receive federal financial participation (FFP) for providing such coverage. Action will also be taken to repeal state-only regulations currently in effect that provide coverage for two groups of legal immigrants using state-only general fund money.

Additionally, this action will serve to promulgate state Plan regulations to provide for full benefit Medicaid coverage for certain groups of lawfully residing noncitizen children under the age of 19 who are currently eligible for federally mandated Medicaid coverage of emergency services only.

The department does not expect that this regulatory action will measurably increase or decrease the numbers of persons who qualify for these groups.

This regulation is essential to protect the health, safety, and welfare of citizens who are children under the age of 19. This regulation will protect the health of noncitizen children by allowing them to receive coverage under the Medicaid program, and provide them with a medical home and comprehensive medical benefits in addition to reducing the amount of uncompensated care provided for this population.

Rationale for Using Fast-Track Process: The fast-track process is being utilized to promulgate this change as it is expected to be a noncontroversial amendment to existing regulations. This regulatory action will allow DMAS to claim FFP for medical services for lawfully admitted noncitizen children under the age of 19 who are currently being paid for using state-only general funds.

Substance: Item 322.V of Chapter 924 of the 1997 Acts of Assembly directed DMAS to provide coverage to lawfully admitted noncitizen children under the age of 19 at the Commonwealth's expense if FFP could not be obtained. Federal reimbursement was not available at the time because these children did not meet the alien criteria established through P.L. 104-193 (The Personal Responsibility and Work Opportunity Reconciliation Act of 1996).

Section 214 of the Childrens Health Insurance Program Reauthorization Act of 2009 (CHIPRA) now provides an option for states to cover certain groups of lawfully residing noncitizens and receive FFP for providing coverage. Virginia is electing to provide coverage under Medicaid to children under the age of 19 who meet the criteria set out in CHIPRA.

Additionally, 12VAC30-110-1300 is being repealed as it will no longer be applicable with the adoption of new language (as

set out in 12VAC30-40-10) to cover these children under Medicaid and receive FFP.

The Personal Responsibility and Work Opportunity Reconciliation Act of 1996, P.L. 104-193, which was enacted on August 22, 1996, substantially changed the Medicaid entitlements for noncitizens. Section 431 of the Act defined "qualified aliens" for the purposes of determining eligibility for public benefits, including Medicaid. Section 401 of the Act provided that aliens who were not "qualified aliens" were not eligible for full coverage under the Medicaid program, although they may be eligible for federally mandated coverage of an emergency medical service.

In an effort to comply with the federal law and avoid disruption in medical services for two vulnerable groups of legal aliens who had resided in the United States prior to the enactment of the new law and who would not be able to meet the new requirements, Chapter 924 of the 1997 Acts of Assembly (Item 322 V) directed DMAS to promulgate regulations to implement the federal policy and to continue to provide medical assistance to elderly individuals receiving an institutional level of care and children younger than 19 years of age.

All aliens receiving Medicaid and residing in long-term institutional facilities or participating in home-based and community-based waivers who were eligible for full Medicaid benefits on June 30, 1997, continued to be eligible for full Medicaid benefits beginning July 1, 1997, at state expense because FFP was not available. Further, in order to continue medical services to immigrant children, Item 322.V of the 1997 Appropriations Act directed DMAS to provide full medical assistance to noncitizens ineligible for Medicaid because of their alien status pursuant to P.L. 104-193, who were under the age of 19 and would be eligible for full Medicaid benefits if the alien requirements prior to the passage of P.L. 104-193 were still in effect. Coverage of these children was provided at state expense as well because FFP was not available.

Since that time, DMAS has continued to provide coverage to these two groups of individuals at state expense. The group of elderly individuals residing in long-term institutional facilities or participating in home-based and community-based waivers was a fixed group of individuals receiving coverage as of June 30, 1997. There is no further need for state coverage of this group as all individuals have expired. Therefore, action is taken with this regulatory change to repeal language requiring the state to provide coverage to this group of individuals at state expense.

DMAS continues to provide coverage at state expense to the group of lawfully admitted noncitizen children under the age of 19 who would be eligible for full Medicaid benefits if the alien requirements prior to the passage of P.L. 104-193 were still in effect. This regulatory action will allow for FFP for coverage of this group of children.

As a result of the option allowed under CHIPRA, DMAS is electing, through this regulatory change, to receive FFP for services currently provided using state general funds. In addition to the children listed in subdivision 3 e of 12VAC30-40-10, DMAS is also including in the covered children list the groups of children listed in subdivision 3 e of 12VAC30-40-10, as the federal Medicaid authority (the Centers for Medicare and Medicaid Services) is requiring the addition of these groups as mandated under CHIPRA.

Issues: There is no disadvantage to the public or the Commonwealth with the adoption of this regulation. Adoption of this regulation will result in the Medicaid program receiving FFP for coverage of some of these children as they are currently covered at state expense.

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

Summary of the Proposed Amendments to Regulation. The proposed regulations will move the statement of coverage of certain groups of legal immigrant children from state-only regulations to the State Plan for Medical Assistance so that the federal matching funds could be claimed on the expenditures related to this coverage.

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

Estimated Economic Impact. The proposed regulations will move the statement of coverage of certain groups of legal immigrant children from state-only regulations to the State Plan for Medical Assistance so that the federal matching funds could be claimed on the expenditures related to this coverage.

Medicaid coverage of non-citizen children has been provided by state-only funds. Section 214 of the Children's Health Insurance Program Reauthorization Act of 2009 now provides an option for states to cover these children and provide federal matching funds. Consequently, the Department of Medical Assistance Services (DMAS) is proposing these changes so that federal funds related to the coverage of legal immigrant children can be claimed. When these regulations become effective, DMAS will be able to retroactively claim funds as of April 1, 2009.

Based on the data Fiscal Year 2010 estimates, approximately $1.4 million in total funds are spent for coverage of 1400 legal immigrant children. The proposed changes will allow DMAS to obtain one half of these funds ($700,000) from the federal government.

Since there is no change in coverage or the services provided, the main economic effect of the proposed changes is strictly fiscal in that the Commonwealth will be saving approximately $700,000 annually. The economic effect of additional funds coming into the Commonwealth will depend on how these savings will be used. If the Commonwealth

spends these funds, the net economic effect is expected to be expansionary.

Businesses and Entities Affected. The proposed changes apply to the Medicaid coverage of approximately 1400 legal children.

Localities Particularly Affected. There are no localities affected more than others.

Projected Impact on Employment. If the expected savings are spent, an expansionary impact on economy is expected which would have a positive impact on employment.

Effects on the Use and Value of Private Property. Depending on where the savings are spent, a positive impact on the asset value of certain businesses may be expected.

Small Businesses: Costs and Other Effects. The proposed regulations do not create any costs or other adverse effects on small business.

Small Businesses: Alternative Method that Minimizes Adverse Impact. No adverse impact on small businesses is expected.

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

Legal Mandate. The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Administrative Process Act and Executive Order Number 107 (09). Section 2.2-4007.04 requires that such economic impact analyses include, but need not be limited to, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. Further, if the proposed regulation has adverse effect on small businesses, § 2.2-4007.04 requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis presented above represents DPB's best estimate of these economic impacts.

Agency's Response to the Department of Planning and Budget's Economic Impact Analysis: The Department of Medical Assistance Services concurs with the economic impact analysis prepared by the Department of Planning and Budget regarding the regulations concerning Legal Immigrant Children (12VAC30-40-10 and 12VAC30-110-1300).

Summary:

This regulatory action moves the statement of coverage of certain groups of lawfully residing noncitizen children from state-only regulations to the State Plan for Medical Assistance in order to permit the Commonwealth to claim Federal Financial Participation (FFP or federal Medicaid matching dollars) for the covered services used by these groups of eligible persons. Currently, the medical services used by these groups of eligible persons are being funded with 100% general funds.

Additionally, this action provides for full benefit Medicaid coverage for certain groups of lawfully residing noncitizen children who currently are eligible only for federally mandated Medicaid coverage of emergency services.

Part I
General Conditions of Eligibility

12VAC30-40-10. General conditions of eligibility.

Each individual covered under the plan:

1. Is financially eligible (using the methods and standards described in Parts II and III of this chapter) to receive services.

2. Meets the applicable nonfinancial eligibility conditions.

a. For the categorically needy:

~~(i)~~ (1) Except as specified under items ~~(ii)~~ (2) and ~~(iii)~~ (3) below, for AFDC-related individuals, meets the nonfinancial eligibility conditions of the AFDC program.

~~(ii)~~ (2) For SSI-related individuals, meets the nonfinancial criteria of the SSI program or more restrictive SSI-related categorically needy criteria.

~~(iii)~~ (3) For financially eligible pregnant women, infants or children covered under § 1902(a)(10)(A)(i)(IV), 1902(a)(10)(A)(i)(VI), 1902(a)(10)(A)(i)(VII), and 1902(a)(10)(A)(ii)(IX) of the Act, meets the nonfinancial criteria of § 1902(l) of the Act.

~~(iv)~~ (4) For financially eligible aged and disabled individuals covered under § 1902(a)(10)(A)(ii)(X) of the Act, meets the nonfinancial criteria of § 1902(m) of the Act.

b. For the medically needy, meets the nonfinancial eligibility conditions of 42 CFR 435.

c. For financially eligible qualified Medicare beneficiaries covered under § 1902(a)(10)(E)(i) of the Act, meets the nonfinancial criteria of § 1905(p) of the Act.

d. For financially eligible qualified disabled and working individuals covered under § 1902(a)(10)(E)(ii) of the Act, meets the nonfinancial criteria of § 1905(s).

3. Is residing in the United States and:

a. Is a citizen; or

b. Is a qualified alien as defined under Public Law 104-193 who arrived in the United States prior to August 22, 1996;

c. Is a qualified alien as defined under Public Law 104-193 who arrived in the United States on or after August 22, 1996, and whose coverage is mandated by Public Law 104-193;

d. Is an alien who is not a qualified alien, or who is a qualified alien who arrived in the United States on or after August 22, 1996, whose coverage is not mandated by Public Law 104-193 (coverage must be restricted to certain emergency services).

e. Is an alien under the age of 19 who is legally residing in the United States and whose coverage is authorized under the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA). CHIPRA provides for coverage of the following individuals:

(1) "Qualified aliens" otherwise subject to the five-year waiting period per § 403 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996;

(2) Citizens of a Compact of Free Association State (i.e., Federated States of Micronesia, Republic of the Marshall Island, and the Republic of Palau) who have been admitted to the United States as nonimmigrants and are permitted by the Department of Homeland Security to reside permanently or indefinitely in the United States;

(3) Individuals described in 8 CFR 103.12(a)(4) who do not have a permanent residence in the country of their nationality and are in statuses that permit them to remain in the United States for an indefinite period of time pending adjustment of status. These individuals include:

(a) Individuals currently in temporary resident status as amnesty beneficiaries pursuant to § 210 or 245A of the Immigration and Nationality Act (INA);

(b) Individuals currently under Temporary Protected Status pursuant to § 244 of the INA;

(c) Family Unity beneficiaries pursuant to § 301 of P.L. 101-649 as amended, as well as pursuant to § 1504 of P.L. 106-554;

(d) Individuals currently under Deferred Enforced Departure pursuant to a decision made by the President; and

(e) Individuals who are the spouse or child of a United States citizen whose visa petition has been approved and who has a pending application for adjustment of status; and

(4) Individuals in nonimmigrant classifications under the INA who are permitted to remain in the United States for an indefinite period, including the following who are specified in § 101(a)(15) of the INA:

(a) Parents or children of individuals with special immigrant status under § 101(a)(27) of the INA as permitted under § 101(a)(15)(N) of the INA;

(b) Fiancees of a citizen as permitted under § 101(a)(15)(K) of the INA;

(c) Religious workers under § 101(a)(15)(R);

(d) Individuals assisting the Department of Justice in a criminal investigation as permitted under § 101(a)(15)(U) of the INA;

(e) Battered aliens; and

(f) Individuals with a petition pending for three years or more as permitted under § 101(a)(15)(V) of the INA.

4. Is a resident of the state, regardless of whether or not the individual maintains the residence permanently or maintains it a fixed address.

The state has open agreement(s).

5. Is not an inmate of a public institution. Public institutions do not include medical institutions, nursing facilities and intermediate care facilities for the mentally retarded, or publicly operated community residences that serve no more than 16 residents, or certain child care institutions.

6. Is required, as a condition of eligibility, to assign rights to medical support and to payments for medical care from any third party, to cooperate in obtaining such support and payments, and to cooperate in identifying and providing information to assist in pursuing any liable third party. The assignment of rights obtained from an applicant or recipient is effective only for services that are reimbursed by Medicaid. The requirements of 42 CFR 433.146 through 433.148 are met.

An applicant or recipient must also cooperate in establishing the paternity of any eligible child and in obtaining medical support and payments for himself or herself and any other person who is eligible for Medicaid and on whose behalf the individual can make an assignment; except that individuals described in § 1902(1)(1)(A) of the Social Security Act (pregnant women and women in the post-partum period) are exempt from these requirements involving paternity and obtaining support. Any individual may be exempt from the

cooperation requirements by demonstrating good cause for refusing to cooperate.

An applicant or recipient must also cooperate in identifying any third party who may be liable to pay for care that is covered under the state plan and providing information to assist in pursuing these third parties. Any individual may be exempt from the cooperation requirements by demonstrating good cause for refusing to cooperate.

7. a. Is required, as a condition of eligibility, to furnish his social security account number (or numbers, if he has more than one number) except for aliens seeking medical assistance for the treatment of an emergency medical condition under § 1903(v)(2) of the Social Security Act (§ 1137(f)).

b. Applicant or recipient is required, under § 1903(x) to furnish satisfactory documentary evidence of both identity and of U.S. citizenship upon signing the declaration of citizenship required by § 1137(d). Qualified aliens signing the declaration of satisfactory immigration status required by § 1137(d) must also present and have verified documents establishing the claimed immigration status under § 137(d). Exception: Nonqualified aliens seeking medical assistance for the treatment of an emergency medical condition under § 1903(v)(2) as described in § 1137(f).

8. Is not required to apply for AFDC benefits under Title IV-A as a condition of applying for, or receiving Medicaid if the individual is a pregnant women, infant, or child that the state elects to cover under § 1902(a)(10)(A)(i)(IV) and 1902(a)(10)(A)(ii)(IX) of the Act.

9. Is not required, as an individual child or pregnant woman, to meet requirements under § 402(a)(43) of the Act to be in certain living arrangements. (Prior to terminating AFDC individuals who do not meet such requirements under a state's AFDC plan, the agency determines if they are otherwise eligible under the state's Medicaid plan.)

10. Is required to apply for coverage under Medicare A, B and/or D if it is likely that the individual would meet the eligibility criteria for any or all of those programs. The state agrees to pay any applicable premiums and cost-sharing (except those applicable under Part D) for individuals required to apply for Medicare. Application for Medicare is a condition of eligibility unless the state does not pay the Medicare premiums, deductibles or co-insurance (except those applicable under Part D) for persons covered by the Medicaid eligibility group under which the individual is applying.

11. Is required, as a condition of eligibility for Medicaid payment of long-term care services, to disclose at the time of application for or renewal of Medicaid eligibility, a description of any interest the individual or his spouse has in an annuity (or similar financial instrument as may be specified by the Secretary of Health and Human Services). By virtue of the provision of medical assistance, the state shall become a remainder beneficiary for all annuities purchased on or after February 8, 2006.

12. Is ineligible for Medicaid payment of nursing facility or other long-term care services if the individual's equity interest in his home exceeds $500,000. This dollar amount shall be increased beginning with 2011 from year to year based on the percentage increase in the Consumer Price Index for all Urban Consumers rounded to the nearest $1,000.

This provision shall not apply if the individual's spouse, or the individual's child who is under age 21 or who is disabled, as defined in § 1614 of the Social Security Act, is lawfully residing in the individual's home.

~~Part VIII~~
~~Medicaid Eligibility for Aliens~~

12VAC30-110-1300. ~~Medicaid eligibility for certain aliens and immigrants.~~ (Repealed.)

~~A. All aliens (qualified and unqualified) receiving Medicaid and residing in long-term institutional facilities or participating in home and community-based waivers on June 30, 1997, who are eligible for full Medicaid benefits on June 30, 1997, will continue to be eligible for full Medicaid benefits after June 30, 1997, at state expense if federal financial participation is not available.~~

~~B. All noncitizens ineligible for Medicaid because of alienage pursuant to the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, Public Law 104-193, shall be provided full medical assistance services, who~~

~~1. Are under age 19; and~~

~~2. Would be eligible for full Medicaid benefits if the alien requirements prior to the passage of Public Law 104-193 were still in effect.~~

~~Part IX~~ Part VIII
Applications for Medicaid

VA.R. Doc. No. R11-2263; Filed December 10, 2010, 4:23 p.m.

TITLE 16. LABOR AND EMPLOYMENT

VIRGINIA EMPLOYMENT COMMISSION

Fast-Track Regulation

Titles of Regulations: **16VAC5-5. Public Participation Guidelines (adding 16VAC5-5-10 through 16VAC5-5-110).**

16VAC5-10. Definitions and General Provisions (repealing 16VAC5-10-20, 16VAC5-10-21, 16VAC5-10-22, 16VAC5-10-30).

Statutory Authority: §§ 2.2-4007.02 and 60.2-111 of the Code of Virginia.

Public Hearing Information: No public hearings are scheduled.

Public Comment Deadline: February 2, 2011.

Effective Date: February 17, 2011.

Agency Contact: Coleman Walsh, Chief Administrative Law Judge, Virginia Employment Commission, 703 E. Main St., Room 126, Richmond, VA 23219, telephone (804) 786-7263, FAX (804) 786-9034, or email coleman.walsh@vec.virginia.gov.

Basis: Chapter 321 of the 2008 Acts of Assembly (effective July 1, 2008) mandated that agencies adopt model public participation guidelines issued by the Department of Planning and Budget by December 1, 2008.

