

**State of Board of Health
Agenda
March 16, 2017 – 9:00 a.m.
Perimeter Center – Boardroom 2**

Call to Order and Welcome	Bruce Edwards, Chair
Pledge of Allegiance	Faye Prichard
Introductions	Mr. Edwards
Review of Agenda	Joseph Hilbert Director of Governmental and Regulatory Affairs
Approval of September 15, 2016 Minutes	Mr. Edwards
Approval of October 24, 2016 Minutes	Mr. Edwards
Approval of December 1, 2016 Minutes	Mr. Edwards
Commissioner’s Report	Marissa Levine, MD, MPH, FAAFP State Health Commissioner
Budget Update	Steve Sullivan, Deputy Director Office of Financial Management
Break	
Legislative Update	Mr. Hilbert
Abortion Facility Licensure Status Report	Erik Bodin, Director Office of Licensure and Certification
Regulatory Action Update	Mr. Hilbert
Public Comment Period	
Working Lunch	
Lunch Speakers – Gary Brown, Director, Office of Emergency Medical Services Gary Critzer, Chair, State Emergency Medical Services Advisory Board Michel Aboutanos, MD, MPH, Chair, Trauma System Oversight & Management Committee	
Topic – Overview of Statewide EMS and Trauma Systems	
<u>Board Action Item</u>	
State Emergency Medical Services Plan (§ 32.1-111.3 of the Code of Virginia)	Gary Brown, Director Office of Emergency Medical Services

Regulatory Action Items

Virginia Radiation Protection
Regulations: Fee Schedule
12VAC5-490
(Final Amendments, X-Ray Device
Registration and Inspection Fees)

Steve Harrison, Director
Office of Radiological Health

Regulations for Physician Assistant
Scholarship Program
12VAC5-525
(Final Regulations)

Dr. Adrienne McFadden, Director
Office of Health Equity

Regulations Governing the Dental
Scholarship and Loan Repayment Programs
12VAC5-520
(Proposed Amendments)

Dr. Vanessa Walker Harris, Director
Office of Family Health Services

Virginia's Rules and Regulations Governing
Cooperative Agreements
12VAC5-221
(Fast Track Regulations)

Mr. Bodin

Regulations for the Licensure of
Nursing Facilities
12VAC5-371
(Fast Track Amendments)

Mr. Bodin

Appointment of Nominating Committee

Mr. Edwards

Member Reports

Other Business

Adjourn



COMMONWEALTH of VIRGINIA
Department of Health

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State Health Commissioner

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February 16, 2017

Bruce W. Edwards, MPA, NRP, Chair
Virginia State Board of Health
109 Governor Street
Richmond, Virginia 23219

Dear Mr. Edwards:

Section 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 nineteen objectives outlined in § 32.1-111.3.

OEMS, in coordination with the Executive Committee of the State EMS Advisory Board, the Legislative and Planning (L&P) 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), the Institute of Medicine (IOM) Report “EMS at the Crossroads”, as well as the Five Year Strategic Plan of the Federal Interagency Committee on EMS (FICEMS) were included in the development and 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 its November 9, 2016 meeting.

As the Code of Virginia mandates, this plan must be reviewed, updated, and published by the Virginia State Board of Health. Progress on achieving the objectives of each strategic initiative in the state EMS Plan will be reported to the state EMS Advisory Board on an annual basis, and to the Board of Health upon request.

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. Any questions related to this document can be forwarded to Tim Perkins, EMS Systems Planner, at 804.888.9100, or tim.perkins@vdh.virginia.gov.

Sincerely,

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

VIRGINIA OFFICE OF EMERGENCY MEDICAL SERVICES STATE STRATEGIC AND OPERATIONAL PLAN



2017 – 2019

VIRGINIA OFFICE OF EMS STATE STRATEGIC AND OPERATIONAL PLAN
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VIRGINIA OFFICE OF EMS STATE STRATEGIC AND OPERATIONAL PLAN

INTRODUCTION

Section 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) which shall incorporate, but not be limited to, the plans prepared by the regional emergency medical services councils. 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 nineteen objectives outlined in Section 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 reports, namely the Joint Legislative Audit and Review Commission (JLARC), and the Institute of Medicine (IOM) Report "EMS at the Crossroads". The recommendations made in these documents 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. Additionally, OEMS is prepared to report on the progress of the plan to the Board of Health or other interested parties upon request, and through the OEMS Annual Reports, and Service Area Plans as required by VDH, and the Code of Virginia.

This operational plan identifies the specific initiatives required of the OEMS staff in executing the 2017 – 2019 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 is not included in the Operational Plan.

No later than three (3) months prior to the end of each 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.

In most cases "accountability" should be the name of a person, division, or entity that has the lead responsibility for the implementation of the objective or action step. The plan will be reviewed quarterly, and only those objectives and items relevant to the time frame will be a part of the review. Any changes in the objective or action steps should be noted in writing on the form at that time.

Definitions of acronyms included in the plan can be found on **pages 5 and 6**.

VIRGINIA OFFICE OF EMS STATE STRATEGIC AND OPERATIONAL PLAN

Virginia Office of Emergency Medical Services Mission Statement

To reduce death and disability resulting from sudden or serious injury and illness in the Commonwealth through planning and development of a comprehensive, coordinated statewide EMS system; and provision of other technical assistance and support to enable the EMS community to provide the highest quality emergency medical care possible to those in need.

Virginia Office of Emergency Medical Services Vision Statement

To establish a unified, comprehensive and effective EMS system for the Commonwealth of Virginia that provides for the health and safety of its citizens and visitors.

What is the Emergency Medical Services system in Virginia?

The Virginia Emergency Medical Services (EMS) system is very large and complex, involving a wide variety of EMS agencies and personnel, including volunteer and career providers functioning in volunteer rescue squads, municipal fire departments, commercial ambulance services, hospitals, and a number of other settings to enable the EMS community to provide the highest quality emergency medical care possible to those in need. Every person living in or traveling through the state is a potential recipient of emergency medical care.

The Virginia Department of Health, Office of Emergency Medical Service (OEMS) is responsible for development of an efficient and effective statewide EMS system. The EMS System in Virginia is designed to respond to any and all situations where emergency medical care is necessary. This is accomplished through a coordinated system of over 35,000 trained, prepared and certified providers, nearly 4,500 permitted EMS vehicles, and over 680 licensed EMS agencies, to provide ground and air emergency medical care to all people in the Commonwealth of Virginia.

VIRGINIA OFFICE OF EMS STATE STRATEGIC AND OPERATIONAL PLAN

Glossary of Commonly Used Acronyms

AEMS	Atlantic EMS Council (PA, WV, NJ, DE, MD, VA, DC, NC)
AHA	American Heart Association
AMS	Air Medical Services
COOP	Continuity Of Operations Plan
DGS	Virginia Department of General Services
DBDHS	Department of Behavioral Health and Developmental Services
DW	VDH Data Warehouse
EMSC	EMS For Children
FARC	Financial Assistance Review Committee (Subcommittee of state EMS Advisory Board)
FCC	Federal Communications Commission
FICEMS	Federal Interagency Committee on EMS
HMERT	Health and Medical Emergency Response Team
LZ	Landing Zone
MCI	Mass Casualty Incident
MDC	Medical Direction Committee (Subcommittee of state EMS Advisory Board)
NASEMSO	National Association of State EMS Officials
NEMSIS	National EMS Information System
NFFF	National Fallen Firefighters Foundation
OEMS	Virginia Office of EMS
OMD	Operational Medical Director
OMHHE	Virginia Office of Minority Health and Health Equity
PDC	Professional Development Committee (Subcommittee of state EMS Advisory Board)
PSAP	Public Service Answering Point
PSHS	Secretary of Public Safety and Homeland Security
RC	Virginia's Regional EMS Councils
RSAF	Rescue Squad Assistance Fund
TCC	Training and Certification Committee
TSO&MC	Trauma System Oversight and Management Committee (Subcommittee of state EMS Advisory Board)
VAGEMSA	Virginia Association of Governmental EMS Administrators
VAVRS	Virginia Association of Volunteer Rescue Squads
VDEM	Virginia Department of Emergency Management
VDFP	Virginia Department of Fire Programs
VDH	Virginia Department of Health
VFCA	Virginia Fire Chiefs Association

VIRGINIA OFFICE OF EMS STATE STRATEGIC AND OPERATIONAL PLAN

Glossary of Commonly Used Acronyms (Cont.)

VHAC	Virginia Heart Attack Coalition
VHHA	Virginia Hospital and Healthcare Association
VPFF	Virginia Professional Firefighters
VPHIB	Virginia Pre Hospital Information Bridge
VSP	Virginia State Police
VSTR	Virginia State Trauma Registry
WDC	Workforce Development Committee (Subcommittee of state EMS Advisory Board)

FINAL DRAFT

VIRGINIA OFFICE OF EMS STATE STRATEGIC AND OPERATIONAL PLAN

Planning Strategy Matrix

Strategic Initiative 1.1- Promote Collaborative Approaches			
Objectives	Accountability	Action Steps	
Core Strategy 1: Develop Partnerships	1.1.1 Use technology to provide accurate and timely communication within the Virginia EMS System	OEMS, Regional EMS Councils (RC)	1.1.1.1 Track and report on amount and general content of material posted to OEMS and Regional EMS Council websites and social media on a monthly and quarterly basis.
	1.1.2 Promote collaborative activities between local government, EMS agencies, and hospitals, and increase recruitment and retention of certified EMS providers.	OEMS, System stakeholders	1.1.2.1. Develop method to measure the number of new EMS providers recruited via recruitment and retention programs and activities. 1.1.2.2. Revise “Keeping The Best!” programs for online access. 1.1.2.3. Maintain informational items regarding benefits and incentives for local governments to provide to volunteer fire and EMS providers. 1.1.2.4. Educate and familiarize local government officials on the importance in taking a greater role in EMS planning and coordination.
	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.	OEMS, State Agencies (VDEM, PSHS, VSP, VDFP), RC, System Stakeholders.	1.1.3.1. Encourage agencies and providers to visit OEMS web page regularly, subscribe to OEMS e-mail list, and access OEMS social media sites. 1.1.3.2. Encourage stakeholder use of OEMS Provider and Agency Portals.
	1.1.4 Identify resources and/or opportunities to work collaboratively with other state agencies, organizations, and associations to improve processes and patient outcomes.	OEMS	1.1.4.1. Attend meetings of, and exchange knowledge with, the National Association of State EMS Officials. 1.1.4.2. Encourage appropriate state agencies and organizations to participate in meetings and activities hosted or sponsored by OEMS. 1.1.4.3. Collaboration among Air Medical Services (AMS) entities to ensure systems enhancements.

