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September 28, 2010

Craig A. Reed, DVM, Chair
Virginia State Board of Health
109 Governor Street
Richmond, VA 23219

Dear Chairman Reed:

§32.1-111.3 of the Code of Virginia requires the development of a comprehensive, coordinated, statewide emergency medical services plan, heretofore referred to as “The Plan” by the Virginia Office of EMS (OEMS). The Board of Health must review, update, and publish the plan triennially, making such revisions as may be necessary to improve the effectiveness and efficiency of the Commonwealth’s emergency care system. The objectives of the plan shall include, but not be limited to the eighteen objectives outlined in §32.1-111.3.

OEMS, in coordination with the Executive Committee of the State EMS Advisory Board, the Finance, Legislation and Planning (FLAP) Committee, and the chairs of all the standing committees of the State EMS Advisory Board submitted planning templates created by OEMS; pertaining to each aspect of the EMS system that committee is tasked with. Much of the information included in each planning template, as well as information in many EMS review reports, namely the Joint Legislative Audit and Review Commission (JLARC), and the Institute of Medicine (IOM) Report “EMS at the Crossroads”, was included in the draft version of the plan.

Attached to this document is the current version of the Strategic and Operational State EMS plan. It is comprised of four main core strategies, with each core strategy having several key strategic initiatives. This plan was unanimously approved by the State EMS Advisory Board at their August 13, 2010 meeting.

As the Code of Virginia mandates, this plan must be reviewed, updated, and published by the Virginia State Board of Health. The Office of EMS appreciates the opportunity to present this document to the Board, and values any input that the Board provides, as well as the input of any other stakeholder, or interested party.

Respectfully submitted,

Gary R. Brown, Director
Office of Emergency Medical Services
Virginia Department of Health
INTRODUCTION

§32.1-111.3 of the Code of Virginia requires the development of a comprehensive, coordinated, statewide emergency medical services plan by the Virginia Office of EMS (OEMS). The Board of Health must review, update, and publish the plan triennially, making such revisions as may be necessary to improve the effectiveness and efficiency of the Commonwealth’s emergency care system. The objectives of the plan shall include, but not be limited to the eighteen objectives outlined in §32.1-111.3.

Over the past few years, much attention has been paid to the development of the plan. Some of this is due to review of reports, namely the Joint Legislative Audit and Review Commission (JLARC) Review of Emergency Medical Services in Virginia, the National Association of State EMS Officials “State Emergency Medical Services Systems: A Model” report, the Institute of Medicine (IOM) Report “EMS at the Crossroads”, the Association & Society Management International (ASMI) report “Regional Emergency Medical Services Council Study”, the planning session report of the Regional EMS Council Process Action Team, as well as planning sessions conducted by the standing committees of the state EMS Advisory Board. The recommendations made by these committees have assisted in driving the planning process forward.

As the Code of Virginia mandates, this plan must be reviewed, updated, and published triennially by the Board of Health. The Office of EMS appreciates the opportunity to present this document to the Board, and values any input that the Board provides, as well as the input of any other stakeholder, or interested party.

This operational plan identifies the specific initiatives required of the OEMS staff in executing the 2010 – 2013 Strategic Plan. Each objective and action step is intended to accomplish those items most critical to the Strategic Plan in the given fiscal year. The Strategic Plan is designed to improve priority areas of performance and initiate new programs. Therefore, much of the routine, but important work of the OEMS staff (i.e., EMS agency licensure, EMS vehicle permitting, EMS provider certification, grant awards, technical assistance, etc.), is not included in the Operational Plan.

No later than 3 months prior to the end of a particular fiscal year the OEMS staff will evaluate progress on the plan and begin the process of creating the Operational Plan for the next fiscal year.
Core Strategy 1: Develop Partnerships

Key Strategic Initiatives

1.1  Promote collaborative approaches.

1.1.1 Use technology to provide accurate and timely communication within the Virginia EMS System
1.1.2 Promote collaborative activities between local government, EMS agencies, hospitals, and community colleges to support more community based EMS programs which lead to increased recruitment and retention of certified EMS providers.
1.1.3 Provide a platform for clear, accurate, and concise information sharing and improved interagency communications between the Office of EMS, state agencies and EMS system stakeholders in Virginia.
1.1.4 Identify resources and/or opportunities to work collaboratively with other state agencies, organizations, and associations to improve processes and patient outcomes.

1.2  Coordinate responses to emergencies both natural and man-made.

1.2.1 Support, coordinate and maintain deployable emergency response resources.
1.2.2 Increase knowledge of Emergency Operations capabilities with Emergency Managers, leaders, and supervisors on a local, regional, and state level.
1.2.3 Assist EMS agencies to prepare and respond to natural and man-made emergencies by incorporating strategies to develop emergency response plans (the plan) that address the four phases of an emergency (preparedness, mitigation, response, and recovery) and to exercise the plan.
Core Strategy 2: Create Tools and Resources

Key Strategic Initiatives

2.1 Sponsor EMS related research and education.

2.1.1 Sponsor research and other projects that contribute to high quality EMS and improve patient outcomes utilizing data collected by the EMS Registries.
2.1.2 Determine quality of EMS service and conduct analysis of trauma triage effectiveness.
2.1.3 Establish scholarships for EMS provider education.
2.1.4 Evaluate the impact of an aging workforce on service provision around the State.

2.2 Supply quality education and certification of EMS personnel.

2.2.1 Ensure adequate, accessible, and quality EMS provider training and continuing education.
2.2.2 Enhance competency based EMS training programs.
2.2.3 Develop, implement and promote leadership and management standards for EMS agency leaders.
2.2.4 Align all initial EMS education programs to that of other allied health professions to promote professionalization of EMS.
2.2.5 Increase the amount and quality of pediatric training and educational resources for EMS providers, emergency department staff and primary care providers in Virginia.
2.2.6 Provide an increased number of training opportunities for EMS personnel in Emergency Operations methods and activities.
Core Strategy 3: Develop Infrastructure

Key Strategic Initiatives

3.1 EMS Regulations, Protocols, Policies, and Standards

3.1.1 Review and assess state and federal legislation related to the EMS system.
3.1.2 Establish standards for the utilization of Air Medical Services.
3.1.3 Establish statewide Air/Ground Safety Standards.
3.1.4 Develop criteria for a voluntary Virginia Standards of Excellence Accreditation Program for EMS Agencies.
3.1.5 Maintain and enhance the Trauma Center designation process.
3.1.6 Maintain and enhance the Regional EMS Council designation process.
3.1.7 Establish standardized methods and procedures for the inspection and licensing and/or permitting of all EMS agencies and vehicles, including equipment and supply requirements.
3.1.8 Through a consensus process, develop a standard set of evidence-based patient care guidelines and standard formulary.

3.2 Focus recruitment and retention efforts

3.2.1 Develop, implement, and promote a comprehensive recruitment and retention campaign for EMS personnel and physicians, supporting the needs of the EMS system.
3.2.2 Support and expand the Virginia Recruitment and Retention Network.
3.2.3 Develop, implement, and promote the EMS Leadership and Management standards program.

3.3 Upgrade technology and communication systems

3.3.1 Assist with, and promote, the compliance of all emergency medical radio systems with state and federal regulations for narrow banding and interoperability.
3.3.2 Promote emergency medical dispatch standards and accreditation among 911 Public Safety Answering Points (PSAPs) in Virginia.
3.3.3 Provide technical assistance on wireless communication products available for use in the emergency medical community.
3.3.4 Establish statewide centralized dispatch system for air medical service.
Core Strategy 3 – Develop Infrastructure (Continued)

3.4 Stable support for EMS funding

3.4.1 Standardize EMS grant review and grading process by graders at regional and state level.
3.4.2 Develop a “Best Practices” resource guide on the procurement of EMS and rescue vehicles to include the use of existing or “cooperative” contracts in conjunction with the Department of General Services – Division of Purchases and Supply.
3.4.3 Develop uniform pricing schedule for state funded items.
3.4.4 Develop standard specifications for state grant funded equipment awarded to eligible non-profit EMS agencies.
3.4.5 Assist EMS agencies to identify grant programs and funding sources for EMS equipment, training, and supplies.
3.4.6 Integrate state grant funding programs with other related grant funding programs.
3.4.7 Develop guidance documents to assist EMS agencies account for the use of state grant funds and develop internal audit processes.

3.5 Enhance regional and local EMS efficiencies

3.5.1 Standardize performance and outcomes based service contracts with designated Regional EMS Councils and other qualified entities.
3.5.2 Improve regulation and oversight of air medical services statewide.
3.5.3 Educate local government officials and communities about the value of a high quality EMS system to promote development in economically depressed communities and the importance of assuming a greater responsibility in the planning, development, implementation, and evaluation of its emergency medical services system.
Core Strategy 4: Assure Quality and Evaluation

Key Strategic Initiatives

4.1 Assess compliance with EMS performance driven standards

4.1.1 Maintain statewide data-driven performance improvement process.
4.1.2 Maintain statewide pre-hospital and inter-hospital trauma triage plan.
4.1.3 Maintain statewide pre-hospital and inter-hospital stroke triage plan.
4.1.4 Develop and maintain statewide pre-hospital and inter-hospital STEMI triage plan.
4.1.5 Review and evaluate data collection and submission efforts.
4.1.6 Review functional adequacy and design features of EMS vehicles utilized in Virginia and recommend changes to improve EMS provider safety, unit efficiency and quality of patient care.
4.1.7 Measure EMS system compliance utilizing national EMS for Children (EMSC) performance measures.

4.2 Assess and enhance quality of education for EMS providers

4.2.1 Update the certification process to assure certification examinations continue to be valid, psychometrically sound, and legally defensible.
4.2.2 Update quality improvement process to promote a valid, psychometrically sound, and legally defensible certification process.
4.2.3 Explore substitution of practical examination with successful completion of a recognized competency based training program conducted by accredited training sites and using computer based technology for written examinations.

4.3 Pursue new initiatives that support EMS

4.3.1 Engage the EMS system in unintentional injury, illness, and violence prevention efforts.
4.3.2 Develop, implement, and promote programs that emphasize safety, wellness, and the physical health of fire and EMS personnel.
Resources

In developing this plan several resources were used in addition to meetings and interviews with the Director and Assistant Director of OEMS.

- **Code of Virginia: § 32.1-111.3. Statewide emergency medical care system.** Requires a comprehensive, coordinated EMS system in the Commonwealth and identifies specific objectives that must be addressed.

- **EMS Agenda for the Future:** A document created by the National Highway Traffic and Safety Administration (NHTSA) that outlines a vision and objectives for the future of EMS. August 1996

- **OEMS 5-Year Plan:** July 1, 2007-June 30, 2010

- **Service Area Strategic Plan** State Office of Emergency Medical Services (601 402 04) which describes the statutory authority and expectations for OEMS and identifies the growing EMS needs of the citizens and visitors of Virginia.