Purpose: Public participation guidelines (PPGs) exist to promote public involvement in the development, amendment, or repeal of an agency's regulations. This action is being taken pursuant to § 2.2-4007.02 of the Code of Virginia which requires every rulemaking body in the Commonwealth to adopt PPGs and to use those guidelines in the development of its regulations.

Rationale for Using Fast-Track Process: This action is not expected to be controversial.

Substance: This action repeals Virginia Employment Commission's existing regulations on regulation development and public participation and creates a new chapter with text from the model PPGs developed by the Department of Planning and Budget.

Issues: The model PPGs will provide advantages to the public in the form of more consistent public participation requirements for agencies in the rulemaking process. No disadvantages are anticipated for the public, the agency, or the Commonwealth.

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

Summary of the Proposed Amendments to Regulation. The Virginia Employment Commission (VEC) proposes to adopt model public participation guidelines as mandated in Chapter 321 of the 2008 Acts of Assembly.

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

Estimated Economic Impact. Pursuant to Chapter 321 of the 2008 Acts of Assembly, the Department of Planning and Budget, in consultation with the Office of the Attorney General, (i) developed model public participation guidelines (PPGs) and (ii) provided these model PPGs to each agency that has the authority to promulgate regulations. Chapter 321 required that, by December 1, 2008, state agencies either (a) adopt these model public participation guidelines as an exempt action or (b) if significant additions or changes are proposed, promulgate the model public participation guidelines with the proposed changes as fast-track regulations pursuant to Code of Virginia Section 2.2-4012.1. Pursuant to Chapter 321, Model PPGs promulgated by agencies after January 1, 2009, are subject to the normal requirements of the Administrative Process Act. Because of this mandate, the VEC now proposes to promulgate the model PPGs as a fast track action.

The purposes of the model PPG legislation are threefold: first, to ensure that each agency or board has a current set of PPGs in place.[1] Second, to ensure that each agency's or board's PPGs incorporate the use of technology such as the Virginia Regulatory Town Hall, email to the extent possible, and the use of electronic mailing lists. Last, but perhaps most importantly, to have uniform guidelines in place to facilitate citizen participation in rulemaking and to make those guidelines consistent, to the extent possible, among all executive branch boards and agencies. For all of these reasons, citizens who are interested in participating in the VEC's rulemaking process will benefit from the promulgation of these PPGs.

Businesses and Entities Affected. These proposed amendments to the VEC's public participation guidelines potentially affect all citizens and entities in the Commonwealth.

Localities Particularly Affected. The proposed amendments do not disproportionately affect particular localities.

Projected Impact on Employment. The proposal amendments do not directly affect employment.

Effects on the Use and Value of Private Property. The proposal amendments do not directly affect the use and value of private property.

Small Businesses: Costs and Other Effects. The proposed amendments do not directly affect small businesses.

Small Businesses: Alternative Method that Minimizes Adverse Impact. The proposed amendments do not adversely affect small businesses.

Real Estate Development Costs. The proposed amendments do not directly affect real estate development costs.

Legal Mandate. The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Administrative Process Act and Executive Order Number 36 (06). Section 2.2-4007.04 requires that such economic impact analyses include, but need not be limited to, the projected number of businesses or other entities to whom the regulation

would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. Further, if the proposed regulation has adverse effect on small businesses, § 2.2-4007.04 requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis presented above represents DPBs best estimate of these economic impacts.

[1] Some agencies and boards have not updated their PPGs since the mid-late 1980s.

Agency's Response to the Department of Planning and Budget's Economic Impact Analysis: The responsible Virginia Employment Commission agency representatives have reviewed the Department of Planning and Budget's (DPB) Economic Impact Analysis of 16VAC5-5. The agency feels the analysis is thorough and appropriately covers any and all predictable circumstances involving this proposed change in regulation. The agency is in agreement with DPB's analysis.

Summary:

The regulations repeal existing regulations on regulation development and public participation and incorporate the model public participation guidelines developed by the Department of Planning and Budget pursuant to Chapter 321 of the 2008 Acts of Assembly. Highlights of the model public participation guidelines include the addition of negotiated rulemaking panels and regulatory advisory panels and instructions for notification.

CHAPTER 5
PUBLIC PARTICIPATION GUIDELINES

Part I
Purpose and Definitions

16VAC5-5-10. Purpose.

The purpose of this chapter is to promote public involvement in the development, amendment, or repeal of the regulations of the Virginia Employment Commission. This chapter does not apply to regulations, guidelines, or other documents exempted or excluded from the provisions of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).

16VAC5-5-20. Definitions.

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

"Administrative Process Act" means Chapter 40 (§ 2.2-4000 et seq.) of Title 2.2 of the Code of Virginia.

"Agency" means the Virginia Employment Commission, which is the unit of state government empowered by the agency's basic law to make regulations or decide cases. Actions specified in this chapter may be fulfilled by state employees as delegated by the agency.

"Basic law" means provisions in the Code of Virginia that delineate the basic authority and responsibilities of an agency.

"Commonwealth Calendar" means the electronic calendar for official government meetings open to the public as required by § 2.2-3707 C of the Freedom of Information Act.

"Negotiated rulemaking panel" or "NRP" means an ad hoc advisory panel of interested parties established by an agency to consider issues that are controversial with the assistance of a facilitator or mediator, for the purpose of reaching a consensus in the development of a proposed regulatory action.

"Notification list" means a list used to notify persons pursuant to this chapter. Such a list may include an electronic list maintained through the Virginia Regulatory Town Hall or other list maintained by the agency.

"Open meeting" means any scheduled gathering of a unit of state government empowered by an agency's basic law to make regulations or decide cases that is related to promulgating, amending, or repealing a regulation.

"Person" means any individual, corporation, partnership, association, cooperative, limited liability company, trust, joint venture, government, political subdivision, or any other legal or commercial entity and any successor, representative, agent, agency, or instrumentality thereof.

"Public hearing" means a scheduled time at which members or staff of the agency will meet for the purpose of receiving public comment on a regulatory action.

"Regulation" means any statement of general application having the force of law, affecting the rights or conduct of any person, adopted by the agency in accordance with the authority conferred on it by applicable laws.

"Regulatory action" means the promulgation, amendment, or repeal of a regulation by the agency.

"Regulatory advisory panel" or "RAP" means a standing or ad hoc advisory panel of interested parties established by the agency for the purpose of assisting in regulatory actions.

"Town Hall" means the Virginia Regulatory Town Hall, the website operated by the Virginia Department of Planning and Budget at www.townhall.virginia.gov, that has online public comment forums and displays information about regulatory meetings and regulatory actions under consideration in Virginia and sends this information to registered public users.

"Virginia Register" means the Virginia Register of Regulations, the publication that provides official legal notice of new, amended, and repealed regulations of state agencies, which is published under the provisions of Article 6 (§ 2.2-4031 et seq.) of the Administrative Process Act.

Part II
Notification of Interested Persons

16VAC5-5-30. Notification list.

A. The agency shall maintain a list of persons who have requested to be notified of regulatory actions being pursued by the agency.

B. Any person may request to be placed on a notification list by registering as a public user on the Town Hall or by making a request to the agency. Any person who requests to be placed on a notification list shall elect to be notified either by electronic means or through a postal carrier.

C. The agency may maintain additional lists for persons who have requested to be informed of specific regulatory issues, proposals, or actions.

D. When electronic mail is returned as undeliverable on multiple occasions at least 24 hours apart, that person may be deleted from the list. A single undeliverable message is insufficient cause to delete the person from the list.

E. When mail delivered by a postal carrier is returned as undeliverable on multiple occasions, that person may be deleted from the list.

F. The agency may periodically request those persons on the notification list to indicate their desire to either continue to be notified electronically, receive documents through a postal carrier, or be deleted from the list.

16VAC5-5-40. Information to be sent to persons on the notification list.

A. To persons electing to receive electronic notification or notification through a postal carrier as described in 16VAC5-5-30, the agency shall send the following information:

1. A notice of intended regulatory action (NOIRA).

2. A notice of the comment period on a proposed, a reproposed, or a fast-track regulation and hyperlinks to, or instructions on how to obtain, a copy of the regulation and any supporting documents.

3. A notice soliciting comment on a final regulation when the regulatory process has been extended pursuant to § 2.2-4007.06 or 2.2-4013 C of the Code of Virginia.

B. The failure of any person to receive any notice or copies of any documents shall not affect the validity of any regulation or regulatory action.

Part III
Public Participation Procedures

16VAC5-5-50. Public comment.

A. In considering any nonemergency, nonexempt regulatory action, the agency shall afford interested persons an opportunity to submit data, views, and arguments, either orally or in writing, to the agency. Such opportunity to comment shall include an online public comment forum on the Town Hall.

1. To any requesting person, the agency shall provide copies of the statement of basis, purpose, substance, and issues; the economic impact analysis of the proposed or fast-track regulatory action; and the agency's response to public comments received.

2. The agency may begin crafting a regulatory action prior to or during any opportunities it provides to the public to submit comments.

B. The agency shall accept public comments in writing after the publication of a regulatory action in the Virginia Register as follows:

1. For a minimum of 30 calendar days following the publication of the notice of intended regulatory action (NOIRA).

2. For a minimum of 60 calendar days following the publication of a proposed regulation.

3. For a minimum of 30 calendar days following the publication of a reproposed regulation.

4. For a minimum of 30 calendar days following the publication of a final adopted regulation.

5. For a minimum of 30 calendar days following the publication of a fast-track regulation.

6. For a minimum of 21 calendar days following the publication of a notice of periodic review.

7. Not later than 21 calendar days following the publication of a petition for rulemaking.

C. The agency may determine if any of the comment periods listed in subsection B of this section shall be extended.

D. If the Governor finds that one or more changes with substantial impact have been made to a proposed regulation,

he may require the agency to provide an additional 30 calendar days to solicit additional public comment on the changes in accordance with § 2.2-4013 C of the Code of Virginia.

E. The agency shall send a draft of the agency's summary description of public comment to all public commenters on the proposed regulation at least five days before final adoption of the regulation pursuant to § 2.2-4012 E of the Code of Virginia.

16VAC5-5-60. Petition for rulemaking.

A. As provided in § 2.2-4007 of the Code of Virginia, any person may petition the agency to consider a regulatory action.

B. A petition shall include but is not limited to the following information:

1. The petitioner's name and contact information;

2. The substance and purpose of the rulemaking that is requested, including reference to any applicable Virginia Administrative Code sections; and

3. Reference to the legal authority of the agency to take the action requested.

C. The agency shall receive, consider, and respond to a petition pursuant to § 2.2-4007 and shall have the sole authority to dispose of the petition.

D. The petition shall be posted on the Town Hall and published in the Virginia Register.

E. Nothing in this chapter shall prohibit the agency from receiving information or from proceeding on its own motion for rulemaking.

16VAC5-5-70. Appointment of regulatory advisory panel.

A. The agency may appoint a regulatory advisory panel (RAP) to provide professional specialization or technical assistance when the agency determines that such expertise is necessary to address a specific regulatory issue or action or when individuals indicate an interest in working with the agency on a specific regulatory issue or action.

B. Any person may request the appointment of a RAP and request to participate in its activities. The agency shall determine when a RAP shall be appointed and the composition of the RAP.

C. A RAP may be dissolved by the agency if:

1. The proposed text of the regulation is posted on the Town Hall, published in the Virginia Register, or at such other time as the agency determines is appropriate; or

2. The agency determines that the regulatory action is either exempt or excluded from the requirements of the Administrative Process Act.

16VAC5-5-80. Appointment of negotiated rulemaking panel.

A. The agency may appoint a negotiated rulemaking panel (NRP) if a regulatory action is expected to be controversial.

B. An NRP that has been appointed by the agency may be dissolved by the agency when:

1. There is no longer controversy associated with the development of the regulation;

2. The agency determines that the regulatory action is either exempt or excluded from the requirements of the Administrative Process Act; or

3. The agency determines that resolution of a controversy is unlikely.

16VAC5-5-90. Meetings.

Notice of any open meeting, including meetings of a RAP or NRP, shall be posted on the Town Hall and Commonwealth Calendar at least seven working days prior to the date of the meeting. The exception to this requirement is any meeting held in accordance with § 2.2-3707 D of the Code of Virginia allowing for contemporaneous notice to be provided to participants and the public.

16VAC5-5-100. Public hearings on regulations.

A. The agency shall indicate in its notice of intended regulatory action whether it plans to hold a public hearing following the publication of the proposed stage of the regulatory action.

B. The agency may conduct one or more public hearings during the comment period following the publication of a proposed regulatory action.

C. An agency is required to hold a public hearing following the publication of the proposed regulatory action when:

1. The agency's basic law requires the agency to hold a public hearing;

2. The Governor directs the agency to hold a public hearing; or

3. The agency receives requests for a public hearing from at least 25 persons during the public comment period following the publication of the notice of intended regulatory action.

D. Notice of any public hearing shall be posted on the Town Hall and Commonwealth Calendar at least seven working days prior to the date of the hearing. The agency shall also notify those persons who requested a hearing under subdivision C 3 of this section.

16VAC5-5-110. Periodic review of regulations.

A. The agency shall conduct a periodic review of its regulations consistent with:

1. An executive order issued by the Governor pursuant to § 2.2-4017 of the Administrative Process Act to receive comment on all existing regulations as to their effectiveness, efficiency, necessity, clarity, and cost of compliance; and

2. The requirements in § 2.2-4007.1 of the Administrative Process Act regarding regulatory flexibility for small businesses.

B. A periodic review may be conducted separately or in conjunction with other regulatory actions.

C. Notice of a periodic review shall be posted on the Town Hall and published in the Virginia Register.

16VAC5-10-20. ~~Development of regulations.~~ (Repealed.)

~~A. Pursuant to the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia), the commission shall solicit the input of interested parties in the formulation and the development of its rules and regulations. The commission shall receive petitions from any party proposing new regulations or amendment of existing regulations. All such proposals shall be reviewed by the commission and receive response within 180 days. Formulation and development of all new or amended regulations shall be subject to the following public participation guidelines.~~

~~B. Interested parties for the purpose of this chapter shall be:~~

~~1. The Governor's Cabinet Secretaries.~~

~~2. Members of the Senate Committee on Commerce and Labor.~~

~~3. Members of the House Committee on Labor and Commerce.~~

~~4. Special interest groups known to the Virginia Employment Commission.~~

~~5. Any individual or entity submitting a written request to be included as an interested party.~~

~~6. Those parties who have expressed an interest in VEC regulations through oral or written comments in the past.~~

~~C. An ad hoc advisory committee will be established to develop regulatory changes upon petition of five or more people during the Notice of Intended Regulatory Action public comment period established pursuant to § 2.2-4008 B of the Code of Virginia. Such ad hoc advisory committee shall be chosen from individuals registering with the agency as interested parties and shall include representatives of business, labor, the bar, and public interest associations.~~

~~D. Prior to the formulation of a proposed regulation, notice of an intended regulatory action may appear in any newspaper circulated in localities particularly affected by the proposed regulation and on the commission's web page. Other media may also be utilized where appropriate, including but not limited to, trade or professional publications. Notice of an intended regulatory action shall also be mailed to all interested parties and shall be posted in all VEC offices across the Commonwealth and on the Virginia Regulatory Town Hall. These individuals, groups and the general public shall be invited to submit written data, views, and arguments on the formulation of the proposed regulation to the commission at its administrative office in Richmond, Virginia.~~

~~E. Publication of the intent to draft a regulation, as well as the proposed regulation, shall also appear in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall.~~

~~F. Failure of any interested party to receive notice to submit data, views, or oral or written arguments to the commission shall not affect the implementation of any regulation if such regulation was formulated, developed and adopted in compliance with the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).~~

~~G. The public participation guidelines of this chapter shall not apply to emergency regulations or those regulations excluded or exempted by any section of the Administrative Process Act.~~

~~H. During the formal procedures required by the Administrative Process Act and these public participation guidelines, written input will be solicited from interested parties and the general public. At the discretion of the commission, and in accordance with applicable law, one or more public hearings may be held in Richmond or at any other location deemed appropriate to ensure adequate public participation.~~

16VAC5-10-21. ~~Notification lists.~~ (Repealed.)

~~A. The commission shall maintain lists of persons who have requested to be notified of the formation and promulgation of regulations.~~

~~B. Any person may request to be placed on a notification list by indicating so electronically or in writing to the commission. The commission may also add to a list any person it believes will serve the purpose of enhancing the regulatory process.~~

~~C. The board may maintain additional lists for persons who have requested to be informed of specific regulatory issues, proposals, or actions.~~

~~D. The board shall periodically request those persons on the notification lists to indicate their desire to either continue to receive documents by regular mail, be notified electronically or be deleted from the lists. Persons who elected to be included on an electronic mailing list may also request that all notices and mailings be sent in hard copy. When either regular or electronic mail is returned as undeliverable or there~~

~~has been no response to the request from the commission, such persons shall be deleted from the list.~~

16VAC5-10-22. ~~Documents to be sent to persons on notification lists.~~ (Repealed.)

~~Persons on the notification lists described in 16VAC5-10-21 shall be mailed or have electronically transmitted the following documents related to the promulgation of regulations:~~

~~1. Notice of intended regulatory action;~~

~~2. Notice of the comment period for a proposed regulation and instructions as to how to obtain a copy of the regulation and any supporting documents, either electronically or from the commission office.~~

~~3. Notification of the adoption of a final regulation and instructions as to how to obtain a copy of the regulation and any supporting documents, either electronically or from the commission office.~~

~~4. Notice soliciting comment on a final regulation when the regulatory process has been extended.~~

16VAC5-10-30. ~~Review of regulations.~~ (Repealed.)

~~At least every three years, or more often as may be mandated by statute or Executive Order, a regulatory review committee consisting of commission staff shall meet to review these regulations and general rules. The committee shall recommend deletion and amendment of the existing rules and regulations, and additions thereto, as needed, in light of their impact upon the general public and employers.~~

VA.R. Doc. No. R11-1455; Filed December 10, 2010, 3:24 p.m.