VIRGINIA OFFICE OF EMS STATE STRATEGIC AND OPERATIONAL PLAN

Strategic Initiative 1.1- Promote Collaborative Approaches (Cont.)			
	Objectives	Accountability	Action Steps
Core Strategy 1: Develop Partnerships	1.1.5 Promote data sharing projects which benefit internal and external projects.	OEMS	1.1.5.1. Further data sharing, including the most recent version of NEMSIS, among the highway safety community, as well as internal and external stakeholders. 1.1.5.2 Utilize the national EMS database to monitor national data trends. 1.1.5.3 Provide a means for VDH bio-surveillance programs to utilize VPHIB data.

Strategic Initiative 1.2 – Coordinate responses to emergencies both natural and man-made.			
	Objectives	Accountability	Action Steps
Core Strategy 1: Develop Partnerships	1.2.1 Support, coordinate and maintain deployable emergency response resources.	OEMS, VDEM	1.2.1.1. Create recruiting and selection process for resource management team. 1.2.1.2 Work with partner agencies to develop mission ready packages and the process for implementation and use.
	1.2.2 Increase knowledge of Emergency Operations capabilities with Emergency Managers, leaders, and supervisors on a local, regional, and state level.	OEMS	1.2.2.1. Continue to promote Emergency Operations resources, training courses, and abilities to localities across the Commonwealth.
	1.2.3 Assist EMS agencies to prepare and respond to natural and man-made emergencies (including pandemic diseases) 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.	OEMS, VDEM	1.2.3.1. Create and promote planning templates aimed at EMS agencies, specifically related to COOP, Emergency Preparedness, and response concerns (MCI, Surge Planning, etc.)

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Strategic Initiative 2.1 - Sponsor EMS related research and education.

	Objectives	Accountability	Action Steps
Core Strategy 2: Create Tools and Resources	2.1.1 Encourage research and other projects that contribute to high quality EMS and improve patient outcomes utilizing data collected by the EMS Registries.	OEMS	2.1.1.1. Provide state and regional EMS data summaries, and compare with other similar state EMS data. 2.1.1.2. Develop VSTR and VPHIB research data set to be available for entities upon request and that have obtained institutional review board approval. 2.1.1.3. Support the development, implementation, and evaluation of evidence-based guidelines (EBGs) according to the National Prehospital EBG Model Process 2.1.1.4. Promote standardization and quality improvement of prehospital EMS data by supporting the adoption and implementation of NEMSIS-compliant systems 2.1.1.5. Improve linkages between NEMSIS data, VDH data warehouse and other databases, registries, or other sources to measure system effectiveness and improve clinical outcomes
	2.1.2 Determine quality of EMS service and conduct analysis of trauma triage effectiveness.	OEMS, Designated Trauma Centers, TSO & MC, RC	2.1.2.1. Trauma Performance Improvement Committee and/or EMS staffs will provide quarterly reports to the regional trauma committees via their representative on the TSO&MC that identify over and under triage events due on the established schedule that OEMS staff submits its contribution to the EMS Quarterly Report to the EMS Advisory Board. The statewide version of this quarterly report shall be included in the quarterly report and posted on the OEMS Web site. 2.1.2.2. Develop and implement OEMS component of VDH Data Warehouse (DW) <ul style="list-style-type: none"> • Use DW to integrate VPHIB and VSTR • Use DW to access and integrate VHI and Vital Statistics data OEMS databases. • Provide agency-wide access to EMS data to be used in other public health efforts. 2.1.2.3. Use the DW to support bio-surveillance projects being performed within the VDH.
	2.1.3 Evaluate challenges that impact the workforce on service provision around the State.	OEMS, Workforce Development Committee (WDC), VAGEMSA, VAVRS	2.1.3.1. Assess demographic and profile characteristics of EMS Providers in Virginia through EMS Provider Portal. 2.1.3.2. Utilize EMS databases to evaluate information related to challenges that impact the workforce in the provision of EMS service.

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Strategic Initiative 2.2 - Supply quality education and certification of EMS personnel.

Objectives	Accountability	Action Steps
2.2.1 Ensure adequate, accessible, and quality EMS provider training and continuing education exists in Virginia.	OEMS, TCC, Regional EMS Councils	2.2.1.1. Widely publicize the availability of and ensure adequate, accessible and quality EMS provider training and continuing education through course offerings held across the state. 2.2.1.2. Review student disposition on a bi-annual basis, identifying areas of concern for TCC input and possible corrective action. 2.2.1.3 Provide continued support for an annual multi-disciplinary EMS Symposium (i.e. Virginia EMS Symposium) as a primary statewide EMS system continuing education event.
2.2.2 Enhance competency based EMS training programs.	OEMS, TCC, MDC	2.2.2.1. Compare and contrast traditional versus competency based programs. 2.2.2.2 Identify and document aspects from competency based programs that directors feel enhance their programs as compared to the traditional approach.
2.2.3 Align all initial EMS education programs to that of other allied health professions to promote professionalism of EMS.	OEMS, TCC, MDC, Board of Health Professions	2.2.3.1. Proactively promote Advanced Level EMT Training (AEMT)
2.2.4 Increase the amount and quality of pediatric training and educational resources for EMS providers, and emergency department staff in Virginia.	OEMS, EMSC Committee, VHHA	2.2.4.1. Purchase and distribute pediatric training equipment for EMS agencies. 2.2.4.2. Sponsor pediatric training related instructor courses. 2.2.4.3. Provide support for speakers and topics at the annual VA EMS Symposium. 2.2.4.4 Participate in the National Pediatric Readiness Project.
2.2.5 Assure an adequate amount and quality of geriatric training and educational resources for EMS providers, emergency department staff and primary care providers in Virginia.	OEMS, TCC, MDC	2.2.5.1. Sponsor geriatric training related instructor courses. 2.2.5.2. Provide support for speakers and topics at the annual VA EMS Symposium.
2.2.6 Assure an adequate amount and quality of crisis/behavioral health training and educational resources for EMS providers.	OEMS, TCC, MDC, RC, Virginia Department of Behavioral Health and Developmental Services (VBHDS)	2.2.6.1 Coordinate and sponsor crisis/behavioral health courses for instructors and students throughout the Commonwealth. 2.2.6.2 Provide support for speakers and topics at the annual VA EMS Symposium.

**Core Strategy 2:
Create Tools and Resources**

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Strategic Initiative 3.1 - EMS Regulations, Protocols, Policies, and Standards		
Objectives	Accountability	Action Steps
3.1.1 Review and assess state and federal legislation related to the EMS system.	OEMS, Rules and Regulations Committee, Legislation and Planning Committee	3.1.1.1. Review legislation to determine impact of legislation on VA EMS system. 3.1.1.2. Gather legislative news and interest items from NASEMSO, and NAEMSP, FICEMS, and related organizations.
3.1.2 Establish statewide Air/Ground Safety Standards.	OEMS, State Medevac Committee	3.1.2.1. Identify and adopt universal safety standards. 3.1.2.2. Maintain weather turn down system. 3.1.2.3. Establish standard safety protocols and training based on protocols. 3.1.2.4. Standardize air/ground safety standards. 3.1.2.5. Standardize LZ procedures. 3.1.2.6. Maintain process for consistent use of air to air communication.
3.1.3 Develop criteria for a voluntary Virginia Standards of Excellence Recognition Program for EMS Agencies.	OEMS, Workforce Development Committee	3.1.3.1. Promote and incentivize voluntary accreditation standards. 3.1.3.2. Implement and market program to interested agencies. 3.1.3.3. Evaluate efficacy of program based on feedback of EMS agency officials and Technical Assistance Teams.
3.1.4 Maintain and enhance the Trauma Center designation process.	OEMS, TSO & MC, EMSC	3.1.4.1. Maintain the trauma designation criteria to include American College of Surgeons (ACS) Trauma Center standards. 3.1.4.2. Conduct an analysis to determine the benefits of adding Level IV designation to the trauma care system, based on public need.
3.1.5 Maintain and enhance the Regional EMS Council designation process.	OEMS	3.1.5.1. Evaluate the structure of the designation process. 3.1.5.2. Incorporate input of applicants and evaluators into next round of designations. 3.1.5.3. Conduct re-designation of councils.
3.1.6 Establish standardized methods and procedures for the inspection and licensing and/or permitting of all EMS agencies and vehicles, including equipment and supply requirements.	OEMS, Transportation Committee	3.1.6.1. Development of standard inspection checklist, to include all aspects of agency and EMS vehicle inspection.
3.1.7 Through a consensus process, develop a recommendation for evidence-based patient care guidelines and formulary.	OEMS, State EMS Medical Director, MDC, Board of Pharmacy.	3.1.7.1. Resource document being developed to assist regional medical directors, agency medical director and agency personnel as patient care guidelines and protocols are produced.

Core Strategy 3: Develop Infrastructure

VIRGINIA OFFICE OF EMS STATE STRATEGIC AND OPERATIONAL PLAN

Strategic Initiative 3.2 - Focus recruitment and retention efforts

	Objectives	Accountability	Action Steps
Core Strategy 3: Develop Infrastructure	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.	OEMS, State EMS Medical Director, MDC, WDC, FARC, RC	3.2.1.1. Continue to support “VA EMS Jobs” website. 3.2.1.2. Develop and implement voluntary “Standards of Excellence” for EMS agencies. 3.2.1.3. Maintain Leadership & Management Track at the VA EMS Symposium, and recommend topics and presenters. 3.2.1.4. Continue to promote and support special RSAF applications related to recruitment and retention of EMS providers. 3.2.1.5 Review and promote the OMD Workshop Curriculum. 3.2.1.6 Support the transition of military EMS providers to civilian practice.
	3.2.2 Support and expand the Virginia Recruitment and Retention Network.	OEMS, WDC	3.2.2.1. Continue to support information and education for distribution. 3.2.2.2. Seek new avenues for EMS recruitment outreach. 3.2.2.3. Recommend strategies to expand existing programs and distribute to EMS stakeholders.
	3.2.3 Develop, implement, and promote EMS leadership programs, utilizing best practices.	OEMS, WDC	3.2.3.1. Develop and promote leadership programs to assist EMS agencies to provide high quality leadership to include all levels of the EMS Officer training program. 3.2.3.2. Develop and/or review leadership criteria and qualifications for managing an EMS agency. 3.2.3.3. Develop model job descriptions for EMS Officers. 3.2.3.4. Test efficacy of standards annually.

Strategic Initiative 3.3 – Upgrade technology and communication systems

	Objectives	Accountability	Action Steps
Core Strategy 3	3.3.1 Assist with, and promote, the compliance of all emergency medical communications systems with state and federal regulations for interoperability.	OEMS, Communications Committee	3.3.1.1. Continue to ensure that all emergency medical communications systems meet state and federal regulations.
	3.3.2 Promote emergency medical dispatch standards and accreditation among 911 Public Safety Answering Points (PSAPs) in Virginia.	OEMS, Communications Committee	3.3.2.1. Support concept of accredited PSAPs, operating with emergency medical dispatch (EMD) standards, and assist agencies in achieving accreditation, and/or adopting EMD as standard operating procedure.
	3.3.3 Provide technical assistance on-communication products available for use in the emergency medical community.	OEMS, Communications Committee	3.3.3.1. Support new products and technologies, state and federal interoperability initiatives, including First Net, and serve as information conduit to entities.