- **Service Area Strategic Plan** Financial Assistance for Non Profit Emergency Medical Services Organizations and Localities (601 402 03) This service area includes Virginia Rescue Squads Assistance Fund grants program, Financial Assistance to Localities to support Non Profit Emergency Medical Service (EMS) agencies, and funding provided to support Virginia Association of Volunteer Rescue Squads (VAVRS).

- **State Emergency Medical Services Systems: A Model:** National Association of State EMS Officials – July 2008

- **EMS at the Crossroads:** Institute of Medicine - 2006

- **Agency Planning Handbook: A Guide for Strategic Planning and Service Area Planning Linking to Performance-Based Budgeting:** Department of Planning and Budget 2006-2008 Biennium, May 1, 2005


- **EMS Advisory Board Committee Planning Templates** – Developed May-August 2009

September 28, 2010

Craig A. Reed, DVM, Chair
Virginia State Board of Health
109 Governor Street
Richmond, VA 23219

Dear Chairman Reed:

In the past, vaccine administration has not been considered part of the routine scope of practice of Emergency Medical Services (EMS) providers in the Commonwealth. EMS providers have generally been held to function within a scope of practice that enables them to provide immediate care in emergencies, not elective or preventive care.

During the 2010 General Assembly, House Bill 173 (Pogge) and Senate Bill 328 (Stuart) were combined resulting in legislation authorizing emergency medical technicians (EMTs) certified at the intermediate and paramedic levels that are operating under the direction of their Operational Medical Director (OMD) to administer vaccines to any person in accordance with established protocols of the Board of Health. EMS providers that administer vaccines will be required to utilize the Virginia Immunization Information System (VIIS) to document and record their activity. This legislation, as a result of an emergency clause, became effective March 23, 2010 with the Governor’s signature.

The Office of EMS (OEMS) was assigned the responsibility in developing a policy following existing guidelines and protocols established by the Board of Nursing and the Board of Health. Participants included the following:

- Marissa Levine, MD, MPH, Deputy Commissioner, Public Health & Preparedness
- George Lindbeck, MD, State EMS Medical Director, OEMS
- Gary R. Brown, Director, OEMS
- P. Scott Winston, Assistant Director, OEMS
- Warren Short, Manager, Education and Training, OEMS
- Michael D. Berg, Manager, Regulation and Compliance, OEMS
- Elizabeth Singer, Public Relations Coordinator, OEMS
- Marian Hunter, Asst. Public Relations Coordinator, OEMS
- Jim Farrell, Director, Division of Immunization, VDH
- Joanne Wakeham, Community Health Services, VDH
- Sandra Sommer, Division of Immunization, VDH
The attached Policy for Vaccine Administration by EMS Providers in Virginia has been presented to the State EMS Advisory Board on August 13, 2010 and to the Medical Direction Committee of the Board. In addition, the policy has been reviewed and approved by Eric Gregory, JD, Liaison to the Health Department, Office of the Attorney General. The policy requires Board of Health approval.

Respectfully submitted,

Gary R. Brown, Director
Office of Emergency Medical Services
Virginia Department of Health
Policy for Vaccine Administration by Emergency Medical Services Providers in Virginia

Purpose

This policy is designed to provide guidance to Virginia Emergency Medical Services (EMS) Operational Medical Directors (OMD), EMS agencies, and EMS providers in the development of a program for the administration of vaccines by appropriately certified, authorized, and supervised EMS providers.

Background

Previously, EMS providers had not been recognized by the Code of Virginia as having the ability to administer vaccines under routine circumstances. EMS providers could be authorized to administer vaccines in the event of a declared emergency by the Governor and under the direction and authorization of the Commissioner of Health.

Amendments to the Code of Virginia, effective March 29, 2010 recognized certain EMS providers among those identified as able to administer vaccinations to minors. Amendments to the Code of Virginia, effective March 29, 2010 recognized certain EMS providers as being authorized to administer vaccinations under the authority of their operational medical director without the physical presence of the medical director. Appendix A

Personnel and Responsibilities

An Operational Medical Director serves as the “prescriber” identified in the Code of Virginia, and as the supervising physician for the EMS providers administering vaccines.

- A prescriber is a practitioner licensed in the Commonwealth who is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription for a covered substance or a practitioner licensed in another state to so issue a prescription for a covered substance
- OMD’s supervising a vaccination program must hold current endorsement as an EMS physician in Virginia and be affiliated with the EMS agency developing the vaccination program
- The OMD is ultimately responsible for the supervision of the vaccination program
- Provides authorization for purchase of vaccine and other necessary supplies for vaccine administration
- Ensures appropriate physical management and handling of vaccine
- Ensures that the vaccine program is registered with the Virginia Immunization Information System (VIIS)
• Develops/approves protocols for approval and training of vaccinators, provision of specific vaccine information/education and informed consent to recipients of vaccine, specific procedures for administration of vaccine and management of any vaccination related complications, development and approval of appropriate record keeping, reporting of vaccination information and any adverse events or complications, and implementation of an ongoing quality management program for the vaccination program.

• A model protocol for the administration of vaccines by pharmacists in Virginia has been developed by the Board of Nursing and provides a concise outline of requirements for a vaccination program, as well as vaccine specific information on patient screening and provision of consent, administration of specific vaccines, and record keeping including sample documents and record forms:
  

EMS providers participating in a vaccination program must:

• Hold a valid, unrestricted Virginia certification as an Intermediate or Paramedic
• Must be affiliated with the Virginia EMS agency developing the vaccination program
• Must be individually approved by their agency OMD as a vaccinator
• Must follow protocols approved by their OMD for vaccine administration

The EMS Agency developing the vaccination program must:

• Hold current licensure as an ALS agency in Virginia

Procedures

The OMD must direct the development of a plan for purchase/acquisition of vaccine, including proper storage and handling of each type of vaccine according to recommendations by the Centers for Disease Control (CDC) and the vaccine’s manufacturer.

• Specific information regarding vaccine management in general as well as information for specific vaccines is available from the CDC:
  
  http://www.cdc.gov/vaccines/recs/storage/default.htm

• The OMD must ensure that each provider who will administer vaccine has been individually approved by the OMD and has
received appropriate training in the handling of the vaccine, screening and provision of information and informed consent to vaccine recipients, specific administration protocols for each vaccine administered, observation of vaccine recipients and management of complications of vaccine administration (including severe allergic reaction) and the maintenance of appropriate records regarding vaccine administration.

- The OMD/Agency will keep a written record of those providers approved to administer vaccine: an example is provided in Appendix B

- General information regarding vaccine administration as well as vaccine-specific information is available from the CDC: [http://www.cdc.gov/vaccines/recs/vac-admin/default.htm](http://www.cdc.gov/vaccines/recs/vac-admin/default.htm)

- The OMD must assure that before administering any vaccine, a copy of the most recent Vaccine Information Statements (VIS) is provided to the recipient or their legal guardian. Provision of the appropriate VIS is required by Federal law for many vaccines. Such information must be reviewed with the adult recipient, or if a minor by their parent, legal guardian or person standing in loco parentis to confirm their understanding of the benefits and risks of the intended vaccine. Non-English speaking individuals seeking vaccination for themselves or their child/children should be provided a copy of the VIS in their native language. VIS are available for specific vaccines in a variety of languages: [http://www.cdc.gov/vaccines/pubs/vis/default.htm](http://www.cdc.gov/vaccines/pubs/vis/default.htm)

- The Operational Medical Director must assure that every provider screens every recipient for indications and contraindications prior to administering the vaccine. Screening tools shall at a minimum follow CDC and manufacturer’s recommendations. Examples are available for children and teens: [http://www.immunize.org/catg.d/p4060.pdf](http://www.immunize.org/catg.d/p4060.pdf), and for adults: [http://www.immunize.org/catg.d/p4065.pdf](http://www.immunize.org/catg.d/p4065.pdf)

- A record of vaccine administration must be kept in the recipient’s vaccination record and a second copy kept at the administering location documenting the date that the vaccine was administered, the route, dose, site, manufacturer and lot number, the publication date of the Vaccine Information Statements (VIS), along with the name and title of the person administering the vaccine. Sample vaccination recording materials are available through the CDC: [http://www.cdc.gov/vaccines/recs/immuniz-records.htm#recording](http://www.cdc.gov/vaccines/recs/immuniz-records.htm#recording)
Vaccine record keeping should conform to guidelines of the Virginia Immunization Information System (VIIS), and each vaccination program should be registered with the VIIS. Information regarding registration and record keeping is available: https://viis.vdh.virginia.gov/VIIS/portalHeader.do

The OMD must also develop a protocol for the care and observation of vaccine recipients, and for management of adverse events related to vaccine administration. These protocols would be expected to dovetail with existing agency patient care protocols for the management of serious allergic reactions and anaphylaxis.

The OMD must ensure that the vaccination program is prepared to identify and report adverse reactions to vaccine administration, and be familiar with the Vaccine Adverse Event Reporting System (VAERS). Information regarding adverse events associated with vaccination is available generally through the CDC: http://www.cdc.gov/vaccines/vac-gen/safety/default.htm, and specifically about the VAERS: http://vaers.hhs.gov/about/index
Appendix A

§ 32.1-46.02. Administration of influenza vaccine to minors.
The Board shall, together with the Board of Nursing and by August 31, 2009, develop and issue guidelines for the administration of influenza vaccine to minors by licensed pharmacists, registered nurses, or licensed practical nurses, certified emergency medical technicians-intermediate, or emergency medical technicians-paramedic pursuant to § 54.1-3408. Such guidelines shall require the consent of the minor's parent, guardian, or person standing in loco parentis, and shall be consistent with applicable guidelines developed by the Centers for Disease Control and Prevention.

§ 54.1-3408. Professional use by practitioners.
I. A prescriber may authorize, pursuant to a protocol approved by the Board of Nursing, the administration of vaccines to adults for immunization, when a practitioner with prescriptive authority is not physically present, by (i) by licensed pharmacists, (ii) by registered nurses, or (iii) licensed practical nurses under the immediate and direct supervision of a registered nurse. A prescriber acting on behalf of and in accordance with established protocols of the Department of Health may authorize the administration of vaccines to any person by a pharmacist or, nurse, certified emergency medical technician-intermediate, or emergency medical technician-paramedic under the direction of an operational medical director when the prescriber is not physically present. Emergency medical services personnel shall provide documentation of the vaccines to be recorded in the Virginia Immunization Information System.
**Appendix B**

I, , MD/DO licensed in the Commonwealth of Virginia do hereby authorize , NAME OF VIRGINIA LICENSED EMS AGENCY, a Virginia licensed Emergency Medical Services agency for whom I serve as an Operational Medical Director as recognized by the Virginia Office of EMS and those affiliated and certified Intermediates and Paramedics listed below to administer vaccines to patients in accordance with the laws and regulations of the Commonwealth of Virginia. In exercising this authority, the participants shall comply with the protocol for administration of vaccines. This medical directive also covers emergency care if it is necessary.