◆ ◆

TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF DENTISTRY

Proposed Regulation

Title of Regulation: **18VAC60-20. Regulations Governing the Practice of Dentistry and Dental Hygiene (amending 18VAC60-20-10, 18VAC60-20-30; adding 18VAC60-20-332, 18VAC60-20-342, 18VAC60-20-352).**

Statutory Authority: §§ 54.1-2400 and 54.1-2708.3 of the Code of Virginia.

Public Hearing Information:

February 25, 2011 – 9 a.m. - Board of Dentistry, Perimeter Center, 9960 Mayland Drive, 2nd Floor, Board Room 3, Richmond, VA

Public Comment Deadline: March 4, 2011.

Agency Contact: Sandra Reen, Executive Director, Board of Dentistry, 9960 Mayland Drive, Suite 300, Richmond, VA 23233-1463, telephone (804) 367-4538, FAX (804) 527-4428, or email sandra.reen@dhp.virginia.gov.

Basis: Section 54.1-2400 of the Code of Virginia provides the Board of Dentistry the authority to promulgate regulations to administer the regulatory system. The specific mandate to promulgate regulations for the registration of mobile dental clinics is found in § 54.1-2708.3 of the Code of Virginia.

Purpose: To protect the health and safety of persons served in mobile dental clinics, amendments to 18VAC60-20 require registration to include information about where and when the practices will be operating and which practitioners will be providing care. The clinics must also certify to agreements for follow-up care, emergency contact arrangements, access to all essential equipment, and conformity to laws and regulations. There must be written consent to dental care in a mobile clinic, and patients must be provided with an information sheet that details who provided treatment, a description of the treatment and any additional dental needs, a recommendation or referral for follow-up care, and emergency contact information. Such requirements are necessary to ensure that patients (often school children) are not left with unresolved dental problems or with little or no information about what was done during a visit by a mobile clinic. Finally, regulations stipulate that the same rules and standards of care apply for practice in a mobile clinic as in a fixed facility.

Substance: The key provisions of the regulations are: (i) establishment of definitions of a mobile dental clinic and a portable dental operation; (ii) requirements for registration including information on locations, dates, and practitioners providing services; certifications of agreements for follow-up care and access to emergency care; certification of availability of certain equipment and resources; and conformity to operational and permitting standards; (iii) requirements for operation of the clinic, including posting of licenses, written consent for treatment, information on treatment and needed follow-up for patients, and maintenance of patient records; and (iv) exemptions from the requirements for registration for governmental agencies and periodic volunteer clinics providing free care.

Issues: The primary advantage to the public is more accountability for mobile dental clinics providing services to school children and others in Virginia. Information on practitioners and locations, appropriate procedures for follow-up care and emergencies, and adequate equipment for such clinics will provide some assurance that the care being given is safe and competent. The disadvantage could be that the registration process may discourage some clinic operations from coming into Virginia, thus reducing access to care. In passing the mandate for registration, members of the General Assembly determined that the advantages for greater

protection in dental care outweighed the potential for any loss of access.

There are no advantages or disadvantages to the Commonwealth; the board set the application and renewal fee with the goal of covering expenditures related to registration of mobile dental clinics.

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

Summary of the Proposed Amendments to Regulation. Pursuant to Item 303 of the 2009 Appropriation Act and Chapter 405 of the 2010 Acts of Assembly, the Board of Dentistry proposes to require that mobile dental clinics: 1) register with the Department of Health Professions (Department), 2) pay an initial $250 application fee and an annual $150 renewal fee, 3) provide the Department with the locations of where services are provided, and identity and license numbers of staff, 4) have a written agreement for emergency follow-up care for patients to include identification of and arrangements for treatment in a dental office which is permanently established within a reasonable geographic area, 5) certify that that the facility or operation has access to communication facilities that enable the dental personnel to contact assistance in the event of a medical or dental emergency, 6) certify that the facility has a water supply and all equipment necessary to provide the dental services to be rendered therein, 7) certify that the facility or operation conforms to all applicable federal, state and local laws, regulations and ordinances, 8) certify that the applicant possesses all applicable city or county licenses or permits to operate the facility, 9) obtain written consent from the patient, parent, guardian or authorized representative prior to treatment, 10) provide each patient with an information sheet that includes information such as description of the treatment rendered, names of staff providing treatment, billed service codes and fees, description of any additional dental needs diagnosed, referral recommendation to another dentist if the facility or operation is unable to provide follow-up treatment, and emergency contact information, and 11) maintain secure records. The proposed regulations also specify that federal, state, and local governmental agencies and dental treatment which is provided without charge to patients or to any third party payer are exempt.

Result of Analysis. There is insufficient data to accurately compare the magnitude of the benefits versus the costs. Detailed analysis of the benefits and costs can be found in the next section.

Estimated Economic Impact. In terms of fees (initial $250 application fee and an annual $150 renewal fee) and paperwork (listed in above summary) there are non-negligible new costs associated with the proposed new requirements for mobile dental clinics, but the costs are not likely large enough to discourage most potential for-profit clinics. Given that treatment which is provided without charge to patients is exempt and that the costs are not likely large enough to discourage most potential for-profit clinics, the proposed regulations are unlikely to result in diminished dental services.

The required registration, fees, recordkeeping, and associated procedures for mobile dental clinics do likely provide benefits for the public in that there is greater accountability for the dental services being provided and increased assurance that follow-up care has been arranged. The degree to which mobile clinics would provide necessary information for follow-up care and quality service without these proposed requirements is not known. Thus an accurate estimate of the magnitude of the benefits cannot be definitively established.

Businesses and Entities Affected. The proposed amendments affect the two current mobile dental clinics in Virginia plus any potential future mobile dental clinics. According to the Department, the larger current mobile dental clinic primarily serves children at schools throughout the Commonwealth, while the other current mobile dental clinic primarily serves older adults in central Virginia.

Localities Particularly Affected. The proposed amendments do not disproportionately affect particular localities.

Projected Impact on Employment. The proposal amendments do raise costs for mobile dental clinics, but likely not enough to significantly affect total employment.

Effects on the Use and Value of Private Property. The proposed amendments increase costs for mobile dental clinics through an application fee of $250 and an annual renewal fee of $150, as well as required paperwork and recordkeeping.

Small Businesses: Costs and Other Effects. Essentially all dental clinics qualify as small businesses. The proposed amendments increase costs for mobile dental clinics through an application fee of $250 and an annual renewal fee of $150, as well as required paperwork and recordkeeping.

Small Businesses: Alternative Method that Minimizes Adverse Impact. There are no clear alternatives that both satisfy the legislative mandate and reduce costs.

Real Estate Development Costs. The proposed amendments are unlikely to significantly affect real estate development costs.

Legal Mandate. The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Administrative Process Act and Executive Order Number 107 (09). Section 2.2-4007.04 requires that such economic impact analyses include, but need not be limited to, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to

implement or comply with the regulation, and the impact on the use and value of private property. Further, if the proposed regulation has adverse effect on small businesses, § 2.2-4007.04 requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis presented above represents DPBs best estimate of these economic impacts.

Agency's Response to the Department of Planning and Budget's Economic Impact Analysis: In general, the Board of Dentistry concurs with the analysis of the Department of Planning and Budget for the proposed regulation, 18VAC60-20, Regulations Governing the Practice of Dentistry and Dental Hygiene, relating to registration of mobile dental clinics with two exceptions:

1. The requirement for a written agreement for follow-up care is to include identification of and arrangements for treatment in a dental office that is permanently established within a reasonable geographic area, rather than a written agreement for emergency follow-up care as described in #4 of the first paragraph. There is also a requirement for access to communication facilities that enable the dental personnel to contact assistance in the event of a medical or dental emergency; and

2. It should be noted that the two mobile clinics registered and operating in Virginia have already paid an application fee pursuant to emergency regulations, so the proposed regulations do not impose a new requirement or cost for registration.

Summary:

Pursuant to Item 303 of the 2009 Appropriation Act (Chapter 781 of the 2009 Acts of Assembly) and Chapter 405 of the 2010 Acts of Assembly, the proposed regulations establish requirements for registration of mobile dental clinics and other portable dental operations. The proposed regulations require that mobile dental clinics and other portable dental operations (i) register with the Department of Health Professions; (ii) pay an initial $250 application fee and an annual $150 renewal fee; (iii) provide the department with the (a) locations of where services are provided and (b) identity and license numbers of staff; (iv) have a written agreement for emergency follow-up care for patients to include identification of and arrangements for treatment in a dental office that is permanently established within a reasonable geographic area; (v) certify that that the facility or operation has access to communication facilities that enable the dental personnel to contact assistance in the event of a medical or dental emergency; (vi) certify that the facility has a water supply and all equipment necessary to provide the dental services to be rendered at the facility; (vii) certify that the facility or operation conforms to all applicable federal, state, and local laws, regulations, and ordinances; (viii) certify that the applicant possesses all applicable city or county licenses or permits to operate the facility; (ix) obtain written consent from the patient, parent, guardian, or authorized representative prior to treatment; (x) provide each patient with an information sheet that includes information such as description of the treatment rendered, names of staff providing treatment, billed service codes and fees, description of any additional dental needs diagnosed, referral recommendation to another dentist if the facility or operation is unable to provide follow-up treatment, and emergency contact information; and (xi) maintain secure records. Governmental agencies and periodic volunteer clinics providing free care are exempted from the registration requirements.

Emergency regulations implementing registration requirements are currently in effect.

Part I
General Provisions

18VAC60-20-10. Definitions.

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

"ADA" means the American Dental Association.

"Advertising" means a representation or other notice given to the public or members thereof, directly or indirectly, by a dentist on behalf of himself, his facility, his partner or associate, or any dentist affiliated with the dentist or his facility by any means or method for the purpose of inducing purchase, sale or use of dental methods, services, treatments, operations, procedures or products, or to promote continued or increased use of such dental methods, treatments, operations, procedures or products.

"Analgesia" means the diminution or elimination of pain in the conscious patient.

"Anxiolysis" means the diminution or elimination of anxiety through the use of pharmacological agents in a dosage that does not cause depression of consciousness.

"Conscious sedation" means a minimally depressed level of consciousness that retains the patient's ability to independently and continuously maintain an airway and respond appropriately to physical stimulation and verbal commands, produced by pharmacological or nonpharmacological methods, including inhalation, parenteral, transdermal or enteral, or a combination thereof.

"Deep sedation/general anesthesia" means an induced state of depressed consciousness or unconsciousness accompanied by a complete or partial loss of protective reflexes, including the inability to continually maintain an airway independently and/or respond purposefully to physical stimulation or verbal command and is produced by a pharmacological or nonpharmacological method or a combination thereof.

"Dental assistant" means any unlicensed person under the supervision of a dentist who renders assistance for services provided to the patient as authorized under this chapter but shall not include an individual serving in purely a secretarial or clerical capacity.

"Direction" means the dentist examines the patient and is present for observation, advice, and control over the performance of dental services.

"Enteral" is any technique of administration in which the agent is absorbed through the gastrointestinal tract or oral mucosa (i.e., oral, rectal, sublingual).

"General supervision" means that the dentist has examined the patient and issued a written order for the specific, authorized services to be provided by a dental hygienist when the dentist is not present in the facility while the services are being provided.

"Inhalation" is a technique of administration in which a gaseous or volatile agent, including nitrous oxide, is introduced into the pulmonary tree and whose primary effect is due to absorption through the pulmonary bed.

"Inhalation analgesia" means the inhalation of nitrous oxide and oxygen to produce a state of reduced sensibility to pain without the loss of consciousness.

"Local anesthesia" means the loss of sensation or pain in the oral cavity or the maxillofacial or adjacent and associated structures generally produced by a topically applied or injected agent without depressing the level of consciousness.

"Mobile dental facility" means a self-contained unit in which dentistry is practiced that is not confined to a single building and can be transported from one location to another.

"Parenteral" means a technique of administration in which the drug bypasses the gastrointestinal tract (i.e., intramuscular, intravenous, intranasal, submucosal, subcutaneous, or intraocular).

"Portable dental operation" means a nonfacility in which dental equipment used in the practice of dentistry is transported to and utilized on a temporary basis at an out-of-office location, including patients' homes, schools, nursing homes, or other institutions.

"Radiographs" means intraoral and extraoral x-rays of hard and soft tissues to be used for purposes of diagnosis.

18VAC60-20-30. Other fees.

A. Dental licensure application fees. The application fee for a dental license by examination, a license to teach dentistry, a full-time faculty license, or a temporary permit as a dentist shall be $400. The application fee for dental license by credentials shall be $500.

B. Dental hygiene licensure application fees. The application fee for a dental hygiene license by examination, a license to teach dental hygiene, or a temporary permit as a dental hygienist shall be $175. The application fee for dental hygienist license by endorsement shall be $275.

C. Duplicate wall certificate. Licensees desiring a duplicate wall certificate shall submit a request in writing stating the necessity for such duplicate wall certificate, accompanied by a fee of $60.

D. Duplicate license. Licensees desiring a duplicate license shall submit a request in writing stating the necessity for such duplicate license, accompanied by a fee of $20. If a licensee maintains more than one office, a notarized photocopy of a license may be used.

E. Licensure certification. Licensees requesting endorsement or certification by this board shall pay a fee of $35 for each endorsement or certification.

F. Restricted license. Restricted license issued in accordance with § 54.1-2714 of the Code of Virginia shall be at a fee of $285.

G. Restricted volunteer license. The application fee for licensure as a restricted volunteer dentist or dental hygienist issued in accordance with § 54.1-2712.1 or § 54.1-2726.1 of the Code of Virginia shall be $25.

H. Returned check. The fee for a returned check shall be $35.

I. Inspection fee. The fee for an inspection of a dental office shall be $350.

J. Mobile dental clinic or portable dental operation. The application fee for registration of a mobile dental clinic or portable dental operation shall be $250. The annual renewal fee shall be $150 and shall be due by December 31. A late fee of $50 shall be charged for renewal received after that date.

Part VIII
Mobile Dental Clinics and Portable Dental Operations

18VAC60-20-332. Registration of a mobile dental clinic or portable dental operation.

A. An applicant for registration of a mobile dental facility or portable dental operation shall provide:

1. The name and address of the owner of the facility or operation and an official address of record for the facility

or operation, which shall not be a post office address. Notice shall be given to the board within 30 days if there is a change in the ownership or the address of record for a mobile dental facility or portable dental operation;

2. The name, address, and license number of each dentist and dental hygienist or the name, address, and registration number of each dental assistant II who will provide dental services in the facility or operation. The identity and license or registration number of any additional dentists, dental hygienists, or dental assistants II providing dental services in a mobile dental facility or portable dental operation shall be provided to the board in writing prior to the provision of such services; and

3. The address or location of each place where the mobile dental facility or portable dental operation will provide dental services and the dates on which such services will be provided. Any additional locations or dates for the provision of dental services in a mobile dental facility or portable dental operation shall be provided to the board in writing prior to the provision of such services.

B. The information provided by an applicant to comply with subsection A of this section shall be made available to the public.

C. An application for registration of a mobile dental facility or portable dental operation shall include:

1. Certification that there is a written agreement for follow-up care for patients to include identification of and arrangements for treatment in a dental office that is permanently established within a reasonable geographic area;

2. Certification that the facility or operation has access to communication facilities that enable the dental personnel to contact assistance in the event of a medical or dental emergency;

3. Certification that the facility has a water supply and all equipment necessary to provide the dental services to be rendered therein;

4. Certification that the facility or operation conforms to all applicable federal, state, and local laws, regulations, and ordinances dealing with radiographic equipment, sanitation, zoning, flammability, and construction standards; and

5. Certification that the applicant possesses all applicable city or county licenses or permits to operate the facility or operation.

D. Registration may be denied or revoked for a violation of provisions of § 54.1-2706 of the Code of Virginia.

18VAC60-20-342. Requirements for a mobile dental clinic or portable dental operation.

A. The registration of the facility or operation and copies of the licenses of the dentists and dental hygienists or registrations of the dental assistants II shall be displayed in plain view of patients.

B. Prior to treatment, the facility or operation shall obtain written consent from the patient or, if the patient is a minor or incapable of consent, his parent, guardian, or authorized representative.

C. Each patient shall be provided with an information sheet, or if the patient, his parent, guardian, or authorized agent has given written consent to an institution or school to have access to the patient's dental health record, the institution or school may be provided a copy of the information. At a minimum, the information sheet shall include:

1. Patient name, date of service, and location where treatment was provided;

2. Name of dentist or dental hygienist who provided services;

3. Description of the treatment rendered and tooth numbers, when appropriate;

4. Billed service codes and fees associated with treatment;

5. Description of any additional dental needs observed or diagnosed;

6. Referral or recommendation to another dentist if the facility or operation is unable to provide follow-up treatment; and

7. Emergency contact information.

D. Patient records shall be maintained, as required by 18VAC60-20-15, in a secure manner within the facility or at the address of record listed on the registration application. Records shall be made available upon request by the patient, his parent, guardian, or authorized representative and shall be available to the board for inspection and copying.

E. The practice of dentistry and dental hygiene in a mobile dental clinic or portable dental operation shall be in accordance with the laws and regulations governing such practice.

18VAC60-20-352. Exemptions from requirement for registration.

The following shall be exempt from requirements for registration as a mobile dental clinic or portable dental operation:

1. All federal, state, or local governmental agencies; and

2. Dental treatment that is provided without charge to patients or to any third party payer.

NOTICE: The forms used in administering the above regulation are not being published; however the name of each form is listed below. The forms are available for public inspection at the Board of Dentistry, Perimeter Center, 9960 Mayland Drive, Suite 300, Richmond, Virginia, or at the Office of the Registrar of Regulations, General Assembly Building, 2nd Floor, Richmond, Virginia 23219.

FORMS (18VAC60-20)

Application Requirements for Dentists (rev. 8/08).