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Strategic Initiative 3.4 – EMS Funding			
	Objectives	Accountability	Action Steps
Core Strategy 3: Develop Infrastructure	3.4.1 Standardize EMS grant review and grading process by graders at regional and state level.	OEMS, FARC	3.4.1.1. Revise RSAF grant review sheet developed by FARC and OEMS Staff, and continue to evaluate for efficacy. 3.4.1.2. Solicit and consider concerns/comments of regional EMS councils/stakeholders regarding the grant process.
	3.4.2 Explore feasibility of creating EMS consortium for purchase of EMS equipment and supplies.	OEMS, FARC, Transportation Committee	3.4.2.2. Collaborate with DGS and other stakeholders in developing a resource guide, and distribute to potential grant applicants.
	3.4.3 Develop uniform pricing schedule for state funded items.	OEMS, FARC	3.4.3.1. Determine items that can be standardized. 3.4.3.2. Distribute schedule to potential grant applicants.
	3.4.4 Develop standard specifications for state grant funded equipment awarded to eligible non-profit EMS agencies.	OEMS, FARC, VDH Office of Purchasing and General Services	3.4.4.1. Develop and maintain list of eligible equipment and vehicles that agencies are eligible to purchase using state grant funds. 3.4.4.2. Utilize standard equipment and vehicle lists for future grant applications and cycles.
	3.4.5 Assist EMS agencies to identify grant programs and funding sources for EMS equipment, training, and supplies.	OEMS, FARC	3.4.5.1. Continue to promote RSAF program through Regional EMS Councils. 3.4.5.2. Identify grant opportunities that EMS agencies may be eligible for, and distribute information to EMS system.
	3.4.6 Integrate state grant funding programs with other related grant funding programs.	OEMS, FARC	3.4.6.1. Continue to seek federal and other grant funds for items intended to improve the statewide EMS system.
	3.4.7 Develop guidance documents to assist EMS agencies account for the use of state grant funds and develop internal audit processes.	OEMS, FARC	3.4.7.1. Work with contracted audit firms and Office of Internal Audit to create reference documents to assist agencies to account for grant funds, and ensure sound auditing practices.

Strategic Initiative 3.5 – Enhance regional and local EMS efficiencies			
	Objectives	Accountability	Action Steps
Core Strategy 3	3.5.1 Standardize performance and outcome based service contracts with designated Regional EMS Councils and other qualified entities.	OEMS, RC	3.5.1.1. Maintain annual service contracts with Regional EMS Councils. 3.5.1.2. Provide standard contracts, plan templates, and other reference documents to Regional EMS Councils in each fiscal year. 3.5.1.3. Provide input on contract deliverables to Regional EMS Councils on a quarterly basis.
	3.5.2 Improve regulation and oversight of air medical services (AMS) statewide.	OEMS, State Medevac Committee, Rules & Regulations Committee, MDC	3.5.2.1. Revise/implement state AMS regulations. More clearly define licensure requirements for AMS agencies. 3.5.2.2. Establish response areas for AMS agencies. 3.5.2.3. Develop criteria for ongoing AMS PI program.

VIRGINIA OFFICE OF EMS STATE STRATEGIC AND OPERATIONAL PLAN

Strategic Initiative 3.5 – Enhance regional and local EMS efficiencies (Cont.)			
	Objectives	Accountability	Action Steps
Core Strategy 3	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.	OEMS, WDC OMHHE	3.5.3.1. Give presentations at Virginia Association of Counties (VACO) and Virginia Municipal League (VML) meetings, to educate local government officials about EMS. 3.5.3.2. Contribute EMS related articles and news items to periodic publications of VACO and VML.

Strategic Initiative 4.1 – Assess compliance with EMS performance driven standards.			
	Objectives	Accountability	Action Steps
Core Strategy 4	4.1.1 Maintain statewide data-driven performance improvement process.	OEMS, MDC	4.1.1.1. Utilize VDH resources to conduct risk adjusted data analysis of patients in cooperation with our stakeholders. 4.1.1.2. Develop an EMS performance improvement program.
	4.1.2 Maintain statewide pre-hospital and inter-hospital triage/patient management plans.	OEMS, TSO & MC, State EMS Medical Director, MDC, RC	4.1.2.1. Maintain statewide stroke triage, and trauma triage plans to include regional plan development and maintenance by regional EMS councils. 4.1.2.2. Supply state level data to assist with monitoring individual regional performance compared to state and national benchmarks. 4.1.2.3. Actively participate with organizations, such as AHA that addresses pre-hospital and inter-hospital triage/patient management.

VIRGINIA OFFICE OF EMS STATE STRATEGIC AND OPERATIONAL PLAN

Strategic Initiative 4.1 – Assess compliance with EMS performance driven standards. (Cont.)			
	Objectives	Accountability	Action Steps
Core Strategy 4: Assure Quality and Evaluation	4.1.3 Review and evaluate data collection and submission efforts.	OEMS, MDC	4.1.3.1. Develop standard reports within VPHIB that will allow individual EMS agencies to view the quality of data being submitted. 4.1.3.2. Provide quality “dashboards” where education can improve data quality and update validity rules within the application when education alone cannot correct poor data. 4.1.3.3. Provide quarterly compliance reports to the OEMS, Division of Regulation and Compliance and Executive Management.
	4.1.4 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.	OEMS, Rules & Regulations Committee, Transportation Committee, Health & Safety Committee	4.1.4.1. Evaluation of national/international documents and information related to vehicle and provider safety, with potential incorporation into EMS regulation and inspection procedure.
	4.1.5 Measure EMS system compliance utilizing national EMS for Children (EMSC) performance measures.	OEMS, EMSC	4.1.5.1. Continue to assess the pediatric emergency care readiness of Virginia Emergency Departments.

Strategic Initiative 4.2 – Assess and enhance quality of education for EMS providers.			
	Objectives	Accountability	Action Steps
Core Strategy 4: Assure Quality and Evaluation	4.2.1 Update the certification process to assure certification examinations continue to be valid, psychometrically sound, and legally defensible.	OEMS, TCC	4.2.1.1. Review and revision of psychomotor examination by TCC as needed. 4.2.1.2. Review statistical data and make recommendations for the EC recertification exam.
	4.2.2 Assure adequate and appropriate education of EMS students.	OEMS, TCC, AEMS	4.2.2.1. Review state statistics for certification rates and assist in determining avenues to improve outcomes and implement new processes. 4.2.2.2. Improve instructor compliance with student registration 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.	OEMS, TCC	4.2.3.1. Explore possibility of administering a program summative practical exam in lieu of state practical exam.

VIRGINIA OFFICE OF EMS STATE STRATEGIC AND OPERATIONAL PLAN

Strategic Initiative 4.3 – Pursue initiatives that support EMS

Core Strategy 4: Assure Quality and Evaluation	Objectives	Accountability	Action Steps
	4.3.1 Engage the EMS system in unintentional injury, illness, and violence prevention efforts.	OEMS, Health & Safety Committee, VDH – Div. of Injury and Violence Prevention	4.3.1.1. Participate in intentional and unintentional injury and illness prevention initiatives, and facilitate involvement for EMS agencies and providers. 4.3.1.2 Review VPHIB statistics regarding Line of Duty Death and Line of Duty Injury, and develop prevention materials.
	4.3.2 Develop, implement, and promote programs that emphasize safety, health, and wellness of first responders.	OEMS, TCC, MDC, DBHDS, VDFP, VFCA, VAVRS, VAGEMSA, VPPF, NFFF, RC	4.3.2.1. Maintain OEMS staff support of quarterly meetings of the Health and Safety Committee of the state EMS Advisory Board. 4.3.2.2 – Identify, develop, and distribute safety, health, and wellness programs aimed at first responders, such as Traffic Incident Management, suicide prevention, and EMS fatigue. 4.3.2.3. Ensure health, safety, and wellness training is available at stakeholder conferences, and recommend topics and presenters. 4.3.2.4. Maintain Governor’s EMS Award category for contribution to the EMS system related to the health and safety of EMS providers.
	4.3.3. Research and disseminate information on best practices as it relates to EMS response to active shooter and hostile environment incidents.	OEMS, Health & Safety Committee, State EMS Medical Director, VSP, DFP, RC	4.3.3.1 Develop and maintain website providing information on best practices related to response procedures, policies, team equipment, and other issues related to EMS involvement in active shooter/hostile environment response. 4.3.3.2 – Work with partner agencies to encourage public safety relationships at the local level to enhance response to active shooter/hostile environment incidents.
	4.3.4. Research and disseminate information on best practices as it relates to community risk reduction programs targeted toward improving population health.	All EMS Stakeholder groups	4.3.4.1 Develop partnerships with public and private entities to expand opportunities to improve population health. 4.3.4.2 Develop and promote programs, such as mobile integrated healthcare, targeted toward improving population health.

VIRGINIA OFFICE OF EMS STATE STRATEGIC AND OPERATIONAL PLAN

Appendix A – Sample Planning Matrix

Strategic Initiative			
<i>Objectives</i>		<i>Accountability</i>	<i>Action Steps</i>
Core Strategy			

Appendix B – Glossary of Terms

Glossary of Terms

Action Step: A specific action required to carry out an objective.

Core Strategy: A main thrust or action that will move the organization towards accomplishing your vision and mission.

Operational Plan: This is the plan that implements the strategic intent of the organization on an annual basis.

Objective: A specific, realistic and measurable statement under a strategic initiative.

Strategic Initiative: An action that will address areas needing improvement or set forth new initiatives under the core strategy. This is the planning part of strategy that when combined with the vision, the mission and core strategies complete the strategic effort.

SWOT Analysis: An assessment of the internal strengths and weaknesses of the organization and the organization’s external opportunities and threats.

Template: A guide and/or format that assists the user in accomplishing a task efficiently in a uniform and consistent manner.

VIRGINIA OFFICE OF EMS STATE STRATEGIC AND OPERATIONAL PLAN

Appendix C - Resources

Resources

In developing this plan several resources were used in addition to meetings and interviews with OEMS staff and many system stakeholders.