The participants must agree to any significant changes in the protocol.

Signatures:

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Memorandum

To: State Board of Health

From: Keri Hall, MD, MS
Director, Office of Epidemiology

Subject: Proposed Regulations for the Virginia Immunization Information System (VIIS)

Date: October 15, 2010

Enclosed are draft Regulations for the Virginia Immunization Information System (VIIS) for your review and discussion at the October 15, 2010, meeting of the Board of Health. Their purpose is to establish a system that will contain birth to death immunization histories of participants. The board is required to promulgate regulations to implement VIIS pursuant to the Code of Virginia, § 32.1-46.01.

The comment period for the Notice of Intended Regulatory Action (NOIRA) ended on September 30, 2009. No comments were received. The draft regulations have been reviewed and approved by both Robin Kurz, of the Office of the Attorney General, and Dr. Karen Remley, State Health Commissioner.

If the board approves them, the proposed regulations will be posted to the Virginia Town Hall for Executive Branch review prior to publication in the Virginia Register. The public will be able to comment on the proposed regulations for a 60-day period after publication.
Proposed Regulation
Agency Background Document

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<tr>
<td>Virginia Administrative Code (VAC) citation</td>
<td>12 VAC5-115</td>
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<td>Regulation title</td>
<td>Virginia Immunization Information System</td>
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<td>Regulations for the Virginia Immunization Information System (VIIS)</td>
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This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the Virginia Register Form, Style, and Procedure Manual.

**Brief summary**

*In a short paragraph, please summarize all substantive provisions of new regulations or changes to existing regulations that are being proposed in this regulatory action.*

Section 32.1-46.01 of the *Code of Virginia* requires the State Board of Health to establish regulations for the Virginia Immunization Information System (VIIS). VIIS is a voluntary, statewide immunization registry that consolidates patient immunization histories from birth to death into a complete, accurate, and definitive record that is available to Virginia’s participating health care providers. The VIIS regulations are designed to: (1) define who is allowed access to VIIS; (2) specify requirements for this access; (3) ensure compatibility with current state and federal guidelines in the areas of patient data confidentiality and system security; (4) discuss the security features of the application; (5) define the data to be collected; (6) state the mechanisms for populating and capturing data; (7) define the approved use of data, the authorized recipients, and the procedure for obtaining the data; and, (8) discuss the use of VIIS in a public health emergency.

**Acronyms and Definitions**

“ACIP” means Advisory Committee on Immunization Practices

“CDC” means Centers for Disease Control and Prevention

“Data exchange” means electronically sending immunization information from an
existing information system to VIIS and being able to retrieve information from VIIS

“DOE” means Department of Education
“DMAS” means Department of Medical Assistance Services
“DSS” means Department of Social Services
“EHR” means electronic health record
“FQHC” means a Federally Qualified Health Center

“IID” means an immunization information system
“RHC” means a Rural Health Clinic
“UTD” or “Up-to-date” means the client has received all age-appropriate vaccines
“VDH” means the Division of Immunization within the Virginia Department of Health
“VIIS” means the Virginia Immunization Information System

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., the agency, board or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

Statutory authority to promulgate these regulations is granted to the State Board of Health by §32.1-46.01 of the Code.

Purpose

Please explain the need for the new or amended regulation by (1) detailing the specific reasons why this regulatory action is essential to protect the health, safety, or welfare of citizens, and (2) discussing the goals of the proposal, the environmental benefits, and the problems the proposal is intended to solve.

The purpose of this regulatory action is to comply with two bills dealing with VIIS passed by the 2005 General Assembly: SB 1132 and HB 2519. The identical bills were presented by Senator Janet D. Howell and Delegate John M. O’Bannon, III, MD, and called for the establishment of VIIS. The statewide immunization information system contains birth-to-death immunization histories of participating clients and merges this data from all healthcare providers for that patient into one record. This consolidated record, which is available to participating health care providers in Virginia, will help providers identify appropriate
immunizations to give their patients. It will help to increase immunization rates and protect the public health of all citizens of Virginia in the following ways: (1) ensure that children receive vaccines appropriately, as currently recommended by ACIP; (2) prevent the under- and over-immunization of children; (3) generate parental reminders, recall notices and manufacturer recalls; (4) produce immunization coverage reports; (5) identify areas of under-immunized populations for educational purposes and other immunization rate improvement activities; and, (6) provide, in the event of a public health emergency, a mechanism for tracking the distribution and administration of immunizations, immune globulins or other preventive medications or emergency treatments.

Substance

Please briefly identify and explain new substantive provisions (for new regulations), substantive changes to existing sections or both where appropriate. (More detail about all provisions or changes is requested in the “Detail of changes” section.)

Regulations for VIIS will cover five main areas: 1) authorized participants of VIIS and their registration procedure; 2) data entry by participants either through user interface or data exchange; 3) requirements for patient confidentiality and system security; 4) approved and non-approved use of VIIS data; and, 5) use of VIIS in a public health emergency.

Issues

Please identify the issues associated with the proposed regulatory action, including:

1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;
2) the primary advantages and disadvantages to the agency or the Commonwealth; and
3) other pertinent matters of interest to the regulated community, government officials, and the public.

If the regulatory action poses no disadvantages to the public or the Commonwealth, please indicate.

VIIS regulations will pose no disadvantage to the public or the Commonwealth. Many advantages will occur for both the general public and to the Commonwealth. An accurate patient immunization record allows health care providers to diagnose vaccine preventable diseases more effectively and to recommend immunizations that ensure patients receive all the age-appropriate vaccines recommended by ACIP. Accurate immunization information also decreases costs by preventing unnecessary duplicated immunizations, reminding clients of vaccines that are due or were recalled by the manufacturer, and identifying areas of need for increased education and other activities that may lead to improved immunization coverage rates.

There are also benefits to parents or guardians, which include the following:
- removes the need to provide their child’s immunization record to the healthcare provider(s);
- prevents additional visits to the child’s provider(s) by identifying all age-appropriate immunizations that may be given during the current visit;
- provides emergency department ability to assess the child’s immunization status at the time of an injury;
- provides information needed to create reminder/recall notices for recommended immunizations that are due or overdue;
- simplifies the process for obtaining the child’s immunization history for admission to schools, daycares, camps, etc.;
- enables identification and recall of the child who:
received a vaccine that was later recalled; or,
- did not receive a recommended vaccine due to short supply;
  - guarantees lifetime access to the client’s immunization history even if the health care
    provider’s office is no longer in operation.

### Requirements more restrictive than federal

*Please identify and describe any requirements of the proposal, which are more restrictive than applicable federal requirements. Include a rationale for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.*

There are no applicable federal requirements.

### Localities particularly affected

*Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.*

VIIS is a partnership between the public and private health sectors of Virginia; however, participation in VIIS is voluntary for healthcare providers and citizens. Therefore, no locality would be disproportionately affected by VIIS.

### Public participation

*Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.*

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code. Information may include 1) projected reporting, recordkeeping and other administrative costs; 2) probable effect of the regulation on affected small businesses; and, 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail, email or fax to James Farrell, 109 Governor Street, Room 314 West, Richmond, Virginia 23219; phone (804) 864-8055 or (800) 568-1929; fax (804) 864-8089 or James.Farrell@vdh.virginia.gov. Include the name and address of the commenter. In order to be considered, comments must be received by the last day of the public comment period. A public hearing is not planned.

### Economic impact
Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirements create the anticipated economic impact.

<table>
<thead>
<tr>
<th>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source, and (b) a delineation of one-time versus on-going expenditures.</th>
<th>There are three types of costs incurred with VIIS: building costs for the construction, maintenance costs for the continued operation (including costs for improving and upgrading the application), and user costs for participants. As VIIS has been operational since 2006, building costs have been met with 100% federal financial assistance and only ongoing maintenance will be discussed here. Historically, the maintenance costs for the operation of VIIS are approximately $2.3 M per year. The federal funding codes are 607 40502 1000. This figure includes the following ongoing expenditures: management of VIIS by an outside vendor; salaries for VDH staff necessary for program management, including the planning and performing of daily operations, as well as quality assurance and improvement activities, and recruitment, training and monitoring of participants; adequate technical support for analysis of data and coordination of data exchange with VIIS; program supplies; hardware upgrades for the application’s operation, and travel expenses for necessary visits to the participant’s offices, and continuing education of staff.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Projected cost of the new regulations or changes to existing regulations on localities.</td>
<td>There are no projected costs to localities for VIIS. Enrollment in VIIS is voluntary, and the web-based application is available free of charge. If qualified persons elect to participate, the costs incurred by them are limited and include: a computer with Internet access (high-speed connection is desirable, but not necessary); staff time to complete forms for participation; training and customizing the application for their facility, for adding users within their facility, and, if they elect to do so, for entering the past immunization history of their clients.</td>
</tr>
<tr>
<td>Description of the individuals, businesses or other entities likely to be affected by the new regulations or changes to existing regulations.</td>
<td>Various categories of persons and entities giving immunizations or processing immunization information would be affected by VIIS regulations.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CHART 1- Typical users of VIIS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>VIIS users/sites</td>
<td>Approximate number</td>
</tr>
<tr>
<td>Private doctors, including pediatricians, family medicine practices, internal medicine physicians and OB/GYN practices.</td>
<td>4,500 doctors within 1700 sites that may be large or small medical practices</td>
</tr>
<tr>
<td>Community Health Centers, RHCs and FQHCs</td>
<td>200</td>
</tr>
<tr>
<td>Mobile Vans</td>
<td>5</td>
</tr>
<tr>
<td>Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.</td>
<td>Over 10,140 sites will be affected by VIIS. Many of these sites would be small medical practices or pharmacies. (See Chart 1 for details).</td>
</tr>
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<td>---</td>
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</tr>
<tr>
<td>All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.</td>
<td>VIIS is free to all users who have been approved by VDH. VIIS may be used in two ways: direct entry of immunization data into the application through user interface or by data exchange of immunization data from other information systems (e.g., billing systems, or EHRs). The organization has the cost of staff time for completing registration and security forms and creating a file that puts the data from their existing system in the format that is accepted by VIIS. For persons electing to use VIIS by user interface, there would be the cost of additional staff time to complete registration and security forms for participation, training and customizing the application for their facility, adding users within their facility, and, if they elect to do so, entering the previous immunization history of their clients. After VIIS access is granted to the provider, the staff must enter their vaccine inventory into the system and when giving an immunization, register the client (if not already in the system) and enter the immunization data. A computer with Internet access is necessary (a high-speed connection is desirable but not necessary).</td>
</tr>
<tr>
<td>Beneficial impact the regulation is designed to produce.</td>
<td>1. To provide accurate immunization records 2. To identify age-appropriate vaccines for specific clients 3. To reduce duplicate vaccines 4. To recall recipients of recalled vaccines or recipients not receiving vaccines due to vaccine shortages 5. To improve inventory management 6. To identify areas of the state in need of increased</td>
</tr>
</tbody>
</table>
### Immunization Services

- To provide official immunization records for parents/guardians
- To improve health by the use of health information technology
- To increase immunization rates
- To provide a means of communication to healthcare providers in a public health emergency
- To save the state an estimated one million dollars annually *

* documentation available from VDH/DOI

### Alternatives

*Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.*

No feasible alternative exists. Legislation enacted by the 2005 General Assembly requires these regulations. Also, CDC recommends a statewide immunization registry as a means of protecting public health through appropriate immunizations and for promoting activities that improve immunization rates.