Application for License to Practice Dentistry (rev. 8/08).

Application Requirements for Restricted Dental Volunteer License/Restricted Dental Hygiene License (rev. 8/08).

Application for Restricted Volunteer License to Practice Dentistry or Dental Hygiene (rev. 8/08).

Requirements and Instructions for a Temporary Resident's License to Persons Enrolled in Advanced Dental Education Programs (rev. 5/08).

Application for Temporary Resident's License (rev. 5/08).

Form A, Certification of Dental School for Temporary Resident's License (rev. 5/08).

Form B, Temporary Resident's License (Certification from Dean of Dental School or Director of Accredited Graduate Program) (rev. 5/08).

Form C, Temporary Resident's License (Certification of Dental Licensure) (rev. 5/08).

Form D, Temporary Resident's License (Chronology) (rev. 5/08).

Form A, Certification of Dental/Dental Hygiene School (rev. 8/08).

Form AA, Sponsor Certification for Dental/Dental Hygiene Volunteer License (rev. 8/08).

Form B, Chronology (rev. 8/08).

Form C, Certification of Dental/Dental Hygiene Boards (rev. 8/08).

Application Requirements for Dental Hygienists (rev. 1/08).

Application for Licensure to Practice Dental Hygiene (rev. 1/08).

Instructions for Reinstatement of License (rev. 4/08).

Reinstatement Application for Dental/Dental Hygiene Licensure (rev. 4/08).

Instructions for Application for Reactivation of License (rev. 8/08).

Application for Reactivation of License (rev. 8/08).

Application for Certification to Perform Cosmetic Procedures (rev. 8/08).

Oral and Maxillofacial Surgeon Registration of Practice (rev. 8/08).

Application for Registration for Volunteer Practice (rev. 8/08).

Sponsor Certification for Volunteer Registration (rev. 8/08).

Application for Registration of a Mobile Dental Facility or Portable Dental Operation (eff. 6/10).

VA.R. Doc. No. R10-1945; Filed December 14, 2010, 11:20 a.m.

Proposed Regulation

Title of Regulation: **18VAC60-20. Regulations Governing the Practice of Dentistry and Dental Hygiene (adding 18VAC60-20-18).**

Statutory Authority: §§ 54.1-2400 and 54.1-2708.2 of the Code of Virginia.

Public Hearing Information: No public hearings are scheduled.

Public Comment Deadline: March 4, 2011.

Agency Contact: Sandra Reen, Executive Director, Board of Dentistry, 9960 Mayland Drive, Suite 300, Richmond, VA 23233-1463, telephone (804) 367-4538, FAX (804) 527-4428, or email sandra.reen@dhp.virginia.gov.

Basis: Section 54.1-2400 of the Code of Virginia provides the Board of Dentistry the authority to promulgate regulations to administer the regulatory system. Specific regulatory authority for the Board of Dentistry to impose certain costs is found in Chapter 89 of the 2009 Acts of the Assembly, codified as § 54.1-2708.2 of the Code of Virginia.

Purpose: The purpose of this proposed regulatory action is to initiate rules for recovery of administrative costs relating to the investigation and monitoring of a licensee disciplined by the Board of Dentistry. Legislation passed by the 2009 General Assembly (HB2058) provides statutory authorization for imposition of such costs, and the goal of the amendments is to establish the regulatory framework for which costs may be assessed, how those costs may be determined, and the process for assessment of costs.

Enforcement activities constitute the largest expenditure for the board, although only a small percentage of licensees undergo investigation, and an even smaller percentage are found to be in violation of statutes and regulations governing their professions. Therefore, it is equitable to assess at least a portion of enforcement and monitoring costs to those who are the cause of the expenditure. By recovering a portion of its enforcement costs, the board will be better able to meet its obligation to investigate every complaint it receives and to more efficiently and effectively resolve cases related to patient care. The board will have the additional resources

necessary to adequately investigate reports of misconduct to make the practice of dentistry and dental hygiene safer for patients in Virginia.

Substance: Section 54.1-2708.2 of the Code of Virginia is specific about some aspects of the authority to recover reasonable administrative costs associated with investigating and monitoring a licensee. The recovery of costs will only be implemented if a licensee has had disciplinary action imposed. It will not affect those licensees: (i) who are investigated by the department, but for whom no probable cause is found to indicate a violation may have occurred; (ii) who have a disciplinary proceeding, but for whom no violation is found and no discipline imposed; or (iii) who have matters resolved through a confidential consent agreement or an advisory letter.

Rather than setting specific fees or dollar amounts in regulation, the proposed amendments provide a process for determination of both the investigative and monitoring costs as specified in the Code of Virginia. At the end of each fiscal year, regulations require a calculation of the average hourly cost for enforcement that is chargeable to the work of the Board of Dentistry. The Enforcement Division of the Department of Health Professions tracks the number of hours an investigator spends on a case, so that number can be multiplied by the hourly cost to determine the specific costs relating to the investigation of the case against a specific respondent. In addition, the board would assess any costs relating to hiring expert witnesses and the reports generated by such witnesses. While not inclusive of all related administrative costs, a fee based on the actual number of hours and the hourly cost of an investigation would be reasonable and not arbitrary or selectively punitive. The imposition of the recovery cost would become part of the order from an informal or formal proceeding or part of a consent order agreed to by the parties.

The monitoring costs would be calculated based on the terms and conditions imposed and the length of time the licensee is to be monitored. As with the enforcement costs, the board would annually calculate the average costs of monitoring certain terms, such as the acquisition of continuing education in an area of practice. If the licensee is to be monitored beyond one year, the monitoring cost would be imposed for each of those years. A guidance document would be adopted annually setting out the average investigative and monitoring cost (for the various terms and conditions to be monitored), so the licensees (and their attorneys, if applicable) would have knowledge of the recovery of costs if disciplinary action is imposed. Since the costs would be incorporated in the order, the respondent would have the option to accept the order, request a formal hearing following an informal, or appeal an order from a formal hearing to a circuit court.

As specified in statute, the total of the recovery of costs will not exceed $5,000. However, the regulations reference current fees for inspection of dental offices and returned checks as fees not subject to the recovery maximum. Additionally, the board may seek to recover the collection costs for delinquent fines and fees.

Issues: The primary advantage to the public is that income generated by the partial recovery of disciplinary costs may allow the board to sustain its investigative, adjudication, and monitoring activities without substantial increases in fees charged to licensees who are not in violation of law and regulation. There are no disadvantages.

The primary advantage to the agency is the creation of a new source of revenue to offset ever increasing costs relating to the disciplinary functions of the board. There are no disadvantages, but the agency will have an increased responsibility for collection of assessed costs.

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

Summary of the Proposed Amendments to Regulation. Chapter 89 of the 2009 Virginia Acts of Assembly permits the Board of Dentistry (Board) to recover from any licensee against whom disciplinary action has been imposed reasonable administrative costs associated with investigating and monitoring such licensee and confirming compliance with any terms and conditions imposed upon the licensee as set forth in the order imposing disciplinary action. Further, the legislation specified that such recovery shall not exceed a total of $5,000. Consequently the Board proposes to set out in these regulations the conditions and procedures for assessment of disciplinary costs relating to investigation and monitoring of a licensee for whom there is a finding that a violation of law or regulation has occurred.

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

Estimated Economic Impact. The proposed amendments would establish the conditions and procedures for assessing disciplinary costs relating to the investigation and monitoring of a licensee for whom there is a finding that a violation of law or regulation has occurred. The hourly costs for the investigation and monitoring would be set out annually in a guidance document and then costs would be calculated for each case and assessed. Costs for the investigation and monitoring could not exceed the statutory limit of $5,000.

According to the Department of Health Professions, enforcement activities constitute the largest expenditure for the board, although only a small percentage of licensees undergo investigation, and an even smaller percentage are found to be in violation of statutes and regulations governing their professions. Currently the Board does not charge disciplinary costs to licensees for whom there is a finding that a violation of law or regulation has occurred. Income generated by the partial recovery of disciplinary costs through the proposed assessments may allow the board to sustain its

investigative, adjudication, and monitoring activities without substantial increases in fees charged to licensees who are not in violation of law and regulation. This is more equitable than raising fees for all licenses, including the majority who comply with the law, to cover disciplinary costs.

Businesses and Entities Affected. The proposed amendments affect dental practices.

Localities Particularly Affected. The proposed amendments do not disproportionately affect particular Virginia localities.

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

Effects on the Use and Value of Private Property. The proposed amendments will likely moderately reduce future fee increases for dentists and dental hygienists who comply with the law, and increase costs for dentists and dental hygienists for whom there is a finding that a violation of law or regulation has occurred.

Small Businesses: Costs and Other Effects. The proposed amendments likely moderately reduce costs for small businesses where the staff complies with the law.

Small Businesses: Alternative Method that Minimizes Adverse Impact. The proposed amendments likely moderately reduce costs for small businesses where the staff complies with the law.

Real Estate Development Costs. The proposed amendments will not affect real estate development costs.

Legal Mandate. The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with § 2.2-4007.04 of the Administrative Process Act and Executive Order Number 36 (06). Section 2.2-4007.04 requires that such economic impact analyses include, but need not be limited to, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. Further, if the proposed regulation has adverse effect on small businesses, § 2.2-4007.04 requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis presented above represents DPB's best estimate of these economic impacts.

Agency Response to the Department of Planning and Budget's Economic Impact Analysis: The Board of Dentistry concurs with the analysis of the Department of Planning and Budget for the proposed regulation, 18VAC60-20, Regulations Governing the Practice of Dentistry and Dental Hygiene, relating to assessment of disciplinary costs.

Summary:

In the proposed new section 18VAC60-20-18, the Board of Dentistry sets out the conditions and procedures for assessment of disciplinary costs relating to investigation and monitoring of a licensee for whom there is a finding that a violation of law or regulation has occurred. The hourly costs for an investigation or monitoring will be set out annually in a guidance document, and then costs will be calculated for each case and assessed as a part of an order. Costs for monitoring and investigation will not exceed the statutory limit of $5,000.

18VAC60-20-18. Recovery of disciplinary costs.

A. Assessment of cost for investigation of a disciplinary case.

1. In any disciplinary case in which there is a finding of a violation against a licensee or registrant, the board may assess the hourly costs relating to investigation of the case by the Enforcement Division of the Department of Health Professions and, if applicable, the costs for hiring an expert witness and reports generated by such witness.

2. The imposition of recovery costs relating to an investigation shall be included in the order from an informal or formal proceeding or as part of a consent order agreed to by the parties. The schedule for payment of investigative costs imposed shall be set forth in the order.

3. At the end of each fiscal year, the board shall calculate the average hourly cost for enforcement that is chargeable to investigation of complaints filed against its regulants and shall state those costs in a guidance document to be used in imposition of recovery costs. The average hourly cost multiplied by the number of hours spent in investigating the specific case of a respondent shall be used in the imposition of recovery costs.

B. Assessment of cost for monitoring a licensee or registrant.

1. In any disciplinary case in which there is a finding of a violation against a licensee or registrant and in which terms and conditions have been imposed, the costs for monitoring of a licensee or registrant may be charged and shall be calculated based on the specific terms and conditions and the length of time the licensee or registrant is to be monitored.

2. The imposition of recovery costs relating to monitoring for compliance shall be included in the board order from an informal or formal proceeding or as part of a consent order agreed to by the parties. The schedule for payment of monitoring costs imposed shall be set forth in the order.

3. At the end of each fiscal year, the board shall calculate the average costs for monitoring of certain terms and conditions, such as acquisition of continuing education, and shall set forth those costs in a guidance document to be used in the imposition of recovery costs.

C. Total of assessment. In accordance with § 54.1-2708.2 of the Code of Virginia, the total of recovery costs for investigating and monitoring a licensee or registrant shall not exceed $5,000, but shall not include the fee for inspection of dental offices and returned checks as set forth in 18VAC60-20-30 or collection costs incurred for delinquent fines and fees.

VA.R. Doc. No. R10-2178; Filed December 14, 2010, 11:20 a.m.

BOARD OF PHARMACY

Emergency Regulation

Title of Regulation: **18VAC110-20. Regulations Governing the Practice of Pharmacy (amending 18VAC110-20-20, 18VAC110-20-275, 18VAC110-20-690, 18VAC110-20-700; adding 18VAC110-20-685, 18VAC110-20-725, 18VAC110-20-726, 18VAC110-20-727, 18VAC110-20-728).**

Statutory Authority: §§ 54.1-3307 and 54.1-3420.2 of the Code of Virginia.

Effective Dates: December 20, 2010, through December 19, 2011.

Agency Contact: Caroline Juran, RPh, Acting 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.

Preamble:

Section 2.2-4011 of the Administrative Process Act states that an agency may adopt regulations in an emergency situation: (i) upon consultation with the Attorney General after the agency has submitted a request stating in writing the nature of the emergency, and at the sole discretion of the Governor; (ii) in a situation in which Virginia statutory law, the Virginia appropriation act, federal law, or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of subdivision A 4 of § 2.2-4006; or (iii) in a situation in which an agency has an existing emergency regulation, additional emergency regulations may be issued as needed to address the subject matter of the initial emergency regulation provided the amending action does not extend the effective date of the original action.

Chapter 28 of the 2010 Acts of the Assembly (HB150) requires the Board of Pharmacy to promulgate regulations authorizing a community services board (CSB) and behavioral health authority (BHA) to (i) possess, repackage, and dispense medications and (ii) establish that crisis stabilization units store and administer a stock of drugs needed for emergency treatment. The second enactment of Chapter 28 provides that an emergency existed, so the act became effective upon approval by the Governor on March 4, 2010. The third enactment requires that the board promulgate regulations to implement the provisions of the act to be effective within 280 days of enactment.

Therefore, an emergency situation exists as defined in § 2.2-4011 of the Administrative Process Act. These regulations establish requirements for registration of a CSB or BHA to possess, repackage, and dispense drugs and for a program to train unlicensed persons in repackaging for CSBs or BHAs. These regulations include labeling, storage, recordkeeping, destruction, and other requirements for repackaging in these facilities (that do not have a pharmacy); persons authorized to repackage; and information to clients about repackaged drugs. There are also curricula and instructional criteria for approval of repackaging training programs and for expiration and renewal of program approval. Finally, there are provisions for stocking, recordkeeping, and administration of Schedule VI at a crisis stabilization unit for immediate treatment of patients as necessary.

18VAC110-20-20. Fees.

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

B. Unless otherwise provided, any fees for taking required examinations shall be paid directly to the examination service as specified by the board.

C. Initial application fees.

1. Pharmacist license	$180
2. Pharmacy intern registration	$15
3. Pharmacy technician registration	$25
4. Pharmacy permit	$270
5. Permitted physician licensed to dispense drugs	$270
6. Medical equipment supplier permit	$180
7. Humane society permit	$20
8. Nonresident pharmacy	$270
9. Controlled substances registrations	$90

10. Innovative program approval. If the board determines that a technical consultant is required in order to make a decision on approval, any consultant fee, not to exceed the actual cost, shall also be paid by the applicant in addition to the application fee.	$250
11. Approval of a pharmacy technician training program	$150
12. Approval of a continuing education program	$100
13. Approval of a repackaging training program	$50

D. Annual renewal fees.

1. Pharmacist active license – due December 31	$90
2. Pharmacist inactive license – due December 31	$45
3. Pharmacy technician registration – due December 31	$25
4. Pharmacy permit – due April 30	$270
5. Physician permit to practice pharmacy – due February 28	$270
6. Medical equipment supplier permit – due February 28	$180
7. Humane society permit – due February 28	$20
8. Nonresident pharmacy – due April 30	$270
9. Controlled substances registrations – due February 28	$90
10. Innovative program continued approval based on board order not to exceed $200 per approval period.	
11. Approval of a pharmacy technician training program	$75 every two years
12. Approval of a repackaging training program	$30 every two years

E. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired license within one year of the expiration date or within two years in the case of a pharmacy technician training program. In addition, engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board.

1. Pharmacist license	$30
2. Pharmacist inactive license	$15
3. Pharmacy technician registration	$10
4. Pharmacy permit	$90
5. Physician permit to practice pharmacy	$90
6. Medical equipment supplier permit	$60
7. Humane society permit	$5
8. Nonresident pharmacy	$90
9. Controlled substances registrations	$30
10. Approval of a pharmacy technician training program	$15
11. Approval of a repackaging training program	$10

F. Reinstatement fees. Any person or entity attempting to renew a license, permit, or registration more than one year after the expiration date, or more than two years after the expiration date in the case of a pharmacy technician training program, shall submit an application for reinstatement with any required fees. Reinstatement is at the discretion of the board and, except for reinstatement following license revocation or suspension, may be granted by the executive director of the board upon completion of an application and payment of any required fees.

1. Pharmacist license	$210
2. Pharmacist license after revocation or suspension	$500
3. Pharmacy technician registration	$35
4. Pharmacy technician registration after revocation or suspension	$125
5. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement but shall apply for a new permit or registration. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:	
a. Pharmacy permit	$240
b. Physician permit to practice pharmacy	$240
c. Medical equipment supplier permit	$210
d. Humane society permit	$30
e. Nonresident pharmacy	$115

f. Controlled substances registration	$180
g. Approval of a pharmacy technician training program	$75
h. Approval of a repackaging training program	$50

G. Application for change or inspection fees for facilities or other entities.

1. Change of pharmacist-in-charge	$50
2. Change of ownership for any facility	$50
3. Inspection for remodeling or change of location for any facility	150
4. Reinspection of any facility	$150
5. Board-required inspection for a robotic pharmacy system	$150
6. Board-required inspection of an innovative program location	$150
7. Change of pharmacist responsible for an approved innovative program	$25

H. Miscellaneous fees.

1. Duplicate wall certificate	$25
2. Returned check	$35

I. For the annual renewal due on the stated dates, the following fees shall be imposed for a license, permit or registration:

1. Pharmacist active license – December 31, 2009	$50
2. Pharmacist inactive license – December 31, 2009	$25
3. Pharmacy technician registration – December 31, 2009	$15
4. Pharmacy permit – April 30, 2010	$210
5. Physician permit to practice pharmacy – February 28, 2010	$210
6. Medical equipment supplier permit – February 28, 2010	$140
7. Humane society permit – February 28, 2010	$20
8. Nonresident pharmacy – April 30, 2010	$210
9. Controlled substances registrations – February 28, 2010	$50

18VAC110-20-275. Delivery of dispensed prescriptions.