- 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 3-Year Plan: July 1, 2013-June 30, 2016
- 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
- Joint Legislative Action Review Commission (JLARC) Report – House Document 37, Review of Emergency Medical Services in Virginia. 2004.
- EMS Advisory Board Committee Planning Templates – Revised 2016
- Regional EMS Council Process Action Team (PAT) Retreat Report - November 2008.
- Five-Year Strategic Plan – Federal Interagency Committee on EMS – December 2013



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448

RICHMOND, VA 23218

Marissa J. Levine, MD, MPH, FAAFP
STATE HEALTH COMMISSIONER

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: March 16, 2017

TO: Virginia State Board of Health

FROM: Steven A. Harrison, Director
Office of Radiological Health

SUBJECT: **Final Amendments – 12VAC5-490, Radiation Protection Fee Schedule**

The Virginia Department of Health’s Office of Radiological Health (ORH) proposes to amend the existing Virginia Radiation Protection Regulations: Fee Schedule (12VAC5-490) in order to update fees for non-medical X-ray equipment that is inspected on a three-year frequency; establish fees for the registration of baggage, cabinet/analytical and industrial X-ray equipment; establish fees that would allow an ORH inspector to perform an inspection of this equipment; and establish an associated inspection frequency. A Notice of Intended Regulatory Action was published in the Virginia Register on November 16, 2015 (Vol. 32, Issue 6) notifying the public of our intent to propose changes to this regulation, and no public comments were received. Our specific proposal to modify these fees was published in the Virginia Register on September 19, 2016. One comment was received over the course of the 60-day public comment period. That commenter stated the “fees [are] reasonable for X-ray registrations.”

Purpose of Regulations

The purpose of the X-ray program is to protect the public from unnecessary radiation due to faulty X-ray equipment or substandard practices. The purpose of registering and inspecting facilities that use X-ray machines, including those for non-medical purposes, is to have an accurate database of the machines, to track their inspections and to ensure the machines are properly functioning so as to protect the health and safety of equipment operators and the public.

Upcoming Steps

The final amendments, upon adoption by the Board of Health, will be submitted for executive branch review. Pending gubernatorial approval, the final amendments will be posted on the Regulatory Town Hall, a notice will be sent to registered public Town Hall users, and it will be published in the Virginia Register of Regulations. A 30-day final adoption period will then commence, at the end of which the amendments become effective unless 25 or more individuals request an additional public comment period.



townhall.virginia.gov

Final Regulation Agency Background Document

Agency name	Department of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-490
Regulation title(s)	Virginia Radiation Protection Regulations: Fee Schedule
Action title	Modify radiation protection X-ray device registration and inspection fees.
Date this document prepared	12/13/2016

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary 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.

The Virginia Department of Health's Office of Radiological Health proposes to amend 12VAC5-490, Radiation Protection Fee Schedule. Specifically, this amendment:

- Revises registration fees for equipment inspected every three years;
- Adds three (3) categories and associated fees for the registration of non-medical X-ray equipment (X-ray equipment not used in the healing arts):
 - Baggage, Cabinet and Analytical, and Industrial X-ray equipment.
- Adds three (3) categories and associated fees for the inspection of non-medical X-ray equipment (X-ray equipment not used in the healing arts):
 - Baggage, Cabinet and Analytical, and Industrial X-ray Equipment.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the “Definition” section of the regulations.

KVp – Peak tube potential; the maximum value of the potential difference across the x-ray tube during an exposure
ORH - Office of Radiological Health

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 taking the action; and 3) the title of the regulation.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person’s overall regulatory authority.

These regulations are authorized by §§ 32.1-229 et seq. of the Code of Virginia. Section 32.1-229.1 authorizes the Board of Health to set fees for X-ray equipment and requires the Board of Health to promulgate regulations for the registration, inspection, and certification of X-ray machines by Department of Health personnel (except for audit inspections initiated by the Department). Section 32.1-229.2 requires the Board of Health to set inspection fees to minimize competition with the private sector and include all reasonable costs.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation 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 proposed regulatory action addresses two sets of fees levied by the X-ray machine program: X-ray machine registration fees and X-ray machine inspection fees.

Radiological Control Program regulations currently require the registration of non-medical X-ray equipment (Baggage, Cabinet, Analytical, and Industrial equipment) but do not establish a fee for registration of this equipment, do not establish a fee for the Office of Radiological Health (ORH) to inspect this equipment, and do not specify associated inspection frequencies. Registration and inspection fees for X-ray equipment not used in the healing arts are charged in other states.

The harmful effects of radiation are well known, as well as the many beneficial applications of radiation in industry and healthcare. Adequate regulatory controls for the useful application of radiation are necessary to protect the health, safety and welfare of citizens. The potential exists for accidents associated with this equipment, which have in fact occurred. Accordingly, regulatory attention needs to be applied to promote the safety of non-medical X-ray equipment. These fees will help offset the cost of administrative activities involved in the registration, inspection, and certification of non-medical X-ray equipment. These costs were once absorbed from general funds allocated to ORH, but those general funds have since been abolished.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both.

In Section 10 of the Regulations, the fee for each machine and additional tube(s) that has an inspection frequency of every three years is proposed to increase from \$50 to \$60, collected every three years.

The following annual registration fees are proposed for all operators or owners of baggage, cabinet or analytical, or industrial X-ray machines capable of producing radiation:

- o \$20 for each machine used for baggage inspection;
- o \$25 for each machine identified as cabinet or analytical; and
- o \$50 for each machine used for industrial radiography.

Section 20 of the Regulations is proposed to be amended to add the following inspection fees and required inspection frequencies for operators or owners of baggage, cabinet, analytical, or industrial X-ray machines capable of producing radiation:

- o Baggage X-Ray Unit: \$100 per inspection, inspected every 5 years;
- o Cabinet/Analytical X-ray Unit: \$150 per inspection, inspected every 3 years;
- o Industrial Radiography X-Ray Unit: \$200 per inspection, inspected annually.

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 primary advantage of this change to the public and the regulated community is that registering all X-ray machines allows ORH to maintain an accurate database of the devices, track inspections and ensure that the machines are functioning properly so as to minimize the risk of equipment malfunction and accidental overexposures.

1. Primary advantages and disadvantages to the public:
The primary advantage to the public is that it will ensure the safe operation of non-medical x-ray equipment through the institution of an effective registration and inspection program.

There are no disadvantages to the public in promulgating the proposed fee schedule.

- 2. Primary advantages and disadvantages to the agency and Commonwealth:
Approving the proposed fee structure will allow the Commonwealth to recover more of the costs associated with carrying out the legislative mandate.

There are no disadvantages to the agency and Commonwealth in promulgating the proposed fee schedule.

- 3. Other pertinent matters of interest to the regulated community:

X-ray machine registrants have an interest in keeping inspection fees as low as possible.

Private inspectors of X-ray machines have an interest in ensuring that inspection fees by agency inspectors do not hurt their business by undercutting the private sector pricing, and Virginia Code § 32.1-229.2 requires the agency to establish inspection fees in such a manner so as to minimize competition with the private inspector while recovering costs.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need 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 or no requirements that exceed 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.

There are no localities that would be disproportionately affected by this action.

Family impact

Please assess the impact of this 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.

The proposed changes would not have a direct impact on the institution of the family and family stability.

Changes made since the proposed stage

*Please list all changes that made to the text of the proposed regulation and the rationale for the changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. *Please put an asterisk next to any substantive changes.*

No changes were made since 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. Please distinguish between comments received on Town Hall versus those made in a public hearing or submitted directly to the agency or board.

Commenter	Comment	Agency response
Kevin Donaldson, General Electric	Fees reasonable for X-ray registration. We use 2 cabinet X-rays in our manufacturing facility and the fees seem appropriate and reasonable. No objections.	Concur.

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections. Explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12VAC5-490-10		<p>All operators or owners of diagnostic X-ray machines used in the healing arts and capable of producing radiation shall pay the following registration fee:</p> <p>\$50 for each machine and additional tube(s) that have a required annual inspection, collected annually;</p> <p>\$50 for each machine and additional tube(s) that have a required inspection every three</p>	<p>All operators or owners of diagnostic X-ray machines used in the healing arts and capable of producing radiation shall pay the following registration fee:</p> <p>\$50 for each machine and additional tube(s) that have a required annual inspection, collected annually;</p> <p>\$50 \$60 for each machine and additional tube(s) that have a required inspection every three years, collected every three years.</p>

		<p>years, collected every three years.</p> <p>All operators or owners of therapeutic X-ray, particle accelerators, and teletherapy machines used in the healing arts capable of producing radiation shall pay the following annual registration fee:</p> <p>\$50 for each machine with a maximum beam energy of less than 500 KVp;</p> <p>\$50 for each machine with a maximum beam energy of 500 KVp or greater.</p> <p>Where the operator or owner of the aforementioned machines is a state agency or local government, that agency is exempt from the payment of the registration fee.</p>	<p>All operators or owners of therapeutic X-ray, particle accelerators, and teletherapy machines used in the healing arts capable of producing radiation shall pay the following annual registration fee:</p> <p>\$50 for each machine with a maximum beam energy of less than 500 KVp;</p> <p>\$50 for each machine with a maximum beam energy of 500 KVp or greater.</p> <p><u>All operators or owners of baggage, cabinet or analytical, or industrial X-ray machines capable of producing radiation shall pay the following annual registration fee:</u></p> <p><u>\$20 for each machine used for baggage inspection;</u></p> <p><u>\$25 for each machine identified as cabinet or analytical; and</u></p> <p><u>\$50 for each machine used for industrial radiography.</u></p> <p>Where the operator or owner of the aforementioned machines is a state agency or local government, that agency is exempt from the payment of the registration fee.</p> <p>Intent/Rationale/Impact: This change would increase fees for x-ray producing devices that are required to be registered every three years; and levy fees to register non-medical x-ray producing devices. Owners of x-ray producing devices are already required to register the equipment with ORH, but ORH has not, in the past, been authorized to collect a fee to cover administrative costs. Administrative, personnel, travel and other expenses have increased since the fee schedule was last revised in 2009, and the use of general funds to support the X-ray program was eliminated in SFY16. Instituting these fees will help to sustain the X-ray program.</p>
<p>12VAC5-490-20</p>		<p>The following fees shall be charged for surveys requested by the registrant and performed by a Department of Health inspector:</p>	<p>The following <u>table lists the</u> fees <u>that</u> shall be charged for surveys requested by the registrant and performed by a Department of Health inspector, <u>as well</u></p>