### Regulatory flexibility analysis

*Please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.*

There is no alternative to developing the VIIS regulations because the Code requires it. Participation in VIIS is voluntary, so neither health care practices nor patients are required to participate.

### Public comment

*Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.*

No comments were received following the publication of the NOIRA.
**Family impact**

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one’s spouse, and one’s children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

No adverse impact on the institution of the family or family stability is anticipated in developing the regulations. VIIS should protect and improve the health of Virginians. The most obvious benefit to the family is the provision of complete immunization histories for children, which allows physicians to provide all age-appropriate immunizations recommended by ACIP. For additional benefits, see the “Issues” section.

**Detail of changes**

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact if implemented in each section. Please describe the difference between the requirements of the new provisions and the current practice or if applicable, the requirements of other existing regulations in place.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all provisions of the new regulation or changes to existing regulations between the pre-emergency regulation and the proposed regulation, and (2) only changes made since the publication of the emergency regulation.

For new chapters, use this chart:

<table>
<thead>
<tr>
<th>Section number</th>
<th>Proposed requirements</th>
<th>Other regulations and law that apply</th>
<th>Intent and likely impact of proposed requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>12VAC5-115-10</td>
<td>Definitions of words and terms used in chapter 115</td>
<td>§ 32.1-46.01</td>
<td>To ensure consistency in interpretation of VIIS regulations</td>
</tr>
<tr>
<td>12VAC5-115-20</td>
<td>Authority granted to promulgate regulations for the operation of VIIS</td>
<td>§ 32.1-46.01</td>
<td>To allow the Board of Health to develop regulations for the operation of VIIS</td>
</tr>
<tr>
<td>12VAC5-30</td>
<td>The purpose of addressing the policies and procedures of VIIS</td>
<td>§ 32.1-46.01</td>
<td>To state the purpose of the regulations</td>
</tr>
<tr>
<td>12VAC5-115-40</td>
<td>Authorized participants of VIIS must require immunization data to perform their job function and must be licensed or certified in Virginia to deliver or support health care services or public health. These participants include but are not limited to, any physician, physician assistant, nurse practitioner, registered nurse, school nurse, pharmacist or any entity listed in § 8.01-581.1. Health care entities may only use VIIS for exchanging</td>
<td>§ 32.1-46.01 § 8.01-581.1</td>
<td>To identify persons or organizations who are allowed to use VIIS</td>
</tr>
<tr>
<td>Regulation</td>
<td>Summary</td>
<td>Relevant Section</td>
<td>Details</td>
</tr>
<tr>
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<tr>
<td>12VAC5-115-50</td>
<td>Those persons electing to participate in VIIS must complete registration forms and assure compliance with necessary confidentiality and security access provisions. VDH will train and provide VIIS access after approval. Participants must designate an administrator who may allow VIIS access by other organization employees and in doing so shall assume responsibility for those users.</td>
<td>§ 32.1-46.01</td>
<td>To identify registration forms, agreements and security conditions necessary to gain access to VIIS and to identify the responsibilities of the participants.</td>
</tr>
<tr>
<td>12VAC5-115-60</td>
<td>Patients shall have the opportunity to opt-out of VIIS by contacting VDH or their healthcare provider. Confidentiality of patient VIIS data shall be assured by all users who shall comply with VIIS regulations and state and federal laws, including HIPAA. VIIS records shall be treated with the same confidentiality and privacy as any other patient records. Any inappropriate use shall result in immediate suspension of participant privileges and additional actions may be taken pursuant to Virginia Code § 32 1-27.</td>
<td>§ 32.1-46.01</td>
<td>To assure parents/guardians and healthcare providers of children enrolled in VIIS of the confidentiality of the data and, if they elect to do so, to provide them with an opt-out procedure.</td>
</tr>
<tr>
<td>12VAC5-115-70</td>
<td>Each approved participant is assigned a security role level in VIIS and there is immediate suspension following any violation of security or misuse of data. Participants shall also have password-enabled screen savers, make every effort to protect VIIS screens from unauthorized view and log off whenever leaving the VIIS workstation. Data shall be encrypted and exchanged via a secure connection. The VIIS application, located on a secure website, includes additional security features, including an organizational code, user ID and password. It inactivates after a set period of time and disallows entry of participants if not used for a period of time.</td>
<td>§ 32.1-46.01</td>
<td>To assure the parents/guardians/providers of patients enrolled in VIIS of the security of the data.</td>
</tr>
<tr>
<td>12VAC5-115-80</td>
<td>Birth certificate data are used to populate VIIS and death certificate data are used to make the VIIS record no longer viewable. Enrolled participants or organizations shall report data either by online data entry or by data exchange of files from other information systems. Both demographic and immunization data shall be reported by the participant. The social security number, if provided, is encrypted by the application, appears as asterisks, and does not print out on reports for that client. The application allows only exact matches when the social security number is used for search purposes.</td>
<td>§ 32.1-46.01</td>
<td>To discuss the sources of VIIS data, including the initial population of the application, the ongoing input of data and the inactivation of deceased patients.</td>
</tr>
<tr>
<td>12VAC5-115-90</td>
<td>Specific patient data shall be released to that patient or his parents/guardian only after contacting VDH, who will verify the source and comply with federal and state regulations when releasing the information. Requests for patient-level data from health care entities providing health care services or processing health information for that patient must be in writing to VDH, who will authorize the request. The data shall be erased when no longer needed or when the computer is being terminated, due to replacement or the resignation, retirement or dismissal of the participant. Aggregate data from which personal identifying data has been removed or redacted may be released only after approval by VDH. Any inappropriate use of VIIS data shall result in immediate suspension of user privileges and result in an investigation conducted by VDH.</td>
<td>§ 32.1-46.01</td>
<td>To assure the public that VIIS data will be shared only with appropriate recipients after authorization by VDH and to explain the mechanisms and requirements for requesting data, and the penalties for misuse of data.</td>
</tr>
<tr>
<td>12VAC5-115-100</td>
<td>In the event of a public health emergency, the Commissioner may access VIIS by contacting the Division of Immunization. If additional persons are designated by the Commissioner to view VIIS information during the emergency, VDH shall contact these users, provide instruction and activate their account. The Commissioner, by notifying the Division of Immunization, may include public health emergency information on the main screen which may be viewed immediately by the VIIS participants.</td>
<td>§ 32.1-46.01</td>
<td>To define procedures for the State Health Commissioner to access VIIS or to designate others to view VIIS in a public health emergency.</td>
</tr>
</tbody>
</table>
12VAC5-115-10. Definitions.

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

"Commissioner" means the State Health Commissioner or his designee.

"De-duplication" means the process in information systems that matches incoming data with existing client records and merges those identified as the same client.

"Data exchange" means electronically sending immunization information from an existing information system to VIIS and being able to retrieve information from VIIS.

"Health care entity" means any health care provider, health plan or health care clearinghouse.

"Health care provider" means those entities listed in § 8.01-581.1 except that state-operated facilities shall also be considered health care providers for the purposes of this section. Health care provider shall also include all persons who are licensed, certified, registered or permitted or who hold a multistate licensure privilege issued by any of the health regulatory boards within the Department of Health Professions, except persons regulated by the Board of Funeral Directors and Embalmers or the Board of Veterinary Medicine.

"Health plan" means an individual or group plan that provides or pays the cost of medical care and shall include any entity included in such definition as set out in 45 C.F.R. § 160.103.

"Participant" means a person or organization with a VIIS account.

"Patient" means the client who is receiving health services or his parent/guardian.

"Public health emergency" means any public health event caused by an act of bioterrorism, vaccine-preventable disease outbreak or other public health event resulting from natural or human cause.

"Security role" means the level of security assigned to a participant that determines what information the individual may access in the application and what system functions may be performed.

"VDH" or "Department of Health" means the Division of Immunization within the Virginia Department of Health.

"Virginia Immunization Information System" or "VIIS" means the statewide immunization registry.

"VITA" means the Virginia Information Technologies Agency.

12VAC5-115-20. Authority.

Section 32.1-46.01 of the Code of Virginia requires the Board of Health to establish VIIS and to promulgate regulations for the operation of VIIS.

12VAC5-115-30. Purpose.

The purpose of these regulations is to address the policies and procedures for the implementation of VIIS.
12VAC5-115-40. Authorized participants.

A. Health care providers, including, but not necessarily limited to any physician, physician assistant, nurse practitioner, registered nurse, school nurse, pharmacist or any entity listed in the definition of "health care provider" in Virginia Code § 8.01-581.1 are authorized to participate in VIIS.

B. Any health care entity may participate as long as it is licensed or certified in Virginia to deliver or support health care services or public health, requires immunization data to perform the health service function, and uses VIIS only for exchanging information on persons for whom it provides services.

C. Other state or regional immunization registries may exchange data with VIIS. They may share data and have access to data by contacting the VIIS program manager and complying with the registration procedure discussed in section 12VAC5-115-50.

D. VDH shall give access to VIIS under the condition that having access to immunization information is required to perform the job function of the participant. The VIIS program manager or designee shall assign the security role of the participant based on his needs and job responsibilities.

E. Access to VIIS requires only Internet access and is free to participants.

12VAC5-115-50. Registration procedures.

A. Participation in VIIS is voluntary.

B. Completed registration forms from authorized participants must be processed and approved by VDH before access to the system is allowed. Registration will require the participant to assure compliance with necessary confidentiality and security access provisions that specify security procedures to ensure that VIIS data are protected from unauthorized view and access. The participant shall update and submit the forms to VDH every year.

C. Once the participant is approved, VDH will provide training and activate the participant in the VIIS system.

D. Qualifying participant organizations shall designate an administrator for their organization. The administrator may then allow VIIS access by an employee in his organization, and in doing so shall assume responsibility for registering that person, obtaining the most recent security forms that specify VITA or VDH security requirements, retaining all completed user forms, assigning the security role of the user, accepting legal responsibility for his proper use of VIIS, and terminating access to VIIS if the employee is noncompliant with VIIS requirements or no longer requires access.