A. Pursuant to § 54.1-3420.2 B of the Code of Virginia, in addition to direct hand delivery to a patient or patient's agent or delivery to a patient's residence, a pharmacy may deliver ~~prescriptions~~ a dispensed prescription drug order for Schedule VI controlled substances to another pharmacy, to a practitioner of the healing arts licensed to practice pharmacy or to sell controlled substances, or to an authorized person or entity holding a controlled substances registration issued for this purpose in compliance with this section and any other applicable state or federal law. Prescription drug orders for Schedule II through Schedule V controlled substances may not be delivered to an alternate delivery location unless such delivery is authorized by federal law and regulations of the board.

B. Delivery to another pharmacy.

1. One pharmacy may fill prescriptions and deliver the prescriptions to a second pharmacy for patient pickup or direct delivery to the patient provided the two pharmacies have the same owner, or have a written contract or agreement specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which each pharmacy will comply with all applicable federal and state law.

2. Each pharmacy using such a drug delivery system shall maintain and comply with all procedures in a current policy and procedure manual that includes the following information:

a. A description of how each pharmacy will comply with all applicable federal and state law;

b. The procedure for maintaining required, retrievable dispensing records to include which pharmacy maintains the hard-copy prescription, which pharmacy maintains the active prescription record for refilling purposes, how each pharmacy will access prescription information necessary to carry out its assigned responsibilities, method of recordkeeping for identifying the pharmacist or pharmacists responsible for dispensing the prescription and counseling the patient, and how and where this information can be accessed upon request by the board;

c. The procedure for tracking the prescription during each stage of the filling, dispensing, and delivery process;

d. The procedure for identifying on the prescription label all pharmacies involved in filling and dispensing the prescription;

e. The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information;

f. The policy and procedure for ensuring accuracy and accountability in the delivery process;

g. The procedure and recordkeeping for returning to the initiating pharmacy any prescriptions that are not delivered to the patient; and

h. The procedure for informing the patient and obtaining consent for using such a dispensing and delivery process.

3. Drugs waiting to be picked up at or delivered from the second pharmacy shall be stored in accordance with subsection A of 18VAC110-20-200.

C. Delivery to a practitioner of the healing arts licensed by the board to practice pharmacy or to sell controlled substances or other authorized person or entity holding a controlled substances registration authorized for this purpose.

1. A prescription may be delivered by a pharmacy to the office of such a practitioner or other authorized person provided there is a written contract or agreement between the two parties describing the procedures for such a delivery system and the responsibilities of each party.

2. Each pharmacy using this delivery system shall maintain a policy and procedure manual that includes the following information:

a. Procedure for tracking and assuring security, accountability, integrity, and accuracy of delivery for the dispensed prescription from the time it leaves the pharmacy until it is handed to the patient or agent of the patient;

b. Procedure for providing counseling;

c. Procedure and recordkeeping for return of any prescription medications not delivered to the patient;

d. The procedure for assuring confidentiality of patient information; and

e. The procedure for informing the patient and obtaining consent for using such a delivery process.

3. Prescriptions waiting to be picked up by a patient at the alternate site shall be stored in a lockable room or lockable cabinet, cart, or other device that cannot be easily moved and that shall be locked at all times when not in use. Access shall be restricted to the licensed practitioner of the healing arts or the responsible party listed on the application for the controlled substances registration, or either person's designee.

D. The contracts or agreements and the policy and procedure manuals required by this section for alternate delivery shall be maintained both at the originating pharmacy as well as the alternate delivery site.

E. A controlled substances registration as an alternate delivery site shall only be issued to an entity without a prescriber or pharmacist present at all times the site is open if there is a valid patient health or safety reason not to deliver dispensed prescriptions directly to the patient and if compliance with all requirements for security, policies, and procedures can be reasonably assured.

Part XVI
Controlled Substances Registration for Other Persons or Entities

18VAC110-20-685. Definitions for controlled substances registration.

For purposes of this part, the following definitions shall apply:

"CSB" means a community services board facility licensed by the Department of Behavioral Health and Developmental Services that holds a controlled substances registration issued by the board.

"BHA" means a behavioral health authority facility licensed by the Department of Behavioral Health and Developmental Services that holds a controlled substances registration issued by the board.

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

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

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

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

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

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

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

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

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

D. The application shall be signed by a person who will act as a responsible party for the controlled substances. The responsible party may be a prescriber, nurse, pharmacist, or pharmacy technician for alternate delivery sites or other person approved by the board who is authorized to administer ~~or otherwise possess~~ the controlled substances ~~for that type entity~~.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

18VAC110-20-725. Repackaging by a CSB or BHA.

A. Definition. For purposes of this section, "repackaging" shall mean removing a drug from a container already dispensed and labeled by a pharmacy or medical practitioner authorized to dispense, for a particular client of a CSB or BHA, and placing it in a container designed for a person to be able to repackage his own dispensed prescription medications to assist with self-administration and compliance with dosage instructions. Such repackaging shall not include the preparation of a patient-specific label that includes drug name, strength, or directions for use or any other process restricted to a pharmacist or pharmacy technician under the direct supervision of a pharmacist.

B. Persons authorized to repackage. Repackaging shall be performed by a pharmacist, pharmacy technician, nurse, or such other person who has successfully completed a board-approved training program for repackaging of prescription drug orders as authorized in § 54.1-3420.2 of the Code of Virginia. A CSB or BHA using such other person shall maintain documentation of completion of an approved training program for at least one year from date of termination of employment or cessation of repackaging activities.

C. Requirements for repackaging.

1. The repackaging of a dispensed prescription drug order pursuant to § 54.1-3420.2 of the Code of Virginia shall only be done at a CSB or BHA.

2. The repackaging of dispensed prescription drugs shall be restricted to solid oral dosage forms and a maximum of a 14-day supply of drugs.

3. The drug container used for repackaging pursuant to this section shall bear a label containing the client's first and last name, and name and 24-hour contact information for the CSB or BHA.

4. A clean, well-closed container that assists the client with self-administration shall be used when multiple doses of a repackaged drug are provided to the client at one time.

5. A prescription drug order shall not be repackaged beyond the assigned expiration date noted on the prescription label of the dispensed drug, if applicable, or beyond one year from the date the drug was originally dispensed by a pharmacy, whichever date is earlier.

D. Written information for client. At the time a repackaged drug is initially given to a client, and upon any subsequent change in the medication order, the client shall be provided written information about the name and strength of the drug and the directions for use. Such written information shall have been prepared by a pharmacy or by a nurse at the CSB or BHA.

E. Retention, storage, and destruction of repackaged drugs.

1. Any portion of a client's prescription drug order not placed into a container intended to assist with self-administration may be either given to the client or retained by the CSB or BHA for subsequent repackaging. If retained by the CSB or BHA, the remaining portion shall be stored within the board-approved drug storage location in the original labeled container, and shall only be used for the client for whom the drug was originally dispensed.

2. Any portion of a prescription drug order remaining at the CSB or BHA that has exceeded any labeled expiration date or one year from the original pharmacy dispensing date on the label shall be separated from unexpired drugs, stored within a designated area of the board-approved drug storage location, and destroyed within 30 days of expiration with the written agreement of the client. Remaining portions of discontinued prescription drug orders retained by the CSB or BHA shall also be separated from active stock and either returned to the client or destroyed within 30 days of discontinuance with the written agreement of the client.

F. Recordkeeping.

1. A record of repackaging shall be made and maintained for one year from the date of repackaging and shall include the following:

a. Date of repackaging;

b. Name of client;

c. Prescription number of the originally dispensed prescription drug order;

d. Pharmacy name;

e. Drug name and strength;

f. Quantity of drug repackaged; and

g. Initials of the person performing the repackaging and verifying the accuracy of the repackaged drug container.

2. A record of destruction shall be made and maintained for one year for any prescription drug orders destroyed by the CSB or BHA and shall include the following:

a. Date of destruction:

b. Name of client;

c. Prescription number of the originally dispensed prescription drug order;

d. Drug name and strength;

e. Quantity of drug destroyed; and

f. Initials of the person performing the destruction.

18VAC110-20-726. Criteria for approval of repackaging training programs.

A. Application. Any person wishing to apply for approval of a repackaging training program shall submit the application fee prescribed in 18VAC110-20-20 and an application on a form approved by the board and shall meet the criteria established in this section. The application shall name a program director who is responsible for compliance with this section.

B. Curriculum. The curriculum for a repackaging training program shall include instruction in current laws and regulations applicable to a CSB or BHA for the purpose of assisting a client with self-administration pursuant to § 54.1-3420.2 of the Code of Virginia, and in the following repackaging tasks:

1. Selection of an appropriate container;

2. Proper preparation of a container in accordance with instructions for administration;

3. Selection of the drug;

4. Counting of the drug;

5. Repackaging of the drug within the selected container;

6. Maintenance of records;

7. Proper storage of drugs;

8. Translation of medical abbreviations;

9. Review of administration records and prescriber's orders for the purpose of identifying any changes in dosage administration;

10. Reporting and recording the client's failure to take medication;

11. Identification, separation and removal of expired or discontinued drugs; and

12. Prevention and reporting of repackaging errors.

C. Instructors and program director. Instructors for the program shall be either (i) a pharmacist with a current license in any jurisdiction and who is not currently suspended or revoked in any jurisdiction in the United States; or (ii) a pharmacy technician with at least one year of experience performing technician tasks who holds a current registration in Virginia or current PTCB certification and who is not currently suspended or revoked in any jurisdiction in the United States. The program director shall maintain a list of instructors for the program.

D. Program requirements.

1. The length of the program shall be sufficient to prepare a program participant to competently perform repackaging consistent with § 54.1-3420.2 of the Code of Virginia and 18VAC110-20-725.

2. The program shall include a post-training assessment to demonstrate the knowledge and skills necessary for repackaging with safety and accuracy.

3. A program shall provide a certificate of completion to participants who successfully complete the program and provide verification of completion of the program for a participant upon request by a CSB, BHA, or the board.

4. The program shall maintain records of training completion by persons authorized to repackage in accordance with § 54.1-3420.2 of the Code of Virginia. Records shall be retained for two years from date of completion of training or termination of the program.

5. The program shall report within 14 days any substantive change in the program to include a change in program name, program director, name of institution or business if applicable, address, program content, length of program, or location of records.

E. Expiration and renewal of program approval. A repackaging training program approval expires after two years, after which the program may apply for renewal. For continued approval, the program shall submit the renewal application, renewal fee, and a self-evaluation report on a form provided by the board at the time of renewal notification. Renewal of a program's approval is at the discretion of the board, and the decision to renew shall be based on documentation of continued compliance with the criteria set forth in this section.

18VAC110-20-727. Pharmacists repackaging for clients of a CSB or BHA.

As an alternative to repackaging as defined in 18VAC110-20-725, a pharmacist at a CSB or BHA may repackage a client's prescription drugs that have been dispensed by another pharmacy into compliance packaging that complies with the requirements of 18VAC110-20-340 B and subsections G, H, and J of 18VAC110-20-725. A primary provider pharmacy may also provide this service in compliance with the provisions of 18VAC110-20-535.

18VAC110-20-728. Drugs for immediate treatment in crisis stabilization units.

A. In accordance with § 54.1-3423 of the Code of Virginia, a crisis stabilization unit shall apply and obtain a controlled substances registration in order to maintain a stock of Schedule VI controlled substances for immediate treatment of patients in crisis. Schedule II-V controlled substances shall not be stocked. The responsible party listed on the application shall be a nurse who regularly administers controlled substances at the crisis stabilization unit and the supervising practitioner shall be either the medical director for the unit or a pharmacist from a provider pharmacy.

B. In consultation with a provider pharmacist, the medical director for the unit shall determine the list of controlled substances to be stocked at the crisis stabilization unit. The list shall be limited to Schedule VI controlled substances and only those drugs routinely used for treatment of patients admitted for crisis stabilization. Only drugs on this drug list may be stocked.

C. A nurse administering a drug from this stock pursuant to an oral order of a prescriber in accordance with § 54.1-3423 of the Code of Virginia, shall record such order in the patient's medical record.

D. Records.

1. A record shall be maintained of all drugs received as stock by the crisis stabilization unit.

2. A record shall be made documenting administration or other authorized disposition of stocked drugs that includes the following:

a. Name of patient;

b. Date and time of administration;

c. Drug name, strength, and quantity administered;

d. Name or initials of person administering; and

e. Prescriber name.

3. Records shall be maintained at the same location listed on the controlled substances registration or, if maintained in an off-site database, retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent. Any computerized system used to maintain records shall also provide retrieval via computer monitor display or printout of the history for drugs administered during the past two years. It shall also have the capacity of producing a printout of any data which the registrant is responsible for maintaining.

4. Manual records may be maintained as an electronic image that provides an exact image of the document and is clearly legible.

NOTICE: The forms used in administering the above regulation are listed below. Any amended or added form is reflected in the listing and is not being published; however, the name of each form hyperlinks to the actual form. Online users of this issue of the Virginia Register of Regulations may access the form by clicking on the name of the form. The forms are also available for public inspection at the Board of Pharmacy, 9960 Mayland Drive, Suite 300, Richmond, VA 23233-1463, or at the Office of the Registrar of Regulations, General Assembly Building, 2nd Floor, Richmond, Virginia 23219.

FORMS (18VAC110-20)

Application for Registration as a Pharmacy Intern (rev. 8/07).

Affidavit of Practical Experience, Pharmacy Intern (rev. 8/07).

Application for Licensure as a Pharmacist by Examination (rev. 11/09).

Application to Reinstate or Reactivate a Pharmacist License (rev. 3/10).

Application for Approval of a Continuing Education Program (rev. 8/07).

Application for Approval of ACPE Pharmacy School Course(s) for Continuing Education Credit (rev. 6/09).

Application for License to Dispense Drugs (rev. 8/07).

Application for a Pharmacy Permit (rev. 6/10).

Application for a Nonresident Pharmacy Registration (rev. 7/08).

Application for a Permit as a Medical Equipment Supplier (rev. 3/09).

Application for a Controlled Substances Registration Certificate (rev. 4/09).

Application for Registration as a Pharmacy Intern for Graduates of a Foreign College of Pharmacy (rev. 8/07).

Closing of a Pharmacy (rev. 8/07).

Application for Approval of a Robotic Pharmacy System (rev. 8/07).

Application for Approval of an Innovative (Pilot) Program (rev. 8/07).

Pharmacy Technician Registration Instructions and Application (rev. 3/09).

Application to Reinstate a Pharmacy Technician Registration (rev. 3/10).

Application for Approval of a Pharmacy Technician Training Program (rev. 8/07).

Application for Registration for Volunteer Practice (rev. 8/07).

Sponsor Certification for Volunteer Registration (rev. 8/08).

Application for Reinstatement of Registration as a Pharmacy Intern (eff. 9/07).

Affidavit for Limited-Use Pharmacy Technician (rev. 8/07).

Limited-Use Pharmacy Technician Registration Instructions and Application (rev. 7/08).

Registration for a Pharmacy to be a Collection Site for Donated Drugs (eff. 4/09).

Application for Approval of Repackaging Training Program (eff. 12/10).

VA.R. Doc. No. R11-2366; Filed December 14, 2010, 11:20 a.m.

TITLE 24. TRANSPORTATION AND MOTOR VEHICLES

DEPARTMENT OF MOTOR VEHICLES

Final Regulation

REGISTRAR'S NOTICE: The Department of Motor Vehicles is claiming an exemption from Article 2 (§ 2.2-4006 et seq.) of the Administrative Process Act pursuant to § 2.2-4007.2 of the Code of Virginia. Section 2.2-4007.2 provides that if an

agency chooses to amend a regulation to provide the alternative of submitting required documents or payments by electronic means, such action shall be exempt from the operation of Article 2 provided the amended regulation is (i) adopted by December 31, 2010, and (ii) consistent with federal and state law and regulations.

Title of Regulation: **24VAC20-60. Virginia Commercial Driver's License Regulations (amending 24VAC20-60-120, 24VAC20-60-160, 24VAC20-60-180).**

Statutory Authority: §§ 46.2-203 and 46.2-341.5 of the Code of Virginia.

Effective Date: February 2, 2011.

Agency Contact: Ron Thompson, Senior Policy Analyst, Department of Motor Vehicles, 2300 West Broad Street, Richmond, VA 23269, telephone (804) 367-1844, FAX (804) 367-4336, TTY (800) 272-9268, or email ronald.thompson@dmv.virginia.gov.

Summary:

The amendments facilitate electronic submissions to the Department of Motor Vehicles by providing flexibility to the department for receiving information from third party testers and examiners. The new broad language is intended to allow the department to work in close consultation and partnership with commercial driver training schools to develop and utilize the electronic filing technologies that best address the needs and requirements of the department and these entities.

24VAC20-60-120. Application for certification by the department.

A. Application for third party tester certification.

1. An applicant for certification shall provide the following information ~~upon a form provided~~ in a format prescribed by the department:

a. Name and address and telephone number of principal office or headquarters;

b. Name, title, address and telephone number of an individual in Virginia who has been designated to be the applicant's contact person with the department;

c. Description of the vehicle fleet owned or leased by the applicant, including the number of commercial motor vehicles by class and type;

d. Classes and types of commercial motor vehicles for which the applicant seeks to be certified as a third party tester;

e. Total number of Virginia licensed drivers employed during the preceding 12 months to operate commercial motor vehicles, and the number of such drivers who are full time, part-time and seasonal;

f. Name, driver's license number and home address of each employee who is to be certified as a third party examiner. If any employee has previously been certified as an examiner by the department, the examiner's certification number;

g. The address of each Virginia location where the third party tester intends to conduct skills tests, and a map, drawing or written description of each driving course which satisfies the department's requirements for a skills test course;

h. If the applicant is not a governmental entity, it shall also provide:

(1) A description of the applicant's business and length of time in business in Virginia;

(2) If subject to the FMCSRs, the applicant's Interstate Commerce Commission number or the applicant's federal Department of Transportation number and rating; and

(3) Applicant's State Corporation Commission number; and

i. Any other relevant information required by the department.