		<table border="1"> <thead> <tr> <th>Type</th> <th>Cost Per Tube</th> </tr> </thead> <tbody> <tr> <td>General Radiographic (includes: Chiropractic and Special Purpose X-ray Systems)</td> <td>\$230</td> </tr> <tr> <td>Fluoroscopic, C-arm Fluoroscopic</td> <td>\$230</td> </tr> <tr> <td>Combination (General Purpose-Fluoroscopic)</td> <td>\$460</td> </tr> <tr> <td>Dental Intraoral and Panographic</td> <td>\$90</td> </tr> <tr> <td>Veterinary</td> <td>\$160</td> </tr> <tr> <td>Podiatric</td> <td>\$90</td> </tr> <tr> <td>Cephalometric</td> <td>\$120</td> </tr> <tr> <td>Bone Densitometry</td> <td>\$90</td> </tr> <tr> <td>Combination (Dental Panographic and Cephalometric)</td> <td>\$210</td> </tr> <tr> <td>Shielding Review for Dental Facilities</td> <td>\$250</td> </tr> <tr> <td>Shielding Review for Radiographic, Chiropractic, Veterinary, Fluoroscopic, or Podiatric Facilities</td> <td>\$450</td> </tr> </tbody> </table>	Type	Cost Per Tube	General Radiographic (includes: Chiropractic and Special Purpose X-ray Systems)	\$230	Fluoroscopic, C-arm Fluoroscopic	\$230	Combination (General Purpose-Fluoroscopic)	\$460	Dental Intraoral and Panographic	\$90	Veterinary	\$160	Podiatric	\$90	Cephalometric	\$120	Bone Densitometry	\$90	Combination (Dental Panographic and Cephalometric)	\$210	Shielding Review for Dental Facilities	\$250	Shielding Review for Radiographic, Chiropractic, Veterinary, Fluoroscopic, or Podiatric Facilities	\$450	<p><i>as the required inspection frequencies for each type of X-ray machine:</i></p> <table border="1"> <thead> <tr> <th>Type</th> <th>Cost Per Tube</th> <th><u>Inspection Frequency</u></th> </tr> </thead> <tbody> <tr> <td>General Radiographic (includes: Chiropractic and Special Purpose X-ray Systems)</td> <td>\$230</td> <td><u>Annually</u></td> </tr> <tr> <td>Fluoroscopic, C-arm Fluoroscopic</td> <td>\$230</td> <td><u>Annually</u></td> </tr> <tr> <td>Combination (General Purpose-Fluoroscopic)</td> <td>\$460</td> <td><u>Annually</u></td> </tr> <tr> <td>Dental Intraoral and Panographic</td> <td>\$90</td> <td><u>Every 3 years</u></td> </tr> <tr> <td>Veterinary</td> <td>\$160</td> <td><u>Every 3 years</u></td> </tr> <tr> <td>Podiatric</td> <td>\$90</td> <td><u>Every 3 years</u></td> </tr> <tr> <td>Cephalometric</td> <td>\$120</td> <td><u>Every 3 years</u></td> </tr> <tr> <td>Bone Densitometry</td> <td>\$90</td> <td><u>Every 3 years</u></td> </tr> <tr> <td>Combination (Dental Panographic and Cephalometric)</td> <td>\$210</td> <td><u>Every 3 years</u></td> </tr> <tr> <td>Shielding Review for Dental Facilities</td> <td>\$250</td> <td><u>Initial/Prior to use</u></td> </tr> <tr> <td>Shielding Review for Radiographic, Chiropractic, Veterinary, Fluoroscopic, or Podiatric Facilities</td> <td>\$450</td> <td><u>Initial/prior to use</u></td> </tr> <tr> <td><u>Baggage X-Ray Unit</u></td> <td><u>\$100</u></td> <td><u>Every 5 years</u></td> </tr> <tr> <td><u>Cabinet/Analytical X-ray Unit</u></td> <td><u>\$150</u></td> <td><u>Every 3 years</u></td> </tr> <tr> <td><u>Industrial Radiography X-Ray Unit</u></td> <td><u>\$200</u></td> <td><u>Annually</u></td> </tr> </tbody> </table>	Type	Cost Per Tube	<u>Inspection Frequency</u>	General Radiographic (includes: Chiropractic and Special Purpose X-ray Systems)	\$230	<u>Annually</u>	Fluoroscopic, C-arm Fluoroscopic	\$230	<u>Annually</u>	Combination (General Purpose-Fluoroscopic)	\$460	<u>Annually</u>	Dental Intraoral and Panographic	\$90	<u>Every 3 years</u>	Veterinary	\$160	<u>Every 3 years</u>	Podiatric	\$90	<u>Every 3 years</u>	Cephalometric	\$120	<u>Every 3 years</u>	Bone Densitometry	\$90	<u>Every 3 years</u>	Combination (Dental Panographic and Cephalometric)	\$210	<u>Every 3 years</u>	Shielding Review for Dental Facilities	\$250	<u>Initial/Prior to use</u>	Shielding Review for Radiographic, Chiropractic, Veterinary, Fluoroscopic, or Podiatric Facilities	\$450	<u>Initial/prior to use</u>	<u>Baggage X-Ray Unit</u>	<u>\$100</u>	<u>Every 5 years</u>	<u>Cabinet/Analytical X-ray Unit</u>	<u>\$150</u>	<u>Every 3 years</u>	<u>Industrial Radiography X-Ray Unit</u>	<u>\$200</u>	<u>Annually</u>
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Project 4550 - PROPOSED

DEPARTMENT OF HEALTH

Non-Medical X-Ray Device Registration and Inspection Fee Schedule

1 12VAC5-490-10. Registration fees.

2 All operators or owners of diagnostic X-ray machines used in the healing arts and capable of
3 producing radiation shall pay the following registration fee:

4 \$50 for each machine and additional tube(s) that have a required annual inspection,
5 collected annually;

6 ~~\$50~~ \$60 for each machine and additional tube(s) that have a required inspection every
7 three years, collected every three years.

8 All operators or owners of therapeutic X-ray, particle accelerators, and teletherapy machines
9 used in the healing arts capable of producing radiation shall pay the following annual
10 registration fee:

11 \$50 for each machine with a maximum beam energy of less than 500 KVp;

12 \$50 for each machine with a maximum beam energy of 500 KVp or greater.

13 All operators or owners of baggage, cabinet or analytical, or industrial X-ray machines
14 capable of producing radiation shall pay the following annual registration fee:

15 \$20 for each machine used for baggage inspection;

16 \$25 for each machine identified as cabinet or analytical; and

17 \$50 for each machine used for industrial radiography.

18 Where the operator or owner of the aforementioned machines is a state agency or local
19 government, that agency is exempt from the payment of the registration fee.

20

21 12VAC5-490-20. Inspection fees and inspection frequencies for X-ray machines.

22 The following table lists the fees that shall be charged for surveys requested by the
23 registrant and performed by a Department of Health inspector, as well as the required
24 inspection frequencies for each type of X-ray machine:

Type	Cost Per Tube	<u>Inspection Frequency</u>
General Radiographic (includes: Chiropractic and Special Purpose X-ray Systems)	\$230	<u>Annually</u>
Fluoroscopic, C-arm Fluoroscopic	\$230	<u>Annually</u>
Combination (General Purpose- Fluoroscopic)	\$460	<u>Annually</u>

Dental Intraoral and Panographic	\$90	<u>Every 3 years</u>
Veterinary	\$160	<u>Every 3 years</u>
Podiatric	\$90	<u>Every 3 years</u>
Cephalometric	\$120	<u>Every 3 years</u>
Bone Densitometry	\$90	<u>Every 3 years</u>
Combination (Dental Panographic and Cephalometric)	\$210	<u>Every 3 years</u>
Shielding Review for Dental Facilities	\$250	<u>Initial/Prior to use</u>
Shielding Review for Radiographic, Chiropractic, Veterinary, Fluoroscopic, or Podiatric Facilities	\$450	<u>Initial/Prior to use</u>
<u>Baggage X-ray Unit</u>	<u>\$100</u>	<u>Every 5 years</u>
<u>Cabinet/Analytical X-ray Unit</u>	<u>\$150</u>	<u>Every 3 years</u>
<u>Industrial Radiography X-ray Unit</u>	<u>\$200</u>	<u>Annually</u>

MEMORANDUM

DATE: February 9, 2017

TO: Virginia State Board of Health

FROM: Adrienne McFadden, MD, JD, FACEP, FAAEM, FCLM
Director of Health Equity

SUBJECT: Regulations for Physician Assistant Scholarship Program (12VAC5-525).

Enclosed for your review are the final regulations for the Physician Assistant Scholarship Program (12VAC5-525).

Chapter 806 of the 1997 Virginia Acts of Assembly amended and reenacted § 32.1-122.6:03 of the Code of Virginia to require the establishment of an annual physician assistant scholarship program for students who intend to enter an accredited physician assistant program. Section 32.1-122.6:03 of the Code further mandates the Board of Health to adopt regulations governing the implementation of such a scholarship program within 280 days of its enactment. There is no record within the Agency of any past regulatory action to implement the required regulations. Permanent regulations are necessary to support the implementation of § 32.1-122.6:03. The intent of this regulatory action is to implement the regulatory action required by § 32.1-122.6:03 and address the shortage of trained medical professionals in the Commonwealth.

The Board of Health is requested to approve the final regulations. Should the Board of Health approve the final regulations, they will be submitted to the Office of the Attorney General to begin the executive branch review process, as specified by the Administrative Process Act. Following executive branch review and approval, the final regulations will be published in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall website, and a 30 day final adoption period will begin.



townhall.virginia.gov

Final Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-525
Regulation title(s)	Regulations for Physician Assistant Scholarship Program
Action title	Implement Regulations for Physician Assistant Scholarships
Date this document prepared	February 1, 2017

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary 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.

The proposed new regulations will bring the Board of Health into compliance with § 32.1-122.6:03 of the Code of Virginia, which requires the establishment of an annual physician assistant scholarship program for students who intend to enter an accredited physician assistant program. Currently no implementing regulations exist. The substantive elements are modeled after similar regulatory incentive programs administered by the Agency.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

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 taking the action; and 3) the title of the regulation.

Legal basis

Please identify the (1) the agency (includes any type of promulgating entity) and (2) the state and/or federal legal authority for the proposed regulatory action, including the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable. Your citation should include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

The regulation is promulgated under the authority of § 32.1-122.6:03 of the Code of Virginia. Section 32.1-122.6:03 of the Code of Virginia requires the Board to establish an annual physician assistant scholarship program and mandates that the Board promulgate regulations in order to administer the program.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation 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.

Chapter 806 of the 1997 Virginia Acts of Assembly amended and reenacted § 32.1-122.6:03 of the Code of Virginia to require the establishment of an annual physician assistant scholarship program for students who intend to enter an accredited physician assistant program and mandated the Board of Health to adopt regulations governing the implementation of such a scholarship program. There is no record within the Agency of any past regulatory action to implement the required regulations. Permanent regulations are necessary to support the implementation of § 32.1-122.6:03. The intent of this regulatory action is to implement the regulatory action required by § 32.1-122.6:03 and to help protect the health of citizens by addressing the shortage of trained medical professionals in the Commonwealth.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both.

This regulatory action will implement a new regulatory chapter which will create a physician assistant scholarship program. The substantive elements of this program will be modeled after similar regulatory programs administered by the Agency. Substantive elements that will be created include:

Definitions – Will provide clarification on key or frequently used terms in the regulatory text.

Advisory Committee – Will establish that an Advisory Committee as appointed by the Board of Health shall make all scholarship recommendations.