E. An administrator may terminate his organization's participation at any time by notifying VDH in writing. All data entered by that organization shall remain in the system.

12VAC5-115-60. Patient confidentiality.

A. Access to VIIS information is authorized only under the condition that access to individual immunization information is required to perform the participant's job function.

B. Participants shall not conduct any activity that jeopardizes the proper function or security of VIIS. They shall use patient data only as authorized by law and these regulations, and must immediately notify the patient and VDH of any breach of personal privacy or confidentiality.

C. Patients shall have the opportunity to opt-out of VIIS by doing one of the following:
   1. Contacting their healthcare provider to allow the viewing of their immunizations only by that provider who administered them; or,
2. Contacting VDH in writing requesting to be taken out of VIIS and have their record no longer viewable.

D. Patient immunization records shall not be copied except for authorized use. These copies shall not be left where they are visible by unauthorized personnel and shall be shredded before disposal.

E. VIIS records shall be treated with the same confidentiality and privacy as any other patient record. Any inappropriate use of VIIS records shall result in immediate suspension of participant privileges and an investigation conducted by VDH. Additional actions may be taken pursuant to Virginia Code § 32.1-27. The VIIS program manager may reinstate privileges.

F. Nothing in these regulations alters the provision in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (42 U.S.C.,P.L.104-191; 42 C.F.R. Part 164) that permits covered healthcare entities to disclose protected health information to a public health authority without individual authorization.


A. After VDH gives access to a VIIS participant, a secure connection is established between his browser and VIIS. The system is password-protected.

B. Participants must ensure that employees with authorized access: do not disclose their user identification code or password to anyone; have physical security and password-enabled screen savers on computers accessing VIIS; make every effort to protect VIIS screens from unauthorized view; and, log off the system whenever leaving the VIIS workstation.

C. The VIIS system, which is maintained on a secure website, automatically inactivates a user session after a predetermined period of inactivity. The inactivation period is determined by VITA security policy.

D. The VIIS system inactivates user accounts, denying access to the system when participants have not logged into the system after a predetermined period of time. This inactivation period is determined by VITA security policy. The administrator must reactivate the account.

E. There shall be a secure encrypted connection between VIIS and the participating organization sending or receiving data if data exchange is performed. The encryption process will be determined by VITA and/or VDH.

12VAC5-115-80. Population of VIIS.

A. The VDH Divisions of Immunization and Vital Records have an agreement to populate demographic information in VIIS with birth certificate data. Death certificate data are used to make the VIIS record no longer viewable. Data exchange shall be performed on a periodic basis, but at least monthly.

B. Each participant shall make every effort to ensure the accuracy of all immunization and demographic information and shall include enough identifying information to allow for de-duplication of clients.

C. Data shall be reported in VIIS either by online data entry or by data exchange of files from other information systems. The health care provider or the designated health plan billed for the immunization shall report. Reporting shall occur within seven days of vaccine administration for online data entry participants. For data exchange participants, reporting shall occur within seven days of receipt of the information.

D. Both demographic and immunization data shall be reported by the participant.
1. Patient demographic information shall include, but is not limited to: patient's name, date of birth, gender, telephone number, home address, birth place, and mother's maiden name. The social security number, if provided, is encrypted by the application, appears as asterisks, and does not print out on reports for that client. The application allows only exact matches when the social security number is used for search purposes.

2. Patient immunization information shall include, but is not limited to: the type of immunization administered, using industry standards such as vaccine groups, Health Level 7 codes or Current Procedural Terminology codes; date the immunization was administered; identity of the health care provider who administered the vaccine; manufacturer; trade name; lot number; and if present, any contraindications or religious or medical exemptions.

E. Participants in data exchange shall provide an acceptable level of data quality, such as correct data fields, data accuracy and enough information to correctly merge with existing clients. Upon initial data delivery, and periodically thereafter, data shall be reviewed to determine data quality. Any rejected records shall be resolved by the participant in a timely way. VDH may suspend system privileges and refer to Virginia Code § 32.1-27 for additional action for any organization that submits inaccurate data.

F. If insufficient information is reported to allow de-duplication of clients, incoming data will be placed in a pending file and must be manually merged, if appropriate. All participants shall identify a contact to work with VDH on pending files.

G. VDH shall incorporate immunization data pursuant to subsection E of Virginia Code § 32.1-46 into VIIS by data exchange from other immunization systems, patient care management billing systems or information systems to the extent possible.

12VAC5-115-90. Release of VIIS data.

A. Specific patient data shall be disclosed to the extent required or permitted by state and federal law or regulations, after contacting VDH, who will verify the source of the request.

B. Specific patient data may be disclosed to health care entities to the extent required or permitted by state and federal law or regulations. See Virginia Code § 32.1-127.

C. Patient data shall be erased when no longer needed, or when the computer is being terminated, due to replacement of computer or resignation, retirement or dismissal of the participant.

D. Aggregate data from which personal identifying data has been removed or redacted may be released for the purposes of statistical analysis, research or reporting only after approval by VDH.

E. Any inappropriate use of VIIS data shall result in immediate suspension of user privileges and result in an investigation conducted by VDH. Additional actions may be taken in accordance with Virginia Code § 32.1-27. The VIIS program manager may reinstate privileges upon satisfactory completion of required remedial actions and guarantee of proper use of VIIS in the future.

12VAC5-115-100. Data access in public health emergency.

A. In the event of an epidemic, outbreak of a vaccine-preventable disease or any disease of public health significance or threat, the commissioner may access VIIS in accordance with Virginia Code § 32.1-40 by contacting the Division of Immunization. The commissioner may release VIIS data in accordance with Virginia Code § 32.1-41.
B. The commissioner may designate additional persons to view VIIS information during a public health emergency. VDH shall contact designated authorized users, provide instruction for those who are not current participants, and activate an account.

C. The commissioner, by notifying the Division of Immunization, may include public health emergency announcements and notices or guidelines on the main screen which may be viewed immediately by the VIIS participants.
MEMORANDUM

To: Virginia Board of Health

From: Diane Helentjaris, MD, MPH, Director, Office of Family Health Services

Through: Karen Remley, MD, MBA, FAAP, State Health Commissioner

Date: October 15, 2010

Re: Final Regulation: Dental Scholarship and Loan Repayment Programs (12VAC5-520)

The “Regulations Governing the Dental Scholarship and Loan Repayment Programs” underwent periodic review pursuant to Executive Order 36 (2006). The Virginia Department of Health (VDH) is using this opportunity to make some modifications to the existing regulations.

This regulatory action proposes to clarify ambiguous language, improve the ease of administration, and clarify and make consistent the terms of default and restitution for the dentist scholarship and loan repayment programs. Substantive changes proposed for the scholarship program are to limit eligibility to third- and fourth-year dental students, except in cases of extreme need in underclassmen. Another substantive change affecting the scholarship program is to limit the timeframe for reimbursement of monies paid to dentists who default on their scholarship contract and later fulfill their obligation. Substantive changes proposed for the loan repayment program are to change the time limits for application to the program by dental specialists and to change the amount of the annual award to be consistent with the amount of scholarship award for the particular calendar year. The proposed changes would also allow the amount of both scholarship and loan repayment awards to be capped at the discretion of the State Health Commissioner.

VDH has met with officials at Virginia Commonwealth University School of Dentistry regarding proposed changes to the scholarship program, and they are in accord with the proposed changes.

These amendments are in the final regulation stage, following publication in The Virginia Register of Regulations on February 15, 2010, and the closure of the public comment period on April 16, 2010. After Board of Health approval, the regulatory review package will be forwarded to the Department of Planning and Budget. Once the Office of the Secretary of Health and Human Resources and the Governor’s office approve the final regulation, VDH will forward it for publication.

Should you have any questions regarding this final regulation, please contact Dr. Diane Helentjaris, Director of the Office of Family Health Services, at (804) 864-7650.
Final Regulation
Agency Background Document

<table>
<thead>
<tr>
<th>Agency name</th>
<th>Virginia Department of Health</th>
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<tbody>
<tr>
<td>Virginia Administrative Code (VAC) citation</td>
<td>12 VAC 5-520</td>
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<tr>
<td>Regulation title</td>
<td>Regulations Governing the Dental Scholarship and Loan Repayment Programs</td>
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<tr>
<td>Action title</td>
<td>Amend regulations regarding existing dental scholarship and loan repayment programs as a result of Periodic Review results.</td>
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<td>Date this document prepared</td>
<td>August 16, 2010</td>
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This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the Virginia Register Form, Style, and Procedure Manual.

**Brief summary**

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

This regulatory action proposes to clarify ambiguous language, improve the ease of administration, and clarify and make consistent the terms of default and restitution for the dentist scholarship and loan repayment programs. A substantive change proposed for the scholarship program is to limit scholarship awards' eligibility to junior and senior dental students, except in cases of extreme need in underclassmen. The other substantive change affecting the scholarship program is to limit the timeframe for reimbursement of monies paid to dentists who default on their scholarship contract and later fulfill their obligation. Substantive changes proposed for the loan repayment program are to change the time limits for application to the program by dental specialists and to change the amount of the annual award to be consistent with the amount of scholarship award for the particular calendar year. The proposed changes would also allow the amount of both scholarship and loan repayment awards to be capped at the discretion of the State Health Commissioner.

There have been no changes to the regulation since the proposed regulation was published.
Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency or board taking the action, and (3) the title of the regulation.

This regulation will be presented to the Board of Health (board) on October 15, 2010, for adoption as a final regulation.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

The State Board of Health is authorized to make, adopt, promulgate and enforce regulations by § 32.1-12 of the Code of Virginia.

§ 32.1-122.9 of the Code requires the board to establish annual dental scholarships for students in good standing at Virginia Commonwealth University and to promulgate regulations to administer this scholarship program.

Chapter 174 of the 2000 Acts of Assembly created the Dental Loan Repayment Program in § 32.1-122.9:1 of the Code authorizing the Board to establish “a dentist loan repayment program for graduates of accredited dental schools …who agree to perform a period of dental service in the Commonwealth in an underserved area as defined in § 32.1-122.5 of the dental scholarship program or a dental health professional shortage area designated in accordance with the criteria established in 42 C.F.R. Part 5.”

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The amended regulation is needed to clarify ambiguous language, improve the ease of administration, and clarify and make consistent the terms of default and restitution for the dentist scholarship and loan repayment programs. The rationale behind these changes is to clarify and simplify the administration of the program.