2. An applicant for certification shall also execute an agreement ~~form provided~~ in a format prescribed by the department in which the applicant agrees, at a minimum, to comply with the regulations and instructions of the department for third party testers, including audit procedures, and agrees to hold the department harmless from liability resulting from the third party tester's administration of its CDL skills test program.

B. Application for third party examiner certification.

1. An applicant for certification shall provide the following information ~~on a form provided~~ in a format prescribed by the department:

a. Name and home and business addresses and telephone numbers;

b. Driver's license number;

c. Name, address, and telephone number of the principal office or headquarters of the applicant's employer, who has applied for and received certification as a third party tester;

d. Job title and description of duties and responsibilities;

e. Length of time employed by present employer. If less than two years, list previous employer, address and telephone number;

f. Present employer's recommendation of the applicant for certification;

g. A list of the classes and types of vehicles for which the applicant seeks certification to conduct skills tests; and

h. Any other relevant information required by the department.

C. Evaluation of applicants by the department.

1. The department will evaluate the materials submitted by the third party tester applicant, and, if the application materials are satisfactory, the department will schedule an on-site inspection and audit of the applicant's third party testing program to complete the evaluation.

2. The department will evaluate the materials submitted by the third party examiner applicant as well as the applicant's driving record. If the application materials and driving record are satisfactory, the department will schedule the applicant for third party examiner training. Training may be waived if the applicant is seeking recertification only because he has changed employers.

3. No more than two applications will be accepted from any one third party tester or examiner applicant in any 12-month period, excluding applications for recertification because of a change in employers.

24VAC20-60-160. Notification requirements.

A. Every third party tester must:

1. Notify the department ~~in writing~~ in a format prescribed by the department within 10 days of any change in:

a. The third party tester's name or address; or

b. The third party examiners who are employed by the third party tester.

2. Notify the department ~~in writing~~ in a format prescribed by the department within 10 days of any of the following occurrences:

a. The third party tester ceases business operations in Virginia;

b. The third party tester fails to comply with any of the requirements set forth in this chapter; or

c. Any third party examiner fails to comply with any of the requirements set forth in this chapter.

3. Notify the department of any proposed change in the skills test route at least 30 days before the third party tester plans to change the route.

B. Every third party examiner shall notify the department within 10 days after leaving the employ of the third party tester, of his change in employment.

24VAC20-60-180. The skills test certificate.

A. The department will accept a skills test certificate issued in accordance with this section as satisfaction of the skills test component of the CDL examination.

B. Skills test certificates may be issued only to drivers who are employees of the third party tester who issues the certificate, except as otherwise provided herein. In the case of school boards certified as third party testers, certificates may be issued to employees and to other drivers who have been trained by the school board in accordance with the Virginia School Bus Driver Training Curriculum Guide.

C. Skills test certificates may be issued only to drivers who have passed the skills test conducted in accordance with this chapter and the instructions issued by the department.

D. A skills test certificate will be accepted by the department only if it is:

1. Issued by a third party tester certified by the department in accordance with this chapter;

2. ~~On a valid skills test certificate form provided~~ In a format prescribed by the department, completed in its entirety, without alteration;

3. Submitted to the department within 60 days of the date of the skills test; and

4. Signed by the third party examiner who conducted the skills test.

FORMS (24VAC20-60) (Repealed.)

~~Certificate of Completion Commercial Driver's License Skills Test, S-000001.~~

VA.R. Doc. No. R11-2654; Filed December 13, 2010, 3:00 p.m.

Final Regulation

REGISTRAR'S NOTICE: The Department of Motor Vehicles is claiming an exemption from Article 2 (§ 2.2-4006 et seq.) of the Administrative Process Act pursuant to § 2.2-4007.2 of the Code of Virginia. Section 2.2-4007.2 provides that if an agency chooses to amend a regulation to provide the alternative of submitting required documents or payments by electronic means, such action shall be exempt from the operation of Article 2 provided the amended regulation is (i) adopted by December 31, 2010, and (ii) consistent with federal and state law and regulations.

Title of Regulation: **24VAC20-121. Virginia Driver Training Schools Regulations (amending 24VAC20-121-20, 24VAC20-121-30, 24VAC20-121-60, 24VAC20-121-70, 24VAC20-121-90, 24VAC20-121-100, 24VAC20-121-130, 24VAC20-121-170, 24VAC20-121-180, 24VAC20-121-190, 24VAC20-121-200, 24VAC20-121-220).**

Statutory Authority: §§ 46.2-203 and 46.2-1703 of the Code of Virginia.

Effective Date: February 2, 2011.

Agency Contact: Ron Thompson, Senior Policy Analyst, Department of Motor Vehicles, 2300 West Broad Street, Richmond, VA 23269, telephone (804) 367-1844, FAX (804) 367-4336, TTY (800) 272-9268, or email ronald.thompson@dmv.virginia.gov.

Summary:

The amendments facilitate electronic submissions to the Department of Motor Vehicles by providing flexibility to the department for receiving information. The new broad language is intended to allow the department to work in close consultation and partnership with commercial driver training schools to develop and utilize the electronic filing technologies that best address the needs and requirements of the department and these entities.

24VAC20-121-20. Business office and classroom requirements.

A. No school license shall be issued unless the school has an established place of business in the Commonwealth that is owned, rented or leased by the school. Such established place of business shall:

1. Be the premises of the licensed location of the school;

2. Satisfy all local business licensing and zoning regulations;

3. Have office space devoted exclusively to the driver training school;

4. Contain all records that are required to be maintained under the provisions of these regulations unless the school has been permitted to maintain them elsewhere pursuant to 24VAC20-121-40;

5. Be equipped with a desk, chairs, filing space, working utilities and a working telephone listed in the name of the school;

6. Comply with federal, state and local health, fire and building code requirements, including the Americans with Disabilities Act (42 USC § 12101 et seq.);

7. Be open to the general public a minimum of eight hours per week during normal business hours; and

8. Not share space with a school classroom.

The school shall also provide to the department the street address and physical address of any other business offices maintained by the school in addition to the licensed location office.

In addition to business office addresses, all addresses, physical locations of classrooms, driving simulators or any other facilities used by the school shall be provided to the department in ~~writing~~ a format prescribed by the department. If any such classroom, driving simulator or other facility is not owned by the school, then a copy of all agreements associated with the use of such property by the school shall be provided to the department. Schools shall not use classrooms, driving simulators or other driver training facilities prior to receiving approval for their use from the department.

A school owner's residence may be used as the licensed location of a school if it qualifies for a federal tax deduction of expenses related to the business use of part of the residence and meets the established place of business requirements set forth in these regulations.

B. Any school that engages in classroom instruction shall provide a classroom with the following:

1. Seating arrangements and writing surfaces for each student and a minimum of 10 square feet per student attending at any given time;

2. Blackboards or other visual aids that shall be visible from all seating positions;

3. Driver education reference books, including, when applicable, current curriculum guides, student work books and appropriate textbooks for each student;

4. Appropriate audio/video equipment and screen in good working order; and

5. Restroom facilities that are clean, accessible and in good working order.

C. Office and instruction hours shall be posted in a conspicuous location outside the licensed location and any other business office in a manner that is visible and easily accessible to the public from outside of the licensed location and business.

D. The school license and any notice of the department that limits or restricts training shall be prominently posted at the licensed location office. A copy of the school license and notice, if applicable, also shall be prominently posted in each school classroom and any other business office maintained by the school.

In addition, schools shall display, in a conspicuous location in all their classrooms and their business offices, signs provided by the department that notify students and the public about the department's toll-free hotline.

E. Any school licensed by the department shall notify the department, in ~~writing~~ a format prescribed by the department, 30 days prior to a change of address for the licensed location, any other business office or classroom or other instructional facility. The department will issue a revised license reflecting such changes. The school shall return the current license to the department upon receipt of a revised school license. All school-related business, classroom and instructional locations are subject to approval by the department, as required in these regulations.

F. The location of a school's licensed location, other business offices, classrooms or practice driver training areas shall be a distance of at least 1,500 feet from any property owned, leased or maintained by the department for examining motor vehicle operators. Such distance shall be measured in a straight line from the nearest point of the primary building of the department's property to the nearest point of the school licensed location, business office, classroom or practice driver training area, whichever is closest. This distance requirement may be waived by the department if the licensed location, other business office, classroom or practice driver training area has been previously allowed to be within the 1,500 foot limit as a result of an action or omission on the part of the department. All school-related business, classroom or instructional locations must be approved by the department prior to use.

24VAC20-121-30. Business practices.

A. A school shall not use any name other than that shown on its school license. Schools using the same or similar name of another current or former school or similar business, or using names considered to be offensive in nature, as determined by the department, shall not be licensed by the department.

B. A school that utilizes "Department of Motor Vehicles" or "DMV" in any form of advertising including, but not limited to, telephone directories and websites shall use only the words "Licensed by the Department of Motor Vehicles (DMV) of the Commonwealth of Virginia." A school shall not refer to any other state agency or board in any documentation or advertisement. Schools with web sites shall notify the department of their web addresses when applying for or renewing their license or when the site becomes operational, whichever is sooner.

C. A school shall not use false, deceptive or misleading information in any advertisement or provide this type of information to prospective students.

D. A school, instructor, owner or any other person employed by or otherwise associated with a school shall not:

1. Assert or imply that it will guarantee that any student will pass the state driver's license examination;

2. Assert or imply that the student can secure a driver's license;

3. Assert or imply that the student will be guaranteed employment upon completion of any course of instruction;

4. Transact or solicit driver training school business on property owned, leased or maintained by the department;

5. Provide translation services for any individual who is taking the department's driver's license knowledge examination;

6. Falsify forms, certificates or other documents for use by students or other individuals in order to obtain a driver's license;

7. Possess, use, provide, sell or give the department's driver licensing test questions to students or other individuals;

8. Assist or facilitate the creation of false identification documents of any kind or false residency certification for any individual;

9. Provide instruction at a site not formally approved by the department;

10. Contract or subcontract, without written approval of the parents or legal guardians, with other driver training schools or driver training organizations to provide classroom or in-vehicle instruction for students under 18 years of age who are not married or emancipated;

11. Have, use, keep or be under the influence of alcohol, illegal drugs or substances, or otherwise legal drugs or substances that would affect a person's ability to drive or provide or receive instruction while such person is on the premises of or in vehicles used by the school; or

12. Conduct themselves in a manner not suitable or compatible with school-related activities. Such prohibited conduct includes, but is not limited to:

a. Touching in a manner that would be considered inappropriate by a reasonable person;

b. Telling jokes or making statements or comments that a reasonable person would consider (i) to be hateful or demeaning to a particular race or ethnicity, or (ii) to have sexual or otherwise vulgar content or connotation;

c. Displaying objects or materials that a reasonable person would consider unpleasant, distasteful, nasty, disgusting, hateful or otherwise unsuitable;

d. Berating or otherwise harassing students or other persons;

e. Running errands;

f. Except for emergency situations, using telecommunications or any other audio or video equipment during periods of in-vehicle or classroom instruction that are not part of the course of instruction. If an emergency situation occurs during in-vehicle instruction, such use should, whenever possible, be made once the vehicle is safely off the road and stopped;

g. Eating during periods of instruction;

h. Use of tobacco products during periods of instruction;

i. Creating a training environment considered hostile or otherwise intimidating to a reasonable person; or

j. Allowing any student to engage in such prohibited conduct outlined above.

E. Except when full tuition has not been satisfied, a school shall provide, within five business days of the successful completion of program requirements and in a manner prescribed by the department, ~~an original~~ the certificate of completion needed by the student (i) to obtain a driver's license, (ii) for insurance verification purposes, or (iii) for employment purposes. No fee shall be charged by the school for the original certificate.

F. Schools shall operate in accordance with the driver training school operations manual as provided and updated by the department.

G. No school vehicles shall park on the department's owned, leased or maintained property except for the purposes of conducting official business with the department during normal business hours. At no time whatsoever shall a school provide training to a student on the department's owned, leased or maintained property.

24VAC20-121-60. School licensing requirements.

A. Schools seeking a license shall file with the department, as required by these regulations, a completed application for a driver training school license along with any associated fees and other documentation required by the department. In addition, each school shall collect and submit to the department, as required by these regulations, the instructor applications for those instructors that they employ along with any associated fees and other documentation required by the department.

B. The following shall accompany the school licensing application and shall be in addition to any other application requirements of the department:

1. An application fee;

2. A certificate of insurance;

3. A surety bond;

4. Instructor applications;

5. A local business license or zoning document, or a letter from local authorities indicating none is required; and

6. A national criminal records check completed within 60 days of the application deadline for each individual providing instruction or otherwise employed by or managing the school.

In addition. each owner or principal of the owner of a driver training school shall submit a national criminal records check with the school license application package.

C. The application package shall be submitted to the department ~~at the address shown on the application~~ in a format prescribed by the department. All proper applications will be either approved or denied within 30 business days of receipt by the department.

D. School licenses shall be valid for a period of 12 months and shall display the validity period on the face of the license. The school license shall expire on the last day of the last valid month of the license period.

E. Schools seeking a license shall file with the department evidence of insurance, with a company authorized to do business in the Commonwealth of Virginia, on all vehicles used by schools to provide instruction, at least in the minimum amounts as required by § 46.2-472 of the Code of Virginia.

The school shall provide and maintain evidence of insurance coverage on a certificate of insurance ~~form provided~~ in a format prescribed by the department. The certificate shall be filed upon application and at other times of the licensure period as requested by the department. The certificate shall stipulate the make, model, year, vehicle identification number, vehicle color and license plate number for all vehicles and shall also stipulate that the department will be notified by the insurance carrier (i) 10 calendar days before the school's insurance policy expires or (ii) on the same day that the policy is canceled or not maintained in full force.

Schools shall provide to the department ~~written~~ verification from their insurance company in a format prescribed by the department that the insurance company is aware the vehicles are used for driver training instruction and are operated by student drivers. Schools shall notify the department ~~in writing~~ of any change in liability insurance coverage not later than the effective date of the change.

Each school shall provide ~~written~~ notice to the department's driver training school section in a format prescribed by the department in the event that any motor vehicle is added to or deleted from the insurance policy during the coverage period. The notice shall include the make, model, year, vehicle identification number, vehicle color and the license plate number. The notice shall be received by the department prior to using any added motor vehicle for driver education instruction. Failure to maintain required liability insurance for school vehicles or failure to comply with insurance certification requirements shall result in the suspension or revocation of the school's license or the imposition of other sanctions, or both, as set forth in these regulations.

F. All licensed schools shall file with the department a surety bond in the sum set by statute for Class A and Class B schools, payable to the Commonwealth of Virginia, issued by a corporation licensed to transact surety business in the Commonwealth. The surety bond shall be filed with each application and must provide coverage for the entire licensure period.

G. The department may refuse to approve any application, including originals or renewals, in which the owner or any

principal of the owner, or any of the school's employees or instructors (i) have previously been or would be subject to any sanctions prescribed by these regulations or (ii) has been convicted of a felony, including but not limited to bribery, forgery, fraud or embezzlement under the laws of the Commonwealth or any other jurisdiction, or a conviction of any offense included in Article 7 (§ 18.2-61 et seq.) of Chapter 4 of Title 18.2 of the Code of Virginia (Criminal Sexual Assault) or of any similar laws of any other jurisdiction, or any misdemeanor or felony involving:

1. Sexual assault as established in Article 7 (§ 18.2-61 et seq.) of Chapter 4 of Title 18.2 of the Code of Virginia;

2. Obscenity and related offenses as established in Article 5 (§ 18.2-372 et seq.) of Chapter 8 of Title 18.2 of the Code of Virginia;

3. Drugs as established in Article 1 (§ 18.2-247 et seq.) of Chapter 7 of Title 18.2 of the Code of Virginia;

4. Crimes of moral turpitude;

5. Contributing to the delinquency of a minor;

6. Taking indecent liberties with a minor;

7. The physical or sexual abuse or neglect of a child;

8. Similar offenses in other jurisdictions; or

9. Other offenses, as determined by the department, which would impact ownership, operation or instruction by a school.

Any school license issued may be suspended or revoked if such a conviction occurs during any licensure period.

H. To avoid any conflict of interest, the department will not approve any Class A school license for any applicant that is certified by DMV as a Third Party Tester for the commercial driver's license (CDL) skills testing.

I. Requests to change (i) the name or address of a school or (ii) a school license to add to or eliminate a licensed location, or any other business offices, classrooms or other instructional facilities during the licensure period shall be made to the department at least 30 days prior to such change. Such changes shall be subject to a processing fee, as set forth in these regulations, and the issuance of a modified license, as requested. The expiration on any modified license issued shall be the same as the current license.

24VAC20-121-70. School license renewal required.

A. Every licensed school applying for renewal shall return the following to the department ~~at the address shown on the application~~ in a format prescribed by the department on or before the 15th day of the month in which the current license expires:

1. A renewal application;

2. A certificate of insurance, as required under these regulations;

3. A photocopy of a current business license, if required by the locality, or a letter from the locality that indicates no business license is required;

4. National criminal records checks completed within 60 days of the application deadline for each individual providing instruction or otherwise employed by or managing the school, as required by these regulations; and

5. A fee for each license renewal application, as set forth in these regulations.

If the original surety bond is no longer in force, a new surety bond must also accompany the renewal application.