Eligibility for scholarships – Will provide eligibility requirements including acceptance in or enrollment in an approved education program, a 2.5 cumulative GPA if already enrolled in a program, application, financial need and no active military obligation.

Conditions of scholarships – Will provide guidance and provisions on the contract requirements, calculations of the service obligation, employment requirements, transfer of practice site, default, waiver, partial, hardship, and default payments.

Number of applications, Amounts of scholarships & How to apply- Will provide information and provisions regarding applicant renewals, minimum and maximum award amounts, location of application form and deadline dates for submission of applications.

Selection criteria – Will provide information regarding preferential consideration of applications, including Virginia residents, residents of medically underserved areas and minority students.

Scholarship contract – Will provide information regarding the required elements of the scholarship contract.

Practice site selection – Will provide information regarding where a participant in the program will be able to perform his service obligation.

Functional elements of the repayment program – Will provide program information regarding reporting requirements, breach of contract, and deferments and waivers.

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 primary advantage of the proposed regulatory action to the public will be an increase in the availability of primary care providers in medically underserved communities within the Commonwealth. Additionally, these medically underserved communities will be better positioned to retain qualified primary care providers because of the obligation created by accepting the scholarship funds. The Virginia Department of Health sees no disadvantage to the public, the agency or the Commonwealth associated with the proposed regulatory action.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need 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.

N/A

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.

No locality will be particularly affected by the proposed regulation.

Family impact

Please assess the impact of this 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.

The board anticipates no impact to the family or family stability.

Changes made since the proposed stage

*Please list all changes that made to the text of the proposed regulation and the rationale for the changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. *Please put an asterisk next to any substantive changes.*

Section number	Requirement at proposed stage	What has changed	Rationale for change
40	<u>Scholarships are awarded for single academic years. However, the same student may, after demonstrating satisfactory progress in his studies, which is demonstrated by a cumulative grade point average of 3.0, apply for and receive scholarship awards for a succeeding academic year or years. No student shall receive scholarships for more than a total of four years.</u>	<u>Scholarships are awarded for single academic years. However, the same student may, after demonstrating satisfactory progress in his studies, which is demonstrated by a cumulative grade point average of 3.0, apply for and receive scholarship awards for a succeeding academic year or years. No student shall receive scholarships for more than a total of [four three] years.</u>	Of the existing accredited physician assistant academic programs available in Virginia, no program has a curriculum that exceeds 30 months or three academic years.

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. Please distinguish between comments received on Town Hall versus those made in a public hearing or submitted directly to the agency or board.

No comments were received following the publication of the proposed stage.

All changes made in this regulatory action

Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections. Explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
	10		Defines terms used in this regulatory chapter to assist readers in understanding regulations.
	20		Establishes that an eight member scholarship committee appointed by the board will determine the scholarship awards.
	30		Establishes eligibility criteria for the scholarship program.
	40		Establishes the conditions including requirement for a signed contract with commissioner, minimum requirements for service obligation, and terms for failure of completing condition of scholarship.
	50		Defines the maximum number of scholarships that each applicant is eligible to receive.
	60		Establishes the scholarship value at \$5,000 and clarifies how the number of scholarships awarded is determined.
	70		Establishes the process for applicants to apply for the scholarship.
	80		Establishes selection standards which will serve as guidance to the scholarship committee in selecting the scholarship recipients.
	90		Establishes elements of the scholarship contract that is to be signed by the recipient and commissioner.
	100		Provides standards to use for practice site selection and establishes minimal criteria which

			the practice site must meet to serve as an eligible practice site to repay service obligation.
	105		Establishes the process by which an applicant can change practice sites and provides direction about how to change a practice site once a participant begins their service obligation.
	110		Establishes reporting requirements that each recipient must fulfill during their participation in the scholarship program.
	120		Establishes those conditions which constitute a breach of contract and provides for the terms of reimbursement of the Commonwealth by the recipient in the case of a breach of contract or default.
	130		Establishes a deferment and waiver process and provides clarity about the process by which a deferment may be considered.
	140		Establishes a process by which a participant may be reimbursed by the Commonwealth upon fulfilling service obligation after repaying the Commonwealth for default.

Project 4416 - Proposed

DEPARTMENT OF HEALTH
Promulgate Regulations for Physician Assistant Scholarship Program

CHAPTER 525
REGULATIONS FOR PHYSICIAN ASSISTANT SCHOLARSHIP PROGRAM

Part I
General Information

1 **12VAC5-525-10. Definitions.**

2 The following words and terms when used in this chapter shall have the following meanings:

3 "Approved physician assistant program" means a fully accredited physician assistant school
4 in Virginia as approved by the board.

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

6 "Commissioner" means the State Health Commissioner.

7 "Department" means Virginia Department of Health.

8 "Full-time" means at least 32 hours per week for 45 weeks per year.

9 "Health professional shortage area" or "HPSA" means an area in Virginia designated by the
10 U.S. Secretary of Health and Human Services as having a shortage of health professionals in
11 accordance with the procedures of the Public Health Service Act (42 USC § 254e) and
12 implementing regulations (42 CFR Part 5).

13 "Interest" means the legal rate of interest pursuant to § 6.2-302 of the Code of Virginia.

14 "Participant" or "recipient" means an eligible registered physician assistant student of an
15 approved physician assistant program who enters into a contract with the commissioner and
16 participates in the scholarship program.

17 "Penalty" means twice the amount of all monetary payments to the scholarship participant,
18 less any service obligation completed.

19 "Physician assistant" or "PA" means an individual who has met the requirements of the
20 Board of Medicine for licensure and who works under the supervision of a licensed doctor of
21 medicine, osteopathy, or podiatry as defined in § 54.1-2900 of the Code of Virginia.

22 "Practice" means the practice of medicine by a recipient in one of the defined primary care
23 specialties in a location within Virginia that is designated as a health professional shortage area
24 or a Virginia medically underserved area to fulfill the recipient's service obligation.

25 "Primary care" means the specialties of family practice medicine, general internal medicine,
26 pediatric medicine, and obstetrics and gynecology.

27 "Virginia medically underserved area" or "VMUA" means an area in Virginia designated by
28 the State Board of Health in accordance with the Rules and Regulations for the Identification of
29 Medically Underserved Areas in Virginia (12VAC5-540) or § 32.1-122.5 of the Code of Virginia.

30 **12VAC5-525-20. Physician assistant scholarship committee.**

31 All scholarship awards shall be made by the physician assistant scholarship committee
32 appointed by the board. The physician assistant scholarship committee shall consist of eight
33 members: four deans or directors of physician assistant programs or their designees, two former
34 scholarship recipients, and two members with experience in the administration of student
35 financial aid programs. Committee appointments shall be for two-year terms, and members shall
36 not serve for more than two successive terms.

37 Part II

38 Administration of Physician Assistant Scholarship Program

39 **12VAC5-525-30. Eligibility for scholarships.**

40 In order to be considered for a scholarship, an applicant shall:

- 41 1. Be a United States citizen, national, or a qualified alien pursuant to 8 USC § 1621;
- 42 2. Be accepted for enrollment or enrolled in an approved PA program in the
43 Commonwealth of Virginia preparing him for examination for licensure as a PA in the
44 Commonwealth of Virginia;
- 45 3. If already enrolled in an approved PA program in the Commonwealth, the student
46 must have a cumulative grade point average of 3.0;
- 47 4. Submit a completed application form and appropriate grade transcript prior to the
48 established deadline dates;
- 49 5. Demonstrate financial need, which is verified by the school's financial aid officer or
50 authorized person, as part of the application process; and
- 51 6. Not have an active military obligation.

52 An applicant who fails to meet all of these requirements shall be ineligible for a scholarship.

53 **12VAC5-525-40. Conditions of scholarships.**

54 A. Prior to becoming a participant in the PA scholarship program, the applicant shall enter
55 into a contract with the commissioner agreeing to the terms and conditions upon which the
56 scholarship is granted.

57 B. For each \$5000 of scholarship money received, the participant agrees to engage in the
58 equivalent of one year of full-time primary care medical practice in a HPSA or VMUA within the
59 Commonwealth. The recipient shall notify the department, within 180 days of being awarded a
60 PA degree, of the type of practice to be performed and give the name and address of the
61 employer for approval. Voluntary military service, even if stationed in Virginia, cannot be used to
62 repay the service obligation required when a scholarship is awarded.

63 C. If a participant fails to complete his studies, the full amount of the scholarship or
64 scholarships received, plus the applicable interest charge, shall be repaid.

65 D. If upon graduation a participant leaves the Commonwealth or fails to engage or ceases to
66 engage in primary care medical practice in Virginia before all employment conditions of the
67 scholarship award are fulfilled, the participant shall repay the award amount reduced by the
68 proportion of obligated years served plus the applicable interest and penalty.

69 E. If the participant is in default due to death or permanent disability so as not to be able to
70 engage in medical practice, the participant or his personal representative, upon repayment of
71 the total amount of scholarship funds received plus applicable interest, may be relieved of his
72 obligation under the contract to engage in medical practice. For participants completing part of
73 the PA obligation prior to becoming permanently disabled or in the event of death, the total
74 amount of scholarship funds owed shall be reduced by the proportion of obligated years served.
75 The obligation to make restitution may be waived by the board upon application of the
76 participant or the participant's personal representative to the board.

77 F. All default payments shall be made payable to the Commonwealth of Virginia.

78 **12VAC5-525-50. Number of applications per student.**

79 Scholarships are awarded for single academic years. However, the same student may, after
80 demonstrating satisfactory progress in his studies, which is demonstrated by a cumulative grade
81 point average of 3.0, apply for and receive scholarship awards for a succeeding academic year
82 or years. No student shall receive scholarships for more than a total of [~~four~~ three] years.

83 **12VAC5-525-60. Amounts of scholarships.**

84 The number of scholarships awarded shall be dependent upon the amount of money
85 appropriated by the General Assembly, the amount of funds available within the Physician
86 Assistant Scholarship Fund administered by the board, and the number of qualified applicants.
87 Each participant shall receive an award of \$5,000 per year.

88 **12VAC5-525-70. How to apply.**

89 Eligible applicants shall submit a complete application made available by the department on
90 the department's website. A complete application shall include documentation of all eligibility
91 requirements. The deadline for submission of the application shall be announced by the
92 department on the department's website.

93 **12VAC5-525-80. Selection criteria.**

94 Applicants shall be competitively reviewed and selected for participation in the Physician
95 Assistant Scholarship Program based upon the following criteria pursuant to § 32.1-122.6:03 of
96 the Code of Virginia:

97 1. Qualifications. All of an individual's professional qualifications and competency to
98 practice in an underserved area will be considered, including eligibility for Virginia
99 licensure, professional achievements, and other indicators of competency received from
100 supervisors, program directors, or other individuals who have previously entered into an
101 employment contract with the individual.