The dental scholarship and loan repayment programs help protect and improve the public’s health and welfare by improving the distribution of dentists to ensure that dental health services are available in the underserved areas of Virginia. The Code requires that regulations be adopted for the administration of the programs. The goals of this proposal are to address comments received from the periodic review, as well as to make the existing regulations clearer and more efficient, thus making the programs easier and more cost–effective to administer. Making the administration of programs more efficient and increasing cost-savings is a benefit to the Virginia Department of Health (VDH).
Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the “All changes made in this regulatory action” section.

The following substantive changes to the dental scholarship and loan repayment regulations are proposed to resolve ambiguous language and to improve the ease of administration of the program:
(i) Amend §12 VAC 5-520-10 to more clearly define certain terms used in the regulation; and,
(ii) Amend §12 VAC 5-520-130 to expand the time limit for application to the loan repayment program by dental specialists such as oral surgeons.

Issues

Please identify the issues associated with the proposed regulatory action, including:
1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;
2) the primary advantages and disadvantages to the agency or the Commonwealth; and
3) other pertinent matters of interest to the regulated community, government officials, and the public.
If there are no disadvantages to the public or the Commonwealth, please indicate.

The proposed regulatory actions will make the program more cost-effective to administer, an indirect cost-savings benefit to individual citizens. Further, the actions are necessary to improve the access to dental specialty and general oral health services and to ensure adequate availability of dental services in areas of Virginia where there are presently insufficient dental services. Certain dental specialists also will benefit from the amendments to the dental scholarship and loan repayment programs, as these proposed changes will enable them to be eligible for a loan repayment award. Making the administration of programs more efficient and increasing cost-savings is a benefit to the agency.

Other pertinent matters of interest: None.

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

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar’s office, please put an asterisk next to any substantive changes.

No changes were made to the text of the proposed regulation since the publication of the proposed stage.

Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

No public comments were received after the proposed stage.
<table>
<thead>
<tr>
<th>Current section number</th>
<th>Proposed new section number, if applicable</th>
<th>Current requirement</th>
<th>Proposed change and rationale</th>
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<tbody>
<tr>
<td>5-520-10</td>
<td></td>
<td>&quot;Dentist loan repayment award&quot; means an amount repaid to a dentist for dental school loans in an amount equivalent to one year in-state tuition at Virginia Commonwealth University School of Dentistry for the year in which the loan was acquired and for which the dentist is under a contractual obligation to repay through practice in an underserved area or designated state facility. &quot;Designated state facility&quot; means practice as a dentist in a facility operated by the Virginia Department of Health or Virginia Department of Mental Health, Mental Retardation and Substance Abuse Services. &quot;Governing Board of Virginia Commonwealth University&quot; means the official governing body of the university or their designee. &quot;Interest at the prevailing bank rate from similar amounts of unsecured debt&quot; means the prime lending rate as published in the Wall Street Journal on the last day of the month in which the decision to repay is communicated to the commissioner by the recipient, plus two percentage points.</td>
<td>&quot;Loan repayment award&quot; means an award paid to a dentist for dental school loans in an amount equivalent to the current in-state tuition and mandatory fees at Virginia Commonwealth University School of Dentistry and for which the dentist is under a contractual obligation to repay through practice in an underserved area or designated state facility. This amount may be capped at the discretion of the commissioner. &quot;Designated state facility&quot; means practice as a dentist in a facility operated by the Virginia Department of Health, Virginia Department of Behavioral Health and Developmental Services, Virginia Department of Juvenile Justice or the Virginia Department of Corrections. Delete definition of “Governing Board of Virginia Commonwealth University.” &quot;Interest at the prevailing bank rate from similar amounts of unsecured debt&quot; means the prime lending rate plus 2% as published in the Wall Street Journal on the first day of the month in which the decision to repay is communicated to the commissioner by the recipient or on the first day of the month that the commissioner determines the recipient to be in default.</td>
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<td>Definition</td>
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<td>&quot;Internship or residency at an approved institution or facility&quot;</td>
<td>Delete definition of “Participating dental school.”</td>
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<td>means an advanced dental education program in general dentistry or dental specialty accredited by the Commission on Dental Accreditation and approved by the American Dental Association.</td>
<td>Delete definition of “Penalty.”</td>
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<td>&quot;Participating dental school&quot; means Virginia Commonwealth University School of Dentistry.</td>
<td>Delete definition of “Period of dental service.”</td>
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<td>&quot;Penalty&quot; means an amount of money equal to three times the amount of all monetary scholarship or loan repayment awards paid to the recipient.</td>
<td>Delete definition of “Primary dental health care.”</td>
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<td>&quot;Period of dental service&quot; means one year of service in a dental underserved area in return for one year of scholarship or loan repayment as defined in Part III (12VAC5-520-130 et seq.) of this chapter.</td>
<td>Delete definition of “Public health service.”</td>
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<td>&quot;Primary dental health care&quot; means the practice of general or specialty dentistry.</td>
<td>&quot;Restitution&quot; means three times the award amount received plus interest at the prevailing bank rate for similar amounts of unsecured debt as set forth in this regulation, owed to the Commonwealth of Virginia by a scholarship or loan repayment recipient who is in default of his contractual obligation as provided for in this chapter.</td>
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| 5-520-30 | **Applicability.**  
These definitions shall apply to all recipients who begin practice in an underserved area as fulfillment of their scholarship or loan repayment obligation on July 1, 2001, or later, provided that approval given by the commissioner prior to May 8, 2002 shall remain in full force and effect.  

Rationale: This section is extraneous and adds no needed information to the regulation. |

| | **Rationale:** Makes consistent the amount of annual scholarship and loan repayment awards so that every recipient receives the same amount during a given fiscal year. Also allows for a limit to be placed on the award amount as is consistent with other state and national loan repayment programs. Adds the state departments of Juvenile Justice and Corrections to the list of designated state facilities to be consistent with §32.1-122.5. The agency name of the Virginia Department of Mental Health, Mental Retardation and Substance Abuse Services has changed to Virginia Department of Behavioral Health and Developmental Services. Clarifies definitions of interest and restitution. Removes definitions that are not used in the rest of the chapter. |

| | **Delete §5-520-30.** |

| | **“Specialty dental practice” means the advanced practice of dentistry in any specialty approved by the American Dental Association and accredited by the Commission on Dental Accreditation.** |

| | **“Scholarship award” means an amount equivalent to one year of in-state tuition and mandatory fees at Virginia Commonwealth University School of Dentistry for the academic year a student is enrolled and for which the dental student entered a contractual obligation to repay through practice in an underserved area or designated state facility.** |

| | **“Virginia dental scholarship” means an award of an amount equivalent to one year of in-state tuition at Virginia Commonwealth University School of Dentistry for the academic year a student is enrolled in a participating dental school and for which the dental student entered a contractual obligation to repay through practice in an underserved area or designated state facility.** |

<p>| | <strong>“Specialty dentistry” means the advanced practice of dentistry in any specialty approved by the American Dental Association and accredited by the Commission on Dental Accreditation.</strong> |</p>
<table>
<thead>
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<tr>
<td>5-520-130</td>
<td>B. Any graduate of an accredited dental school in the United States who is establishing a practice in general or specialty dentistry in an underserved area or practicing dentistry in a designated state facility shall be eligible to apply for the Virginia Dentist Loan Repayment Program. Eligible applicants will be within five years of graduation from an accredited undergraduate dental program and have existing loans accumulated as a result of their first professional education. Dentists who have received dental scholarship program awards and dentists who have accepted Exceptional Financial Need (EFN) and Financial Assistance for Disadvantaged Health Professions Students (FADHPS) scholarships are not eligible for the Dentist Loan Repayment Program. Rationale: Differentiates between application time limits for general dentists and specialists. Extends application time limit for specialists, allowing them to apply up to five years after completion of residency training. Removes names of now non-existent federal scholarship programs and replaces them with more generic phrasing with wider applicability.</td>
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<tr>
<td>5-520-150</td>
<td>1. Virginia Commonwealth University School of Dentistry shall establish an application procedure and annually submit the names of qualified students to receive scholarships in accordance with the criteria for preference enumerated in this section. Dental scholarships will be awarded on or before October 30 of each fiscal year with remaining funds disbursed through the Dentist Loan Repayment Program. The total annual number of scholarship awards will be based on availability of funds. Individual scholarship recipients may receive a maximum of five scholarship awards. 1. Virginia Commonwealth University School of Dentistry shall use the application procedure established by the commissioner and annually submit the names of qualified students to receive scholarships in accordance with the criteria for preference enumerated in 12VAC5-520-130 of this chapter. The total number of scholarship awards will be based on availability of funds. Scholarship awards will be made annually by October 30 to third and fourth year dental students. First and second year students will be considered for an award only in the event of extreme financial need. Individual scholarship recipients may receive a maximum of</td>
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2. The application period for the Dentist Loan Repayment Program will follow that for the Dental Scholarship Program, with awards made by January 30 of each fiscal year. Preference for loan repayment awards will be given to dental students graduating from Virginia Commonwealth University School of Dentistry and those with established financial need. Individual loan repayment recipients may receive a maximum of three awards upon graduation from dental school. All awards will be competitive based on the criteria enumerated in this section and will be based on availability of loan repayment funds once scholarship funds are disbursed.

Rational: The default rate for scholarship recipients is an ongoing problem and was particularly high in FY08. After discussion with Virginia Commonwealth University staff, it was decided that by instituting a more substantive application process and essentially limiting the award to upperclassmen, students would be selected who were most likely to fulfill the terms of their obligation upon graduation.

Establishes a more definitive and realistic time line for the application and award process for the Dentist Loan Repayment Program. Removes the unnecessary criteria that loan repayment awards are made after scholarship awards. Removes the criteria that loan repayment awards are made based on financial need, which is almost impossible to ascertain.

1. Provide that the recipient of the dental scholarship award shall pursue the dental course of Virginia Commonwealth University until graduation and upon graduation or upon graduation from an accredited residency program that does not exceed four years, shall notify the commissioner in writing of his proposed practice location or intent to enter a residency not more than 30 days after graduation and begin his approved practice within 90 days after completing dental school.

1. Provide that the recipient of the scholarship award shall pursue the dental course of Virginia Commonwealth University until graduation and upon graduation or upon graduation from an accredited residency program that does not exceed four years, shall notify the commissioner in writing of his proposed practice location or intent to enter a residency not more than 30 days after graduation and begin his approved practice within 90 days after completing dental school or residency.
school or residency, and thereafter continuously engage in full-time dental practice in a dental underserved area of Virginia or in a designated state facility for a period of years equal to the number of annual scholarships received.

7. Provide that the recipient shall receive credit toward fulfillment of his contractual obligation at the rate of 12 months of dental practice for each scholarship or loan repayment award paid to the recipient. The recipient may be absent from the place of approved practice for a total of seven weeks in each 12-month period for personal reasons. Absence for a period in excess of seven weeks without the written permission of the commissioner shall result in proportional reduction of the period of credit toward fulfillment of the contractual obligation.