B. The department will make every effort to mail a renewal notice to the licensee outlining the procedures for renewal at least 90 days prior to the expiration of their license and to mail a follow-up reminder notice 45 days prior to the expiration of their license. Failure to receive these notices shall not relieve the licensee of the obligation to apply if a continuation of the license is desired.

24VAC20-121-90. School contracts.

A. All contracts between any school and any individual or group attending the school shall be in a standard format approved by the department. A school shall not make any changes to the format without review and approval by the department. A copy of the signed contract must be provided to each student who signs the contract for those students 18 years of age or older and those students under 18 years of age who are either married or emancipated. For students under 18 years of age who are not married or emancipated, a copy of the signed contract must be provided to the parents or legal guardians who sign the contract.

Excluding transcripts and certificates of completion, all written correspondence from schools to current or former students and their parents or legal guardians related in any way to course work or the contract between the school and the student shall include standard information about the department's toll-free telephone hotline. The department shall specify to the schools, as part of the school license application package, the content and the font requirements for this hotline information.

Schools may not include any statements in their contracts that place the financial responsibility for accidents occurring in school-owned vehicles during periods of instruction on the student or on the parents or legal guardians of students operating the vehicles.

B. The required elements for all contracts between schools and their independent contractors shall be provided by the department as part of the school license application package.

C. Addenda to any contracts between a school and its students or a school and its independent contractors shall be approved by the department.

D. Licensed driver training schools may conduct training courses at public or private schools, subject to existing statutory and regulatory requirements. Driver training schools offering such training shall provide the department, in a format prescribed by the department, with a copy of the ~~written~~ contract between the driver training school and the public or private school along with ~~written~~ confirmation as to which portion of the training, if any, is being conducted at the public or private school.

24VAC20-121-100. General instructor licensing requirements.

A. Individuals seeking an instructor's license shall submit, as required by these regulations, a completed application along with any associated fees and other appropriate documentation to the school with which they are employed. Schools shall be responsible for submitting the instructor applications, along with any associated fees and other appropriate documentation, to the department, as required by these regulations. Applicants seeking an original or a renewal of an instructor's license shall submit with their application a national criminal records check completed within 60 days of the submission date of the application.

B. Applicants must be at least 21 years of age and must be able to document with driving records at least five years of licensed driving experience, two years of which shall be experience in the United States or a territory thereof. These driving records must exhibit the individual's name, the driver's license number, the date of issue, the issuing jurisdiction, the date of expiration and notations of any convictions, license withdrawals, suspensions, revocations, cancellations, disqualifications or restrictions. In the event an applicant uses driving records from a foreign country to substantiate licensed driving experience, such records must be translated into English by an appropriate authority, as approved by the department, at the applicant's expense.

C. Individuals seeking an instructor's license must be employed by a licensed school. No instructor shall be employed by more than one school unless all the schools are owned by the same person. Instructors employed by more than one school shall have an application and other appropriate documentation and fees submitted to the department by each school that employs them.

D. Individuals licensed as instructors or seeking an instructor's license must be able to effectively communicate in English in an easily understood and comprehensible manner to their students and the department, as determined by the department.

E. Individuals seeking an instructor's license to teach in-vehicle instruction shall hold a valid driver's license from their state of domicile at the time of licensing and throughout the entire licensure period. If such driver's licenses are from another state or jurisdiction, the applicant must provide to the department a copy of their driving record from that jurisdiction with their application and every three months thereafter if they receive an instructor's license. Such driving record must be produced within 30 days of its submission to the department.

All applicants for a license to teach in-vehicle instruction and those persons who are currently licensed to teach in-vehicle instruction must also provide ~~written~~ notice to the department, in a format prescribed by the department, of any traffic accidents, convictions of traffic infractions, misdemeanors, or felonies, as well as any administrative actions relating to driving or any driver's license revocation, suspension, cancellation, disqualification or other loss of driving privileges within 15 calendar days of the conviction or administrative action, or within 15 calendar days of the imposition of the revocation, suspension, cancellation, disqualification or other loss of driving privileges.

Applicants for a license to teach in-vehicle instruction shall not be approved if their current driving privileges are expired, suspended, revoked, cancelled or disqualified. Persons required to submit to periodic medical reviews may also be denied an in-vehicle instructor's license if, as determined by the department, their conditions are considered to pose a threat to the safety, health or welfare of driver training students or the public while these persons operate a motor vehicle.

F. Individuals who obtain an instructor's license shall at the time of licensing have a driving record with no more than six demerit points. After licensing, instructors shall maintain a driving record with no more than six demerit points. If during the licensure period the driving record of such individual accumulates more than six demerit points based on violations occurring in a 12-month period, the department shall suspend the person's instructor license and shall notify the instructor and the driver training school where the instructor is employed of such suspension. Safe driving points shall not be used to reduce the accumulated demerit points. In the event that the driving record is from another state, the department will apply Virginia's equivalent demerit points to convictions noted on such record.

Whenever the driver's license of such individual is suspended or revoked, or such person is convicted in any court of reckless driving, driving under the influence or driving while intoxicated, the department shall suspend the person's instructor license and shall notify the person and the driver training school where the instructor is employed of the suspension.

G. The department may refuse to approve any application, including originals or renewals, in which the applicant has been convicted of a felony, including but not limited to

bribery, forgery, fraud or embezzlement under the laws of the Commonwealth or any other jurisdiction, or a conviction of any offense included in Article 7 (§ 18.2-61 et seq.) of Chapter 4 of Title 18.2 of the Code of Virginia (Criminal Sexual Assault) or of any similar laws of any other jurisdiction, or any misdemeanor or felony conviction involving:

1. Sexual assault as established in Article 7 (§ 18.2-61 et seq.) of Chapter 4 of Title 18.2 of the Code of Virginia;

2. Obscenity and related offenses as established in Article 5 (§ 18.2-372 et seq.) of Chapter 8 of Title 18.2 of the Code of Virginia;

3. Drugs as established in Article 1 (§ 18.2-247 et seq.) of Chapter 7 of Title 18.2 of the Code of Virginia;

4. Crimes of moral turpitude;

5. Contributing to the delinquency of a minor;

6. Taking indecent liberties with a minor;

7. The physical or sexual abuse or neglect of a child;

8. Similar offenses in other jurisdictions; or

9. Other offenses, as determined by the department, which would indicate that the applicant may present a danger to the safety of students or the public.

Instructor licenses may be suspended or revoked if a conviction for any of the offenses outlined in this subsection occurs during any licensure period.

H. Instructor applicants shall not be issued a license if they have a conviction of driving under the influence, reckless driving, refusal to submit to a breath or blood test under § 18.2-268.2 of the Code of Virginia, or vehicular or involuntary manslaughter, or of any similar offense from any other jurisdiction within a period of five years prior to the date of the application. If the applicant's driving privileges were revoked for any such conviction, then the five-year period shall be measured from the license restoration date rather than the conviction date. Instructor licenses issued shall be revoked if a conviction, as outlined in this subsection, occurs during the licensure period.

I. Except as otherwise provided in these regulations, an individual seeking an instructor's license shall have at least a high school diploma or equivalent. After initial licensure or renewal, instructors shall attend annual training sessions provided by the department. These one-day training sessions shall be held in each of the department's regional districts every year, as deemed necessary by the department.

These sessions shall include, as appropriate and necessary, updates on department forms, audit processes and other procedural changes, and new legislation that has implications for driver training. They also shall include discussions about any issues or concerns raised by either the department or the licensees.

When available, these sessions shall also offer information about the latest in driver training instructional techniques as well as other new developments in driver training in order to enhance overall professional training skills and abilities.

The schedule for such training sessions shall be developed by the department and provided to each instructor through the school that employs them at least 30 days in advance of the scheduled sessions. The schedule also shall include provisions for a make-up training session for those licensees who could not attend the training session in their region. Attendance shall be mandatory and shall be at no cost to licensed instructors, other than those costs associated with travel to and from the training session, including lodging and meals.

Each licensed instructor who, without valid excuse, fails to attend and complete a scheduled training session or a scheduled make-up training session shall be subject to a minimum 30-day license suspension, which shall not be lifted until the instructor has completed a special make-up training session. Special make-up training sessions shall be provided only when necessary, and instructors attending such sessions will be required to pay the department's cost for providing the special make-up training session.

J. All instructors shall complete training on the current curriculum and other course work, as required and approved by the department, prior to instructing students. Evidence of such training shall be maintained by the school employing the instructor and provided to the department upon request.

K. The fee for an instructor license shall be set pursuant to these regulations. The instructor's license period shall expire when the respective school license expires. At the discretion of the department, instructor licensing fees may be prorated on a monthly basis.

L. The instructor license application package shall be submitted by the school employing the instructor to the department ~~at the address shown on the application~~ in a format prescribed by the department. All proper applications will be either approved or denied by the department within 30 business days of receipt from the school employing the instructor.

M. All licensed instructors shall have their instructor's license in their possession at all times while providing instruction.

N. Each instructor licensed by the department shall notify the department in ~~writing~~ a format prescribed by the department within 30 days of establishing a new residential address.

O. In the event that a school licensed by the department changes its name or address, the school shall, no later than 30

days prior to such change (i) notify the department of the school's name or address change, (ii) request revised instructor's licenses for the instructors it employs reflecting the change and (iii) submit to the department the processing fees set forth in these regulations for revising and reissuing an instructor's license for each of its instructors.

After receiving the processing fees, the department will revise and reissue the instructor's licenses, as requested, and will cancel the previously issued licenses. Once it receives the revised licenses from the department, the school shall return the cancelled instructor's licenses to the department.

24VAC20-121-130. Notice required to the department.

A. Each school shall notify the department in ~~writing~~ a format prescribed by the department no later than 15 calendar days after the termination of employment of any licensed instructor. The school shall make every reasonable attempt to return to the department the instructor's license.

B. In the event of cessation of business, the school shall submit to the department, within 15 calendar days of such date, a ~~written~~ statement in a format prescribed by the department indicating the business is closing, and forward to the department within 30 calendar days after cessation of business the school license, all instructors' licenses, all student records and any materials furnished to the school by the department. The department will retain such records for a period of three years from the date they are received to ensure such records are available to students and other persons or entities who may want or need access to them.

C. All schools shall notify the department of any proposed structural or other modifications to an existing school, classroom or driving range 30 days prior to initiating such modifications.

D. In the event a school files for bankruptcy, the school shall submit to the department, within 15 calendar days of such filing and in a manner prescribed by the department, a ~~written~~ statement indicating among other things (i) the financial status of the business, and (ii) the anticipated impact of the bankruptcy on the Commonwealth and the school's former, current and future students, if any.

Part II
Specific Requirements Related to Class A Licensure

24VAC20-121-170. Curriculum requirements for Class A licensed schools.

Course curriculum requirements will be established and made available by the department to Class A licensed schools, Class A license applicants and the public. A course curriculum meeting the established requirements must be submitted to the department at the time of Class A license application or renewal application, and must be approved by the department prior to the beginning of course instruction.

The department shall provide and update the list of course curriculum requirements from time to time, as deemed appropriate and necessary by the department, in consultation with all affected schools that are licensed by the department at the time of the update and other interested parties as identified by the department.

The department shall notify the affected schools when and if new relevant topics are added to the course curriculum. Schools shall have 45 calendar days after such notice is issued to update their course curriculum and to certify to the department in ~~writing~~ a format prescribed by the department that the school has added the new topics to the course curriculum.

24VAC20-121-180. Class A instructor license requirements.

A. Applicants for a Class A instructor's license shall possess a valid Virginia nonrestricted interstate commercial driver's license, with the appropriate vehicle classes and endorsements for the type of instruction they intend to provide, and that has been held by the applicant for at least three years.

Applicants for a Class A instructor's license who do not have a high school diploma may nevertheless be licensed if they provide ~~written~~ evidence in a format prescribed by the department that they (i) have at least one year of previous Class A instructing experience or (ii) have successfully completed a Class A driver training course and a minimum of 160 hours of Class A instructor training provided by the hiring school.

Instructor applicants shall provide with their applications certifications that they meet the physical requirements, and any alcohol and drug screening requirements for commercial drivers as specified in the federal motor carrier safety regulations. A copy of such certification shall be kept in the instructor's file maintained by the driver training school employing the instructor.

If applicants for a Class A instructor's license hold a valid commercial driver's license (CDL) from a state other than Virginia at the time of licensing, they shall maintain a valid CDL throughout the entire licensure period and shall provide to the department a copy of their driving record from that other state or states upon application and, if licensed as a Class A instructor by the department, on a quarterly basis thereafter.

Those applicants for and holders of a Class A instructor's license shall also provide ~~written~~ notice to the department in a format prescribed by the department of any conviction of traffic infractions, misdemeanors, or felonies, any administrative actions relating to driving or any driver's license revocation, suspension, cancellation, disqualification or other loss of driving privilege within 15 calendar days of the conviction or administrative action, or within 15 calendar

days of the imposition of the revocation, suspension, cancellation, disqualification or other loss of driving privilege.

B. Instructors shall complete in-service instructor training provided by the school prior to offering student instruction. The requirements of such in-service instructor training shall be established and made available to licensed Class A schools by the department and shall include, but not be limited to, the following topic areas:

1. Basic instructional skills;

2. Student teaching with a mentor;

3. Background in federal, state and local laws and ordinances;

4. Basic skills for operating commercial motor vehicles;

5. Safe operating practices;

6. Maintenance of commercial motor vehicles; and

7. Safe trip planning.

24VAC20-121-190. Equipment requirements for Class A licensed schools; use of driving ranges.

A. All vehicles used for driver education or testing purposes shall be marked by signs affixed to the sides and the rear of the vehicle, in bold letters not less than four inches in height, clearly visible from 100 feet, stating one of the following: "Student Driver," "Learner," "New Driver," "Driver Education" or "Caution-Student."

All vehicles used by a school shall display the name of the school, as shown on the school license, on the outside of the vehicle when engaged in driver education or when the vehicle is being used for testing purposes. The name of the school shall be included on the signs affixed to the sides of the vehicle.

B. The cabs of such vehicles shall be designed to have safety belts for each individual. No more than four students and one instructor shall occupy the cab during periods of instruction.

C. No motor vehicle may be used for driver education unless it displays a valid safety inspection sticker or federal Motor Carrier Safety Administration inspection sticker. In addition to other equipment required by law, each vehicle used for driver education shall have dual-braking capability.

D. Any and all agreements associated with driving ranges used by the school shall be provided to the department in ~~writing~~ a format prescribed by the department. Schools shall not use driving ranges prior to receiving approval for their use from the department.

Part III
Specific Requirements Related to Class B Licensure

24VAC20-121-200. Curriculum requirements for Class B licensed schools.

A. Except as otherwise provided in this subsection, course curriculum shall comply with the provisions of the "Curriculum and Administrative Guide for Driver Education in Virginia" (2001) published by the Virginia Department of Education (or any successor publication so published) and these regulations. A copy of the current guide may be obtained from the Virginia Department of Education at the following Internet link: http://www.doe.virginia.gov/VDOE/Instruction/PE/ca_guide.html

Course curriculum requirements other than those set forth in the "Curriculum and Administrative Guide for Driver Education in Virginia" (2001) may be established by the department. Once established, such requirements shall be made available by the department to Class B licensed schools, Class B license applicants and the public. A course curriculum meeting the established requirements must be submitted to the department at the time of Class B license application or renewal application, and must be approved by the department prior to the beginning of course instruction as provided in and in accordance with § 46.2-1702 of the Code of Virginia.

B. The department shall provide and update the list of course curriculum requirements from time to time, as deemed appropriate and necessary by the department, in consultation with all affected schools that are licensed by the department at the time of the update and other interested parties as identified by the department.

The department shall notify the affected schools when and if new relevant topics are added to the course curriculum. Schools shall have 45 calendar days after such notice is issued to update their course curriculum and to certify to the department in ~~writing~~ a format prescribed by the department that the school has added the new topics to the course curriculum.

C. The length of daily instruction shall comply with the provisions of the "Curriculum and Administrative Guide for Driver Education in Virginia" (2001) or as otherwise provided by these regulations.

D. The number of students in a driver training vehicle during in-vehicle instruction shall be no more than three and no less than two students. Students 18 years of age or older may receive one-on-one driver training with an instructor if such training is agreed to in the contract with the school. Students under 18 years of age who are not married or emancipated must have their parents or legal guardians sign a written release, an original to be maintained with the student's

record, in order to receive one-on-one driver training with an instructor.

E. Except when one-on-one driver training is being provided as outlined in subsection D of this section, a student under 19 years of age riding alone with the instructor shall ride in the back seat of the driver training vehicle until other students are present in the vehicle.

F. Except when a student is driving the vehicle, the time during which a student is being transported in a driver training vehicle for the purposes of picking up a student or other students prior to the beginning of a period of instruction or dropping that student or other students off after the end of a period of instruction shall not count as observation time. Any student involved in one-on-one training with an instructor as permitted under subsection D of this section shall meet the observation requirements with at least one other student in the vehicle during in-vehicle training.

G. Students under 19 years of age shall only receive in-vehicle instruction with other students under 19 years of age.

24VAC20-121-220. Equipment requirements for Class B licensed schools.

A. All vehicles used for driver education or used for testing purposes shall be marked by a rooftop sign, in bold letters not less than two and one-half inches in height, clearly visible 100 feet from the front and rear, stating one of the following: "Student Driver," "Learner," "New Driver," "Driver Education" or "Caution-Student."

All vehicles used by a school shall display the name of the school, as shown on the school license, on the outside of the vehicle when engaged in driver education or when the vehicle is being used for testing purposes. The name of the school shall be included either on the rooftop sign or affixed to both sides of the vehicle.

B. No motor vehicle may be used for driver education unless it is in safe mechanical condition as defined in these regulations. Each vehicle used for driver education in a school shall have dual controls consisting of dual brakes, dual inside rearview mirror and right-hand and left-hand outside mirrors. Any training vehicle or vehicles used for instruction shall not be more than nine model years old. This model year requirement may be waived or altered on a case-by-case basis for vehicles specially equipped to accommodate disabled individuals. The driver training vehicle shall be equipped with a minimum of four safety belts.