102 2. Virginia residents. Preferential consideration shall be given to individuals who are or
103 have been Virginia residents (verification will be obtained by the Virginia Physician
104 Assistant Scholarship Program).

105 3. Residents of medically underserved areas. Preferential consideration shall be given to
106 individuals who reside in rural, Virginia medically underserved areas, or health
107 professional shortage areas (verification shall be obtained by the Virginia Physician
108 Assistant Scholarship Program).

109 **12VAC5-525-90. Scholarship contract.**

110 Applicants selected to receive scholarship awards by the physician assistant scholarship
111 committee shall sign and return a written contract to the department by the specified deadline
112 date. Failure to return the contract by the specified deadline date may result in the award being
113 rescinded. At minimum, the scholarship contract shall include the following elements:

114 1. The total amount of the award and the award period;

115 2. Agreement to pursue a degree at an accredited PA program in the Commonwealth of
116 Virginia that is approved by the board;

117 3. Agreement to begin continuous full-time employment within 180 days of the recipient's
118 graduation;

119 4. Agreement to comply with all reporting requirements;

120 5. Agreement to the terms of service requiring continuous full-time primary care medical
121 practice in the Commonwealth for a specified period of time and the terms and
122 conditions associated with a breach of contract;

123 6. Signature of the applicant; and

124 7. Signature of the commissioner or his designee.

125 A recipient may terminate a contract while enrolled in school after notice to the board and
126 upon repayment within 90 days of the entire amount of the scholarship plus interest.

127 **12VAC5-525-100. Practice site selection.**

128 Each recipient shall perform his service obligation at a practice site in either a health
129 professional shortage area or a Virginia medically underserved area. The participant shall agree
130 to provide health services without discrimination, regardless of a patient's ability to pay. Maps
131 of health professional shortage areas and Virginia medically underserved areas shall be
132 available on the department's website.

133 **12VAC5-525-105. Change of practice site.**

134 Should any participant find that he is unable to fulfill the service commitment at the practice
135 site to which he has committed to practice, he may request approval of a change of practice
136 site. Such requests shall be made in writing. The department in its discretion may approve such
137 a request. All practice sites, including changes of practice sites, shall be selected with the
138 approval of the commissioner.

139 In the event of a dispute between the participant and the practice site, every effort shall be
140 made to resolve the dispute before reassignment will be permitted.

141 **12VAC5-525-110. Reporting requirements.**

142 A. Each participant shall provide information as required by the department to verify
143 compliance with the practice requirements of the PA scholarship program (e.g., verification of
144 employment in a primary care setting form once every six months).

145 B. Each participant shall promptly notify the department in writing within 30 days if any of the
146 following events occur:

147 1. Participant changes name;

148 2. Participant changes address;

149 3. Participant changes practice site. Participant is required to request in writing and
150 obtain prior approval of changes in practice site;

151 4. Participant no longer intends or is able to fulfill service obligation as a PA in the
152 Commonwealth;

153 5. Participant ceases to practice as a PA; or

154 6. Participant ceases or no longer intends to complete his PA academic program.

155 **12VAC5-525-120. Breach of contract.**

156 The following shall constitute a breach of contract:

157 1. The recipient fails to complete his PA studies;

158 2. The recipient fails to begin or complete the term of obligated service under the terms
159 and conditions of the scholarship contract;

160 3. The recipient falsifies or misrepresents information on the program application, the
161 verification of employment forms, or other required documents; and

162 4. The recipient's employment is terminated for good cause as determined by the
163 employer and confirmed by the department. If employment is terminated for reasons
164 beyond the participant's control (e.g., closure of site), the participant shall transfer to
165 another site approved by the board in the Commonwealth within six months of
166 termination. Failure of participant to transfer to another site shall be deemed to be a
167 breach of the contract.

168 In the event of a breach of contract and in accordance with the terms of the contract, the
169 recipient shall make default payments as described in 12VAC5-525-40. In the event of a breach
170 of contract where the recipient has partially fulfilled his obligation, the total amount of
171 reimbursement shall be prorated by the proportion of obligation completed.

172 **12VAC5-525-130. Deferment and waivers.**

173 A. If the participant is in default due to death or permanent disability so as not to be able to
174 engage in primary care practice in a region designated as a HPSA or VMUA in the
175 Commonwealth, the participant or his personal representative may be relieved of his obligation
176 under the contract to engage in practice, upon repayment of the total amount of scholarship
177 received plus applicable interest. For participants completing part of the obligation prior to
178 becoming permanently disabled or in the event of death, the total amount of scholarship funds
179 owed shall be reduced by the proportion of obligated years served. The obligation to make
180 restitution may be waived by the board upon application of the participant or the participant's
181 personal representative to the board.

182 B. Individual cases of undue hardship may be considered for a variance by the board of
183 payment or service pursuant to § 32.1-12 of the Code of Virginia.

184 C. All requests for deferments, waivers, or variances must be submitted in writing to the
185 department for consideration and final disposition by the board.

186 **12VAC5-525-140. Fulfillment after default payments.**

187 In the event that a recipient, in accordance with the terms of the contract, fully repays the
188 Commonwealth for part or all of any scholarship because of breach of contract and later fulfills
189 the terms of the contract after repayment, the Commonwealth shall reimburse the award
190 amount repaid by the recipient minus applicable interest and fees.

191 FORMS (12VAC5-525)

192 [Verification of Employment form \(rev. 6/2016\)](#)

193 [Physician Assistant Scholarship Program Application \(includes Application Checklist and](#)
194 [Requirements\) \(rev. 11/2016\)](#)



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448
RICHMOND, VA 23218

Marissa J. Levine, MD, MPH, FAAFP
STATE HEALTH COMMISSIONER

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: December 28, 2016

TO: Virginia State Board of Health

FROM: Vanessa Walker-Harris, MD, MPH
Director, Office of Family Health Services

SUBJECT: Amendments to 12VAC5-520 – Regulations Governing the Dental Scholarship and Loan Repayment Programs

The Virginia State Board of Health (Board) is asked to review and approve the proposed amendments to 12VAC5-520, which updates the regulatory chapter following a periodic review.

In June of 2016, the Virginia Department of Health (VDH) conducted a periodic review of 12VAC5-520, Regulations Governing the Dental Scholarship and Loan Repayment Programs. As a result of the review, VDH determined it was necessary to use the regulatory process to amend these regulations. It is necessary to amend these regulations as the regulatory chapter has not been comprehensively revised in over a decade. Further, this regulatory action is necessary to amend the regulations to conform to similar regulatory chapters. There are several scholarship and loan repayment programs administered by VDH and 12VAC5-520 as currently written does not resemble those other programs. The proposed amendments will make the regulatory chapter consistent with similar programs. The proposed amendments include corrections to the definitions of terms utilized within the regulatory chapter, formatting changes to make the regulatory chapter easier to read, correcting language and inserting language regarding the penalty to be paid in the event a recipient defaults after graduation.

The Board is requested to approve the proposed amendments. Should the Board approve the proposed amendments, they will be submitted to the Office of the Attorney General to begin the Executive Branch review process, as specified by the Administrative Process Act. Following Executive Branch review and approval, the proposed amendments will be published in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall website and a 60 day public comment period will begin.



townhall.virginia.gov

Proposed Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-520
Regulation title(s)	Regulations Governing the Dental Scholarship and Loan Repayment Programs
Action title	Amend Regulation Following Periodic Review
Date this document prepared	October 26, 2016

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 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.

In June of 2016, the Virginia Department of Health (VDH) conducted a periodic review of 12VAC5-520, Regulations Governing the Dental Scholarship and Loan Repayment Programs. As a result of the review, VDH determined it was necessary to use the regulatory process to amend these regulations. It is necessary to amend these regulations as the regulatory chapter has not been comprehensively revised in over a decade. Further, this regulatory action is necessary to amend the regulations to conform to similar regulatory chapters. There are several scholarship and loan repayment programs administered by VDH and 12VAC5-520 as currently written does not resemble those other programs. The proposed amendments will make the regulatory chapter consistent with similar programs. The proposed amendments include corrections to the definitions of terms utilized within the regulatory chapter, formatting changes to make the regulatory chapter easier to read, correcting language and inserting language regarding the penalty to be paid in the event a recipient defaults after graduation.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the “Definition” section of the regulations.

CFR- Code of Federal Regulations

USC – United States Code

VDH- Virginia Department of Health

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person’s overall regulatory authority.

The regulation is promulgated under the authority of §§ 32.1-12, 32.1-122.9 and 32.1-122.9:1 of Chapter 4 of Title 32.1 of the Code of Virginia (Code). Section 32.1-12 grants the Board of Health the legal authority “to make, adopt, promulgate, and enforce such regulations necessary to carry out the provisions of Title 32.1 of the Code.” Section 32.1-122.9 of the Code directs the Board of Health to establish an annual dental scholarship for students in good standing at Virginia Commonwealth University. Section 32.1-122.9 of the Code also directs the Board of Health to promulgate regulations to administer the scholarship program. Section 32.1-122.9:1 of the Code directs the Board of Health to establish a dental loan repayment program for graduates of accredited dental schools who meet criteria determined by the Board. Executive Order 17 (2014) requires that every existing state regulation be reviewed at least once every four years by the promulgating agency. Pursuant to that order VDH conducted a periodic review of 12VAC5-520 in June of 2016. This regulatory action is necessary in order for the regulatory chapter to be in compliance with the general principles of Executive Order 17 (2014), which requires that regulations be clearly written and easily understandable and that the regulations be designed to achieve their intended objective in the most efficient, and cost effective manner.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation 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.

In June of 2016, VDH conducted a periodic review of 12VAC5-520, “Regulations Governing the Dental Scholarship and Loan Repayment Programs.” As a result of the review, VDH determined it was necessary to use the regulatory process to amend these regulations. It is necessary to amend these regulations as the regulatory chapter has not been comprehensively revised in over a decade. Further, this regulatory action is necessary to amend the regulations to conform to similar regulatory chapters. There are several scholarship and loan repayment programs administered by VDH and 12VAC5-520 as currently written does not resemble those other programs. The regulatory action is essential to protect the

health, safety and welfare of citizens as 12VAC5-520 is currently out of date and is not consistent with other similar programs. This proposed regulatory action shall update the regulatory chapter and encourage the use of the scholarship and loan repayment programs potentially leading to more dentists practicing within underserved areas within the Commonwealth of Virginia.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the “Detail of changes” section below.

Definitions- Add the definition of “Recipient”, repeal the definitions of “Restitution” and “Scholarship recipient”, update the definition of “Dental underserved area” and simplify the definition of “Interest.”

Administration of program- Repeal an unnecessary section.