8. Provide that should the scholarship recipient pay restitution by not serving his scholarship obligation in an underserved area and later fulfills the terms of his contract through dental practice as outlined in this section, that the recipient will be reimbursed for all or part of any scholarship amount paid based on the fulfillment of the scholarship obligation.

Rationale:
Decreasing the length of absence from work from seven to four weeks is more in line with typical vacation or other leave amounts. The current regulation allows an indefinite period of time for a dentist who defaulted to decide to fulfill his obligation and be reimbursed for monies paid. This could put funding for the program in jeopardy years after the default time. The proposed change limits to five years the time period within which a defaulting dentist can decide to fulfill his obligation and be reimbursed for the scholarship amount that he has been paid.
A. With respect to default, the contract shall provide that a scholarship or loan repayment recipient who fails to fulfill his obligation to practice dentistry as described in 12VAC5-520-160 shall be deemed in default under the following circumstances and shall forfeit all monetary scholarship or loan repayment awards made to him and shall make repayment of these funds plus interest plus penalty, where applicable the Commonwealth of Virginia as provided for in this chapter. The contract shall:

3. Provide that if the scholarship or loan repayment recipient is in default due to death or permanent disability so as not to be able to engage in dental practice, the recipient or his personal representative shall repay the Commonwealth all monetary scholarship awards plus 8.0% interest on the amount of the award. Partial fulfillment of the recipient's contractual obligation by the practice of dentistry as provided for in this contract prior to death or permanent disability shall reduce the amount of repayment plus interest due by a proportionate amount of money, such proportion being determined as the ratio of the number of whole months that a recipient has practiced dentistry in an approved location to the total number of months of the contractual obligation the recipient has incurred. The commissioner may waive all or part of the scholarship or loan repayment obligation under application by the recipient or his estate under these conditions and consider whole or partial forgiveness of payment or service in consideration of individual cases of hardship or inability to pay.

4. Provide that any recipient of a scholarship or loan repayment who defaults by evasion or refusal to fulfill
fulfill the obligation to practice dentistry in an underserved area or designated state facility for a period of years equal to the number of annual scholarships or loan repayment awards received shall make restitution by repaying all monetary scholarship or loan repayment awards plus penalty plus interest to the Commonwealth of Virginia.

B2. The recipient has not accepted a placement and commenced his period of obligated practice as provided for in subdivision 2 of 12VAC5-520-160; or

the obligation to practice dentistry in an underserved area or designated state facility for a period of years equal to the number of annual scholarships or loan repayment awards received shall make restitution to the Commonwealth of Virginia.

B2. The recipient has not accepted a placement and commenced his period of obligated practice as provided for in subdivisions 1 and 2 of 12VAC5-520-160; or

Rationale: Simplifies and clarifies wording to make it consistent throughout the regulation.

2. The commissioner in his discretion shall permit extension of the period of payment of restitution plus interest for up to 24 months from the date that the recipient is deemed to be in default.

3. Partial fulfillment of the recipient's contractual obligation by the practice of dentistry as provided for in this contract shall reduce the amount of restitution or payment plus interest due by an amount of money equal to the same percentage of all monetary awards as the number of whole months that the recipient has practiced dentistry in an approved location as a percentage of the total number of months of the contractual obligation the recipient has incurred.

4. Failure of a recipient to make any payment on his debt of restitution plus interest when it is due shall be cause for the commissioner to refer the debt to the Attorney General of the Commonwealth of Virginia for collection. The recipient shall be responsible for any costs of collection as may be provided in Virginia law.

Rationale: Simplifies and clarifies

5-520-200
| 5-520-210 | 2. Each scholarship and loan repayment recipient shall at any time provide information as requested by the commissioner to verify compliance with the practice requirements of the scholarship or loan repayment contract. The recipient shall report any changes of mailing address, change of academic standing, change of intent to fulfill his contractual obligation and any other information that may be relevant to the contract at such time as changes or information may occur. The recipient shall respond within 60 days with such information as may be requested by the commissioner. | 2. Each scholarship and loan repayment recipient shall at any time provide information as requested by the commissioner to verify compliance with the practice requirements of the scholarship or loan repayment contract. The recipient shall report any changes of mailing address, change of academic standing, change of intent to fulfill his contractual obligation and any other information that may be relevant to the contract at such time as changes or information may occur. The recipient shall respond within 30 days with such information as may be requested by the commissioner. |

Rationale: Shortens the length of time that a recipient has to provide information that is essential for the oversight and management of the program.

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**Regulatory flexibility analysis**

Please describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

The regulations and the proposed amendments have no adverse impacts on small businesses.

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**Family impact**

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one’s spouse, and one’s children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.
Many Virginians, mainly in non-metropolitan areas, will benefit from the amendments to the dental scholarship and loan repayment programs. These actions are necessary to improve access to dental specialty and general oral health services and to ensure adequate availability of dental services in areas of Virginia where there are presently insufficient dental services.

Improving access to dental health services is a continuing challenge in many rural areas. Poor dental health has been increasingly linked to general well-being, so improving access to dental health services should not only improve dental health but improve general well-being. Improved access may indirectly serve to strengthen the family.
12VAC5-520-10. Definitions.

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

"Accredited dental school" means any dental school in the United States receiving accreditation from the Commission on Dental Accreditation.

"Accredited residency" means an advanced dental education program in general or specialty dentistry accredited by the Commission on Dental Accreditation and approved by the American Dental Association.

"Board" or "Board of Health" means the State Board of Health.

"Commissioner" means the State Health Commissioner.

"Dental practice" means the practice of dentistry by a recipient in general or specialty dentistry in a geographic area determined to be fulfillment of the recipient's scholarship or loan repayment obligation or practice as a dentist within a designated state facility.

"Dental underserved area" means a geographic area in Virginia designated by the State Board of Health as a county or city in which the ratio of practitioners of dentistry to population is less than that for the Commonwealth as a whole as determined by the commissioner or a dental health professions shortage area using criteria described in Part II (12VAC5-520-80 et seq.) of this chapter.

"Dentist loan repayment award" means an amount repaid to a dentist for dental school loans in an amount equivalent to one year in-state tuition at Virginia Commonwealth University School of Dentistry for the year in which the loan was acquired, and for which the dentist is under a contractual obligation to repay through practice in an underserved area or designated state facility.

"Dentist loan repayment program" means the program established by § 32.1-122.9:1 of the Code of Virginia that allocates funds appropriated in conjunction with the dental scholarship program to increase the number of dentists in underserved areas of Virginia.

"Designated state facility" means practice as a dentist in a facility operated by the Virginia Department of Health, or Virginia Department of Mental Health, Mental Retardation and Substance Abuse Behavioral Health and Developmental Services, Virginia Department of Juvenile Justice or the Virginia Department of Corrections.

"Full-time dental practice" means the practice of dentistry for an average of a minimum of 32 hours per week excluding those exceptions enumerated in Part III (12VAC5-520-130 et seq.) (12VAC5-520-160 et seq.) of this chapter.

"Governing Board of Virginia Commonwealth University" means the official governing body of the university or their designee.

"Interest at the prevailing bank rate for similar amounts of unsecured debt" means the prime lending rate plus 2.0% as published in the Wall Street Journal on the last first day of the month in which the decision to repay is communicated to the commissioner by
the recipient, plus two percentage points or on the first day of the month that the commissioner determines the recipient to be in default.

"Internship or residency at an approved institution or facility" means an advanced dental education program in general dentistry or dental specialty accredited by the Commission on Dental Accreditation and approved by the American Dental Association.

"Loan repayment award" means an award paid to a dentist for dental school loans in an amount equivalent to the current in-state tuition and mandatory fees at Virginia Commonwealth University School of Dentistry and for which the dentist is under a contractual obligation to repay through practice in an underserved area or designated state facility. This amount may be capped at the discretion of the commissioner.

"Participating dental school" means Virginia Commonwealth University School of Dentistry.

"Penalty" means an amount of money equal to three times the amount of all monetary scholarship or loan repayment awards paid to the recipient.

"Period of dental service" means one year of service in a dental underserved area in return for one year of scholarship or loan repayment as defined in Part III (12VAC5-520-130 et seq.) of this chapter.

"Practice of general or specialty dentistry" means the evaluation, diagnosis, prevention and treatment (nonsurgical, surgical or related procedures) of diseases, disorders and conditions of the oral cavity, maxillofacial and adjacent and associated structures and their impact on the human body.

"Primary dental health care" means the practice of general or specialty dentistry.

"Public health service" means employment with the United States Public Health Service.

"Restitution" means the amount of monetary reimbursement, including repayment of all pertinent scholarship or loan repayment awards three times the award amount received plus penalty and applicable interest at the prevailing bank rate for similar amounts of unsecured debt as set forth in this regulation, owed to the Commonwealth of Virginia by a scholarship or loan repayment recipient who is in default of his contractual obligation as provided for in this chapter.

"Scholarship award" means an amount equivalent to one year of in-state tuition and mandatory fees at Virginia Commonwealth University School of Dentistry for the academic year a student is enrolled and for which the dental student entered a contractual obligation to repay through practice in an underserved area or designated state facility. This amount may be capped at the discretion of the commissioner.

"Scholarship recipient" means an eligible dental student who enters into a contract with the commissioner and receives one or more scholarship awards from the Virginia Dental Scholarship Program.

"Specialty practice" means the advanced practice of dentistry in any specialty approved by the American Dental Association and accredited by the Commission on Dental Accreditation.

"Virginia dental scholarship" means an award of an amount equivalent to one year of in-state tuition at Virginia Commonwealth University School of Dentistry for the academic year a student is enrolled in a participating dental school and for which the dental student entered a contractual obligation to repay through practice in an underserved area or designated state facility.

Statutory Authority
§§ 32.1-122.9 and 32.1-122.9:1 of the Code of Virginia.

Historical Notes

12VAC5-520-30. Applicability. (Repealed.)

These definitions shall apply to all recipients who begin practice in an underserved area as fulfillment of their scholarship or loan repayment obligation on July 1, 2001, or later, provided that approval given by the commissioner prior to May 8, 2002, shall remain in full force and effect.

Statutory Authority
§§ 32.1-122.9 and 32.1-122.9:1 of the Code of Virginia.

Historical Notes

Part III
Scholarship and Loan Repayment Awards

12VAC5-520-130. Eligible applicants.

A. Any currently enrolled dental student in good standing and full-time attendance at Virginia Commonwealth University School of Dentistry who has not entered the first year of an accredited residency shall be eligible for the Virginia Dental Scholarship Program. Preference for the scholarship award shall be given to residents of the Commonwealth, students who are residents of a dental underserved area, and students from economically disadvantaged backgrounds.