C. The department may exempt any school teaching disabled individuals from the requirement to provide motor vehicles, on a case-by-case basis. The school may use a vehicle provided by the disabled student for their in-vehicle instruction in the event that it is cost prohibitive for the school to maintain certain specialized equipment or if such equipment is not readily installed and removed or if it provides necessary practical experience for the student in their own vehicle. When using a student's vehicle, the school shall require that the disabled student provide written verification from the company insuring the vehicle that it is aware that the vehicle will be used for driver training instruction and the insurance is in full force during such use.

The school shall also require the disabled student to provide a copy of the current liability insurance policy for the vehicle. The school shall maintain a copy of the current liability insurance policy covering such vehicle in the student's file. The school shall also send prior to beginning instruction a ~~written~~ notice to the department, in a format prescribed by the department, stipulating the reasons for using the student's vehicle and the anticipated dates of instruction as well as a copy of the current liability insurance policy on the vehicle.

Any school that uses a disabled student's motor vehicle must ensure that such vehicle is in safe mechanical condition as defined in these regulations, and displays signage as specified under these regulations.

D. All motor vehicles used by a licensed school for in-vehicle instruction shall be inspected and approved by the department based on the criteria outlined in these regulations before being used for student instruction. All motor vehicles used by a licensed school for the purpose of taking the driving examination shall have a valid registration in the vehicle and be in safe mechanical condition, as defined in these regulations.

VA.R. Doc. No. R11-2655; Filed December 14, 2010, 11:00 a.m.

COMMONWEALTH TRANSPORTATION BOARD

Final Regulation

REGISTRAR'S NOTICE: The Department of Transportation is claiming an exemption from 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 Department of Transportation will receive, consider, and respond to petitions from any interested person at any time with respect to reconsideration or revision.

Title of Regulation: **24VAC30-111. Hauling Permit Manual (repealing 24VAC30-111-10 through 24VAC30-111-280).**

Statutory Authority: § 33.1-12 of the Code of Virginia.

Effective Date: February 2, 2011.

Agency Contact: Emmett Heltzel, P.E., Maintenance Division Administrator, Department of Transportation, 1401 East Broad Street, Richmond, VA 23219, telephone (804) 786-2949, or email emmett.heltzel@vdot.virginia.gov.

Summary:

Chapter 314 of the 2003 Acts of Assembly transferred responsibility for the oversize and overweight vehicle registration and permit program from the Virginia Department of Transportation (VDOT) to the Department of Motor Vehicles (DMV). The legislation provided that the regulations governing this program promulgated by VDOT shall remain in force until such regulations are amended, modified, or repealed by DMV. VDOT's regulations were contained in the Hauling Permit Manual, filed in the Virginia Administrative Code as 24VAC30-111. DMVs replacement regulations, Hauling Permit Regulation (24VAC20-81) went into effect September 29, 2009. As a result, VDOT can now repeal the Hauling Permit Manual as there is no longer a statutory requirement that VDOT's regulations remain in effect.

VA.R. Doc. No. R11-2187; Filed December 14, 2010, 9:22 a.m.

EXECUTIVE ORDER NUMBER 27 (2010)

Establishing the Urban Policy Task Force

Importance of the Issue

The Commonwealth has long faced the challenges of urbanization in a diverse range of policy areas, including but not limited to economic development, education, transportation, public safety, and human services. In particular, recent economic difficulties throughout Virginia, including high unemployment rates and slow economic growth, have had a severe adverse impact on urban communities. The challenges facing local governments and state government in these urban and urbanizing areas have required significant efforts on the part of appointed and elected governmental officials at all levels. In addition, the modernization, expansion, and diversity of new businesses has placed demands on governmental leaders at all levels to provide, in an efficient and timely manner, a full range of relevant and affordable public services.

Establishment of the Task Force

Section 2.2-206 of the Code of Virginia requires creation of a cabinet-level task force on urban policy. By virtue of the authority vested in me as Governor under Article V of the Constitution of Virginia and under the laws of the Commonwealth, including but not limited to Section 2.2-206 of the Code of Virginia, and subject always to my continuing and ultimate authority and responsibility to act in such matters, I hereby establish the Urban Policy Task Force. The Secretary of Commerce and Trade or his designee shall chair the Task Force. Other members shall consist of the Secretaries of Education, Health and Human Resources, Natural Resources, Public Safety, and Transportation or their designees. Additional members may be appointed to the Task Force at the Governor's discretion.

Responsibilities of the Task Force

The Task Force shall develop a comprehensive state urban policy that will give particular attention to actionable, top priorities and establish specific quantifiable benchmarks to address economic and social conditions and inequities within urban areas. It shall include but not be limited to establishing such methods, processes, and approaches as are necessary to recognize the importance of interdependence of localities within metropolitan areas and make recommendations to increase collaboration within all areas. All executive branch agencies shall cooperate fully as requested by the Task Force or its staff. The Task Force shall report to the Governor by January 14, 2011, and include in their report the performance of each agency in meeting established benchmarks.

Effective Date of the Executive Order

This Executive Order shall become effective upon its signing and shall remain in full force and effect until for one year from its signing, unless amended or rescinded by further executive order.

Given under my hand and under the Seal of the Commonwealth of Virginia this 8th day of December, 2010.

/s/ Robert F. McDonnell
Governor

GENERAL NOTICES/ERRATA

DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES

Notices of Periodic Review

Pursuant to Executive Order 14 (2010), the Virginia Department of Agriculture and Consumer Services, on behalf of the Board of Agriculture and Consumer Services, is currently reviewing the regulations listed below to determine whether they should be terminated, amended, or retained in their current form. Each regulation will be reviewed to determine whether (i) the regulation protects public health, safety, and welfare with the least possible intrusion in the lives of citizens; (ii) alternatives in lieu of regulation may achieve the goals of the regulation; (iii) the regulation is based on the best reasonably available scientific, economic, and other information; (iv) the regulation is designed to achieve its intended objective in the most efficient, cost-effective manner; (v) the regulation is clearly written and easily understandable by the individuals and entities affected; and (vi) the regulation has been developed in accordance with laws relating to the impact of regulations on small businesses.

2VAC5-80, Requirements Governing the Branding of Cattle in Virginia

2VAC5-160, Rules and Regulations Governing the Transportation of Horses

2VAC5-240, Rules and Regulations for Enforcement of the Grain Handlers Law

2VAC5-340, Rules and Regulations for the Enforcement of the Virginia Weights and Measures Law

2VAC5-460, Rules and Regulations for the Enforcement of the Virginia Petroleum Products Franchise Act

2VAC 5-470, Rules and Regulations Pertaining to the Registration and Certification of Grape Nursery Stock

2VAC5-480, Regulation Governing the Oxygenation of Gasoline

2VAC5-560, Rules and Regulations Pertaining to Labeling and Sale of Infant Formula

Comment period begins on January 17, 2011, and ends on February 7, 2011.

Agency Contact: Roy E. Seward, Department of Agriculture and Consumer Services, Washington Building, 1100 Bank Street, Room 211, Richmond, VA 23219, telephone (804) 786-3535 or email roy.seward@vdacs.virginia.gov.

DEPARTMENT OF CRIMINAL JUSTICE SERVICES

2010 Changes to Entry-level Law Enforcement Training Standards

The Committee on Training of the Criminal Justice Services Board has approved changes to the training objectives, criteria, and lesson plan guides of the Compulsory Minimum Training Standards for Entry Level Law Enforcement Officers as part of its annual review under 6VAC20-20-25. Copies of the changes may be obtained by contacting Judith Kirkendall at the Department of Criminal Justice Services, 1100 Bank Street, Richmond, VA 23219, or judith.kirkendall@dcjs.virginia.gov. A copy may be downloaded from the Internet by going to http://www.dcjs.virginia.gov/standardstraining/compulsoryminimumtraining/officers.cfm, and click on 2010 Changes to Entry-level Law Enforcement Training Standards at the top of the table of contents.

DEPARTMENT OF ENVIRONMENTAL QUALITY

Announcement of Public Meetings for Initiation of a Water Quality Restoration Study for the James River and Selected Tributaries in the Cities of Richmond, Hopewell, Petersburg, Colonial Heights, and the Counties of Chesterfield, Henrico, Dinwiddie, Prince George, Charles City, and Surry in Virginia

Public meetings: Two public meetings will be held on Tuesday, January 11, 2011. An afternoon meeting will be held at 2 p.m. at the East End Library located at 2414 R Street Richmond, VA 23223. An evening meeting will be held at 6 p.m. at the Department of Environmental Quality (DEQ), Piedmont Regional Office, 4949-A Cox Road, Glen Allen, VA 23060. In case of inclement weather, check the DEQ website for the rescheduled date (www.deq.virginia.gov).

Purpose of notice: DEQ is announcing the initiation of a water quality restoration study for the James River and selected tributaries which are impaired due to Polychlorinated Biphenyls (PCBs). A public comment period will follow the January 11, 2011, meetings and will expire on February 14, 2011.

Meeting description: First public "kick-off" meetings on this study to share ongoing efforts to-date with the public. The meeting will include information regarding PCBs, DEQ monitoring data, how the pollutant will be modeled in the waterways, and ongoing voluntary sampling efforts throughout the watershed by facilities.

Description of study: The following streams are found to exceed the water quality standard for PCBs and are in violation of the fishing designated use in the jurisdictions mentioned in the title above: Appomattox River (to Lake Chesdin Dam), Bailey Creek (to Rt. 360), Bailey Bay,

Chickahominy River (to Walkers Dam). Additionally, the James River is impaired from the fall line to the Hampton Roads Bridge Tunnel. For the purposes of these meetings, the James River from the fall line to the Charles City County and Surry County extents will be discussed. Information regarding the impairments is available on the DEQ website (http://www.deq.virginia.gov/wqa/pdf/2010ir/appendices/ir10_AppendixA_Category5_Factsheets_James.pdf; search factsheet using term "PCB"). Two studies are being developed concurrently due to the size of the impaired watershed. This set of public meetings will focus on the upper tidal portion of the James River and selected tributaries. A second study is being developed for the lower tidal James River and selected tributaries (1st public meetings were held on Dec. 1st). If you would like information on the lower tidal James River PCB study, please contact Jennifer Howell at jennifer.howell@deq.virginia.gov.

The study will report on the sources of PCB contamination and will recommend total maximum daily loads (TMDLs) for the impaired waters. A TMDL is the total amount of a pollutant a water body can contain and still meet water quality standards. To restore water quality, pollutant levels have to be reduced to the TMDL amount.

How a decision is made: The development of a TMDL includes a public comment period, including public meetings. Public comments will be incorporated into the TMDL development. Following the public notice and review of the final TMDL draft report (to be available at some point in the future), DEQ will submit the TMDL report to the U.S. Environmental Protection Agency (EPA) for approval. The final TMDL report is due to EPA in 2014. Given the extent of the impairments and complexities of the pollutant, DEQ is initiating the TMDL study now, in order to allow the time necessary for study development.

How to comment: DEQ accepts written comments by email, fax, or postal mail. Comments should include the name, address, and telephone number of the person commenting and be received by DEQ during the comment period, which will end on February 14, 2011.

Contact for additional information: Margaret Smigo, TMDL Coordinator, Department of Environmental Quality, Piedmont Regional Office, 4949-A Cox Road, Glen Allen, VA 23060, telephone (804) 527-5124, Fax (804)-527-5106, or email margaret.smigo@deq.virginia.gov.

Notice of Public Meetings and an Opportunity for Public Comment on Initiation of Water Quality Study for Nomini and Rosier Creeks in Westmoreland and King George Counties

Public meetings: Two public meetings will be held on Thursday, January 20, 2011. An afternoon public meeting will be held at 2 p.m. at the Newton Memorial Branch Library located at 22 Coles Point Road, Hague, VA 22469. An evening meeting will be held at the Cooper Memorial Branch Library located at 20 Washington Ave., Colonial Beach, VA 22443.

Purpose of notice: The Virginia Department of Environmental Quality (DEQ) and the Department of Conservation and Recreation are announcing a study to restore water quality for a shellfish growing area, two public meetings, and a public comment opportunity following the meeting (expiring on February 22, 2011).

Meeting description: Meeting will provide the public with information gathered to date for the study to include information on the pollutant, monitoring data from Virginia Department of Health, Division of Shellfish Sanitation, and possible bacteria sources in the watershed (non-point and point sources).

Description of study: Virginia agencies are working to identify sources of bacteria contamination in the shellfish growing waters of the following waterways: Rosier Creek, Currioman Creek, Nomini Creek, Pierce Creek, Poor Jack Creek, Davis Creek, Jules Creek, Matthews Cove, and North Prong of Buckner Creek. These streams are impaired for failure to meet the designated use of shellfish consumption because of bacteria water quality standard violations.

The study reports the current status of the creeks via sampling performed by the Virginia Department of Health, Division of Shellfish Sanitation, shellfish area condemnations and the possible sources of bacterial contamination. The study recommends total maximum daily loads (TMDLs) for the impaired waters. A TMDL is the total amount of a pollutant a water body can contain and still meet water quality standards. To restore water quality, bacterial levels have to be reduced to the TMDL amount.

How to comment: DEQ accepts written comments by email, fax, or postal mail. Comments should include the name, address, and telephone number of the person commenting and be received by DEQ during the comment period, which will expire on February 22, 2011.

Contact for additional information: Margaret Smigo, TMDL Coordinator, Department of Environmental Quality, Piedmont Regional Office, 4949A Cox Road, Glen Allen, VA 23060, telephone (804) 527-5124, FAX (804) 527-5106, or email margaret.smigo@deq.virginia.gov.

Total Maximum Daily Loads for the North Fork Rockfish River, South Fork Rockfish River, Rockfish River, and Taylor Creek watersheds in Nelson County

The Department of Environmental Quality (DEQ) and the Department of Conservation and Recreation (DCR) seek written and oral comments from interested persons on the development of total maximum daily loads (TMDLs) for the North Fork Rockfish River, South Fork Rockfish River,

Rockfish River, and Taylor Creek watersheds in Nelson County. The tributaries of the Rockfish were listed on the 2004 and 2006 303(d) TMDL Priority List and Report as impaired due to violations of the state's water quality standard for bacteria; in addition, Taylor Creek was listed in 2008 as impaired due to violations of the state's general water quality standard (benthic) for aquatic life. The bacteria impairment on the North Fork Rockfish begins in the headwaters and extends 7.2 miles to its confluence with the Rockfish River. The South Fork Rockfish bacterial impairment extends 11.6 miles from its headwaters to its confluence with the mainstem Rockfish River. The bacteria impairment on the Rockfish River extends from the confluence of its North and South Forks to its confluence with Davis Creek, which is a total of 6.5 miles. The benthic impairment on Taylor's Creek extends 5 miles from its headwaters to the confluence with North Fork Perry Creek.

Section 303(d) of the Clean Water Act and § 62.1-44.19:7 C of the Code of Virginia require DEQ to develop TMDLs for pollutants responsible for each impaired water contained in Virginia's 303(d) TMDL Priority List and Report.

The first public meeting on the development of these TMDLs will be held on Wednesday, January 19, 2011, 7 p.m., at Rockfish River Elementary School, 200 Chapel Hollow Road, Afton, VA 22920.

The public comment period for the first public meeting will end on February 18, 2011. Written comments should include the name, address, and telephone number of the person submitting the comments and should be sent to Tara Sieber, Department of Environmental Quality, 4411 Early Road, P.O. Box 3000, Harrisonburg, VA 22801, telephone (540) 574-7870, FAX (540) 574-7878, or email tara.sieber@deq.virginia.gov.

STATE LOTTERY DEPARTMENT

Director's Order

The following Director's Order of the State Lottery Department was filed with the Virginia Registrar of Regulations on December 15, 2010. The order may be viewed at the State Lottery Department, 900 East Main Street, Richmond, VA, or at the office of the Registrar of Regulations, 910 Capitol Street, 2nd Floor, Richmond, VA.

Director's Order Number Ninety-Five (10)

Virginia's Instant Game Lottery 1233; "Green Stuff" Final Rules for Game Operation (effective December 15, 2010)

VIRGINIA CODE COMMISSION

Notice to State Agencies

Contact Information: *Mailing Address:* Virginia Code Commission, 910 Capitol Street, General Assembly Building, 2nd Floor, Richmond, VA 23219; *Telephone:* Voice (804) 786-3591; FAX (804) 692-0625; *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/cmsportal3/cgi-bin/calendar.cgi.

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/cumultab.htm.

Filing Material for Publication in the Virginia Register of Regulations: Agencies are required to use the Regulation Information System (RIS) when filing regulations for publication in the *Virginia Register of Regulations*. The Office of the Virginia Register of Regulations implemented a web-based application called RIS for filing regulations and related items for publication in the Virginia Register. The Registrar's office has worked 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.

The Office of the Virginia Register is working toward the eventual elimination of the requirement that agencies file print copies of regulatory packages. Until that time, agencies may file petitions for rulemaking, notices of intended regulatory actions, and general notices in electronic form only; however, until further notice, agencies must continue to file print copies of proposed, final, fast-track, and emergency regulatory packages.

ERRATA

STATE BOARD OF ELECTIONS

Titles of Regulations: **1VAC20-40. Voter Registration (adding 1VAC20-40-70).**

1VAC20-70. Absentee Voting (adding 1VAC20-70-10, 1VAC20-70-40, 1VAC20-70-50).

1VAC20-70. Absentee Voting (adding 1VAC20-70-30).

Publication: 27:8 VA.R. 732-735 December 20, 2010.

Correction to Proposed Regulation:

Public Hearing Information: Change "No public hearings are scheduled" to "January 12, 2011 - 10 a.m. - General Assembly Building, 910 Capitol Street, 4th Floor, 4-West Conference Room, Richmond, VA"

VA.R. Doc. No. R11-2626, 2685, 2686 Filed December 16, 2010