B. Any graduate of an accredited dental school in the United States who is establishing a practice in general or specialty dentistry in an underserved area or practicing dentistry in a designated state facility shall be eligible to apply for the Virginia Dentist Loan Repayment Program. Eligible applicants General practice dentists will be within five years of graduation from an accredited undergraduate dental program and have existing loans accumulated as a result of their first professional education undergraduate dental program. Dentists who have received dental scholarship program awards and dentists who have accepted Exceptional Financial Need (EFN) and Financial Assistance for Disadvantaged Health Professions Students (FADHPS) scholarships are not eligible for the Dentist Loan Repayment Program. Specialty practice dentists will be within five years of completion of their specialty training and have existing loans accumulated as a result of their undergraduate dental program. Dentists who received Virginia scholarship awards or other scholarships that paid their full tuition and fees are not eligible for the Dentist Loan Repayment Program for the years they received those awards.

Statutory Authority
§§ 32.1-122.9 and 32.1-122.9:1 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 18, Issue 15, eff. May 8, 2002.

12VAC5-520-150. Distribution of scholarships and loan repayment awards.

The Virginia General Assembly establishes the total combined appropriation for the dental scholarship and dentist loan repayment programs. Funds shall be awarded for these programs based on the following criteria:
1. Virginia Commonwealth University School of Dentistry shall establish an use the application procedure established by the commissioner and annually submit the names of qualified students to receive scholarships in accordance with the criteria for preference enumerated in this section 12VAC5-520-130. Dental scholarships will be awarded on or before October 30 of each fiscal year with remaining funds disbursed through the Dentist Loan Repayment Program. The total annual number of scholarship awards will be based on availability of funds. Scholarship awards will be made annually by October 30 to third-year and fourth-year dental students. First-year and second-year students will be considered for an award only in the event of extreme financial need. Individual scholarship recipients may receive a maximum of five scholarship awards.

2. The application period for the Dentist Loan Repayment Program will follow that for the Dental Scholarship Program, begin in October with awards made by January 30 the end of each fiscal year. Preference for loan repayment awards will be given to dental students graduating from graduates of Virginia Commonwealth University School of Dentistry and those with established financial need. Individual loan repayment recipients may receive a maximum of three four awards upon graduation from dental school. All awards will be competitive based on the criteria enumerated in this section and will be based on availability of loan repayment funds once scholarship funds are disbursed.

Statutory Authority
§§ 32.1-122.9 and 32.1-122.9:1 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 18, Issue 15, eff. May 8, 2002.

12VAC5-520-160. Contractual practice obligation.

Prior to the payment of money to a scholarship or loan repayment awardee recipient, the commissioner shall prepare and enter into a contract with the recipient. The contract shall:

1. Provide that the recipient of the dental scholarship award shall pursue the dental course of Virginia Commonwealth University until graduation and upon graduation or upon graduation from an accredited residency program that does not exceed four years, shall notify the commissioner in writing of his proposed practice location or intent to enter a residency not more than 30 days after graduation and begin his approved practice within 90 days after completing dental school or residency, and thereafter continuously engage in full-time dental practice in a dental underserved area of Virginia or in a designated state facility for a period of years equal to the number of annual scholarships received.

2. Provide that upon graduation from an accredited dental school and receiving notification of the dentist loan repayment award, the dentist shall begin his approved practice within 90 days and thereafter continuously engage in full-time dental practice in an underserved area of Virginia or in a designated state facility for a period of years equal to the number of loan repayment awards received.

3. Provide that at any time prior to entering practice, the scholarship or loan repayment recipient shall be allowed to select a future practice location from the listing of dental underserved areas maintained by the board.

4. Provide that the recipient may request approval of a change of practice location. The commissioner in his discretion may approve such a request, but
only if the change is to a practice location in a dental underserved area or a state facility designated by the Board of Health.

5. Provide that the recipient shall repay the scholarship or loan repayment obligation by practicing dentistry on a full-time basis in a dental underserved area, shall maintain office hours convenient for the population of the area to have access to the recipient's services and shall participate in all government-sponsored insurance programs designed to ensure access to dental services of recipients of public assistance. The recipient shall not selectively place limits on the numbers of such patients admitted to the practice.

6. Provide that the recipient shall not voluntarily obligate himself for more than the minimum period of military service required of dentists by the laws of the United States and that upon completion of the minimum period of military service, the recipient shall promptly begin and thereafter continuously engage in full-time dental practice in a dental underserved area of Virginia or in a designated state facility for the period of years equal to the number of scholarships received. Dental practice in federal agencies, military service or the U.S. Public Health Service may not be substituted for scholarship obligation.

7. Provide that the recipient shall receive credit toward fulfillment of his contractual obligation at the rate of 12 months of dental practice for each scholarship or loan repayment award paid to the recipient. The recipient may be absent from the place of approved practice for a total of seven four weeks in each 12-month period for personal reasons. Absence for a period in excess of seven four weeks without the written permission of the commissioner shall result in proportional reduction of the period of credit toward fulfillment of the contractual obligation.

8. Provide that should the scholarship recipient pay restitution by not serving his scholarship obligation in a dental underserved area, and later within five years of paying restitution fulfills the terms of his contract through dental practice as outlined in this section, that the recipient will be reimbursed for all or part of any scholarship amount award paid based on the fulfillment of the scholarship and availability of funds.

Statutory Authority

§§ 32.1-122.9 and 32.1-122.9:1 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 18, Issue 15, eff. May 8, 2002.

Part V

Special Circumstances

12VAC5-520-180. Fractional need.

The Board of Health recognizes that instances will occur when the ratio of dental practitioners to population reflects a fractional share of need. In such instances and in recognition of the advantages that accrue to the dentist and the community from two or more dentists working in an associated or cooperative basis, the commissioner may in his discretion favorably consider the approval of an additional dentist in order to facilitate such an arrangement.

Statutory Authority

§§ 32.1-122.9 and 32.1-122.9:1 of the Code of Virginia.

Historical Notes
12VAC5-520-190. Default.

A. With respect to default, the contract shall provide that a scholarship or loan repayment recipient who fails to fulfill his obligation to practice dentistry as described in 12VAC5-520-160 shall be deemed in default under the following circumstances and shall forfeit all monetary scholarship or loan repayment awards made to him and shall make repayment of those funds plus interest plus penalty, where applicable to repay the Commonwealth of Virginia as provided for in this chapter. The contract shall:

1. Provide that if the scholarship recipient defaults while still in dental school, by voluntarily notifying the commissioner in writing that he will not practice dentistry in a Virginia dental underserved area as required by his contract, by voluntarily not proceeding to the next year of dental education, or by withdrawing from dental school, the student shall pay the Commonwealth of Virginia all monetary scholarship awards plus interest at the prevailing bank rate for similar amounts of unsecured debt.

2. Provide that the scholarship recipient who defaults by failing to maintain grade levels that will allow the dental student to graduate, or by reason of his dismissal from dental school for any reason, shall repay the Commonwealth of Virginia all monetary scholarship awards plus interest at the prevailing bank rate for similar amounts of unsecured debt.

3. Provide that if the scholarship or loan repayment recipient is in default due to death or permanent disability so as not to be able to engage in dental practice, the recipient or his personal representative shall repay the Commonwealth all monetary scholarship awards plus 8.0% interest on the amount of the award. Partial fulfillment of the recipient's contractual obligation by the practice of dentistry as provided for in this contract prior to death or permanent disability shall reduce the amount of repayment plus interest due by a proportionate amount of money, such proportion being determined as the ratio of the number of whole months that a recipient has practiced dentistry in an approved location to the total number of months of the contractual obligation the recipient has incurred. The commissioner may waive all or part of the scholarship or loan repayment obligation under application by the recipient or his estate under these conditions and consider whole or partial forgiveness of payment or service in consideration of individual cases of extraordinary hardship or inability to pay.

4. Provide that any recipient of a scholarship or loan repayment who defaults by evasion or refusal to fulfill the obligation to practice dentistry in an underserved area or designated state facility for a period of years equal to the number of annual scholarships or loan repayment awards received shall make restitution by repaying all monetary scholarship or loan repayment awards plus penalty plus interest to the Commonwealth of Virginia.

B. A scholarship or loan repayment recipient will be considered to be in such default on the date:

1. The commissioner is notified in writing by the recipient that he does not intend to fulfill his contractual obligation;
2. The recipient has not accepted a placement and commenced his period of obligated practice as provided for in subdivision 1 and 2 of 12VAC5-520-160; or

3. The recipient absents himself without the consent of the commissioner from the place of dental practice that the commissioner has approved for fulfillment of his contractual obligation.

Statutory Authority
§§ 32.1-122.9 and 32.1-122.9:1 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 18, Issue 15, eff. May 8, 2002.

Part VII
Repayment

12VAC5-520-200. Repayment.
Repayment requirements for scholarship and loan repayment recipients are as follows:

1. Payment of restitution or repayment of award plus interest shall be due on the date that the recipient is deemed by the commissioner to be in default.

2. The commissioner in his discretion shall permit extension of the period of payment of restitution plus interest repayment for up to 24 months from the date that the recipient is deemed to be in default.

3. Partial fulfillment of the recipient's contractual obligation by the practice of dentistry as provided for in this contract shall reduce the amount of restitution or payment plus interest due by an amount of money equal to the same percentage of all monetary awards as a percentage based on the number of whole months that the recipient has practiced dentistry in an approved location and the total number of months of the contractual obligation the recipient has incurred.

4. Failure of a recipient to make any payment on his debt of restitution plus interest when it is due shall be cause for the commissioner to refer the debt to the Attorney General of the Commonwealth of Virginia for collection. The recipient shall be responsible for any costs of collection as may be provided in Virginia law.

Statutory Authority
§§ 32.1-122.9 and 32.1-122.9:1 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 18, Issue 15, eff. May 8, 2002.

Part VIII
Records and Reporting

12VAC5-520-210. Reporting requirements.
Reporting requirements of Virginia Commonwealth University School of Dentistry scholarship and loan repayment recipients are as follows:

1. Virginia Commonwealth University School of Dentistry shall maintain accurate records of the status of scholarship recipients until the recipient's graduation from dental school. The dental school shall provide a report listing the status of each recipient annually to the commissioner.
2. Each scholarship and loan repayment recipient shall at any time provide information as requested by the commissioner to verify compliance with the practice requirements of the scholarship or loan repayment contract. The recipient shall report any changes of mailing address, change of academic standing, change of intent to fulfill his contractual obligation and any other information that may be relevant to the contract at such time as changes or information may occur. The recipient shall respond within 60 30 days with such information as may be requested by the commissioner.

Statutory Authority
§§ 32.1-122.9 and 32.1-122.9:1 of the Code of Virginia.

Historical Notes
Derived from Virginia Register Volume 18, Issue 15, eff. May 8, 2002.