Population and dentist data- Update CFR reference to proper section

Eligible applicants- Update the format of the section so that it resembles other similar regulatory chapters

Scholarship and loan repayment award- Minor technical amendments

Distribution of scholarships and loan repayment awards- Minor technical amendments

Contractual practice obligation- Update the format of the section to resemble other similar regulatory chapters. Technical amendments. Specify that obligated service must begin within 180 days of graduation rather than 90 days, so the time frame is identical to other similar regulatory chapters. Add the requirement that recipients may only take a total of four weeks of leave for personal reasons without written permission from the commissioner. This is a requirement that is present in other similar regulatory chapters. Movement of information regarding repayment to a new section.

Special requests for approval- Minor technical amendments

Default- Rename the section Breach of Contract and update the format of the section so that it resembles other similar regulatory chapters.

Deferment and waivers- New section- Consists of some language from the previous “Default” now “Breach of Contract” section- Update the format of the section so that it resembles other similar regulatory chapters

Repayment- Minor technical amendments- Addition of the requirement that a scholarship recipient shall pay a penalty in the event of default after graduation.

Reporting requirements- Minor technical amendments- update the format of the section so that it resembles other similar regulatory chapters.

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 primary advantage of the proposed regulatory action to the public is a potential increase in the availability of dentists in underserved areas, should this program be funded. Additionally, these underserved areas will be better positioned to retain qualified dentists because of the obligation created by accepting the scholarship or loan repayment funds. VDH does not foresee any disadvantages to the public, the agency or the Commonwealth associated with the proposed regulatory action.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need 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.

No locality will be particularly affected by the proposed regulation.

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 State Board of Health 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 of Virginia. 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 comments may do so through the Public Forum feature of the Virginia Regulatory Town Hall website at: <http://www.townhall.virginia.gov>. Comments for the public comment file may also be submitted by mail or email to Susan Puglisi, 109 Governor Street, Richmond, VA 23219, (804) 864-7175, and susan.puglisi@vdh.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will not be held following the publication of this stage of this regulatory action.

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 requirement creates the anticipated economic impact.

<p>Projected cost to the state to implement and enforce the proposed regulation, including: a) fund source / fund detail; and b) a delineation of one-time versus on-going expenditures</p>	<p>The projected cost to the state is negligible. This program is not currently funded.</p>
<p>Projected cost of the new regulations or changes to existing regulations on localities.</p>	<p>This regulatory chapter will not cause any cost to localities.</p>
<p>Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.</p>	<p>Dentists and dental students desiring to work in dental underserved areas, patients and facilities within dental underserved areas within the Commonwealth</p>
<p>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: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>Should the program become funded there are approximately nine dental practices across the Commonwealth in dental underserved areas that would be affected and all nine are small businesses.</p>
<p>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 including: a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and b) 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.</p>	<p>None.</p>
<p>Beneficial impact the regulation is designed to produce.</p>	<p>Make the regulatory chapter conform with other similar regulatory programs and conform with the general principals of Executive Order 17 (2014).</p>

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.

Section 32.1-122.9 of the Code directs the Board of Health to establish an annual dental scholarship for students in good standing at Virginia Commonwealth University. Section 32.1-122.9 of the Code also

directs the Board of Health to promulgate regulations to administer the scholarship program. Section 32.1-122.9:1 of the Code directs the Board of Health to establish a dentist loan repayment program for graduates of accredited dental schools who meet criteria determined by the Board. Executive Order 17 (2014) requires that every existing state regulation be reviewed at least once every four years by the promulgating agency. Pursuant to that order VDH conducted a periodic review of 12VAC5-520 in June of 2016. This regulatory action is necessary in order for the regulatory chapter to be in compliance with the general principles of Executive Order 17 (2014), which requires that regulations be clearly written and easily understandable and that regulations shall be designed to achieve their intended objective in the most efficient, and cost effective manner. The regulations are mandated by law, the review of the regulations are mandated by law and there are no viable alternatives to the proposed regulatory action to achieve the necessary regulatory changes determined to be appropriate as determined by the regulatory review.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, 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 alternative regulatory methods are not applicable. The regulations are mandated by law, the review of the regulations are mandated by law and there are no viable alternatives to the proposed regulatory action to achieve the necessary regulatory changes determined to be appropriate as determined by the regulatory review.

Public comment

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

No public comments were received during the public comment period following the publication of the Notice of Intended Regulatory Action.

Family impact

Please assess the impact of this 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.

The board has assessed the impact the proposed amendments will have on the institution of the family and family stability. The board anticipates no impact to the family or family stability.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below.

For changes to existing regulation(s), please use the following chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
10		This section provides definitions for technical terms utilized throughout the regulatory chapter.	Updating the definition of “dental underserved area,” update and simplify the definition of “interest,” add a definition of the term “recipient” and repeal the definitions of “restitution” and “scholarship recipient.” Impact: Greater clarity of the regulations
20		This section states that the State Health Commissioner shall administer the regulatory chapter.	Repeal this unnecessary section. Impact: Less burdensome regulations.
80		This section explains how dental underserved areas are calculated	Updating the CFR reference within the regulations. The previous citation referenced the incorrect section. Impact: Greater clarity of the regulations
130		This section lays out the requirements for an individual to be an eligible applicant of the dental scholarship program and the dental loan repayment program.	Update the format of the section to resemble other similar regulatory chapters. Impact: Greater clarity of the regulations; Less burdensome regulations as similar regulatory chapters shall be governed the same.
140		This section states that any individual awarded a scholarship or loan repayment shall enter into a contract with the commissioner	Minor technical amendment Impact: Greater clarity of the regulations- Use of defined terms
150		This section discusses the establishment of the appropriation for the program along with how the awards shall be distributed	Minor technical amendments Impact: Greater clarity of the regulations
160		This section provides the requirements of the contract	Update the formatting of the section to resemble other similar regulatory

		that a scholarship or loan repayment recipient must enter into with the commissioner	<p>chapters. Specify that obligated service must begin within 180 days of graduation rather than 90 days, so the time frame is identical to other similar regulatory chapters. Add the requirement that recipients may only take a total of four weeks of leave for personal reasons without written permission from the commissioner. This is a requirement that is present in other similar regulatory chapters. Movement of information regarding repayment to a new section. Additional minor technical amendments.</p> <p>Impact: Greater clarity of the regulations; Less burdensome regulations as similar regulatory chapters shall be governed the same.</p>
170		This section lays out the requirements for a recipient to practice in an area that does not qualify as a dental underserved area.	<p>Minor technical amendment.</p> <p>Impact: Greater clarity of the regulations</p>
190		This section describes circumstances under which a recipient will be considered in default and be required to forfeit the monetary award and repay the money to the Commonwealth of Virginia	<p>Amend the section title to “Breach of Contract.” Reformat the section to resemble other similar regulatory programs. Separate the section into what constitutes a breach for scholarship recipients and what constitutes a breach for loan repayment recipients. Removal of certain language which shall be moved to a new section.</p> <p>Impact: Greater clarity of the regulations. Ease of reading for members of the public.</p>
	195		<p>Creation of new section which relates to when a scholarship or loan repayment recipient may receive a waiver or a variance of obligation.</p> <p>Impact: More comprehensive regulations; greater clarity of the regulations; ease of reading the regulations for members of the public.</p>
200		This section lays out the terms of repayment once a recipient defaults.	<p>Addition of the requirement that a scholarship recipient shall pay a penalty in the event of default after graduation. The penalty shall be three times the award amount. This is the same requirement as other similar regulatory chapters. Minor technical amendments.</p> <p>Impact: More comprehensive regulations</p>

210		This section lays out the reporting requirements of the Virginia Commonwealth University School of Dentistry, regarding those students who receive the scholarship. The section also lays out the reporting requirements of scholarship and loan repayment recipients.	Formatting changes to make the section resemble similar sections in other similar regulatory chapters. Minor technical changes. Impact: Greater clarity of the regulations. Less burdensome regulations as similar regulatory chapters shall be governed the same.
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DEPARTMENT OF HEALTH
Chp 520- Amend Regulation Following Periodic Review

Part I
Definitions

1 12VAC5-520-10. Definitions.

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

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

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

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

10 "Commissioner" means the State Health Commissioner.

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

14 "Dental underserved area" means 1) a geographic area in Virginia designated by the State
15 Board of Health as a county or city in which the ratio of practitioners of dentistry to population is
16 less than that for the Commonwealth as a whole as determined by the commissioner or; ~~2) a~~
17 ~~dental health professions~~ professional ~~shortage area using criteria described in Part II (12VAC5-~~
18 ~~520-80 et seq.) of this chapter-;~~ or 3) a designated state facility.

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

22 "Designated state facility" means practice as a dentist in a facility operated by the ~~Virginia~~
23 ~~Department of Health,~~ Virginia Department of Behavioral Health and Developmental Services,
24 Virginia Department of Juvenile Justice, or the Virginia Department of Corrections.

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

28 "~~Interest at the prevailing bank rate for similar amounts of unsecured debt~~" means the prime
29 ~~lending rate plus 2.0% as published in the Wall Street Journal on the first day of the month in~~

30 ~~which the decision to repay is communicated to the commissioner by the recipient or on the first~~
31 ~~day of the month that the commissioner determines the recipient to be in default~~the legal rate of
32 interest pursuant to § 6.2-302 of the Code of Virginia.

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

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

42 "Recipient" means an eligible applicant who enters into a contract with the commissioner
43 and participates in the scholarship or loan repayment program.

44 ~~"Restitution" means three times the award amount received plus interest at the prevailing~~
45 ~~bank rate for similar amounts of unsecured debt as set forth in this regulation, owed to the~~
46 ~~Commonwealth of Virginia by a scholarship or loan repayment recipient who is in default of his~~
47 ~~contractual obligation as provided for in this chapter.~~

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

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

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

58 **12VAC5-520-20. Administration of program. (Repealed.)**

59 ~~The State Health Commissioner, as executive officer of the Board of Health, shall administer~~
60 ~~this program. Any requests for deviation from the prescribed definitions shall be considered on~~
61 ~~an individual basis by the board in regular session.~~

62 **12VAC5-520-30. (Repealed.)**

63 **12VAC5-520-40 to 12VAC5-520-70. [Repealed]**

64 Part II

65 Dental Underserved Area

66 **12VAC5-520-80. Population and dentist data.**

67 In order to determine the population-to-dentist ratio, the commissioner shall:

68 1. Use the population data or projections from the United States Census for independent
69 cities, counties and counties with independent cities within their boundaries;

70 2. Determine the number of practitioners of dentistry from data secured from the Virginia
71 State Board of Dentistry and the American Dental Association, adjusting for those
72 dentists licensed in Virginia but practicing in other states, the military and retired dentists
73 with active licenses;

74 3. Calculate this ratio every five years; and

75 4. Include as dental underserved areas those cities and counties determined to be dental
76 health professions shortage areas as defined by the Department of Health and Human Services
77 or designated a federal shortage area for the practice of dentistry as outlined in ~~42 CFR 5.142~~
78 CFR 5.2.

79 **12VAC5-520-90 to 12VAC5-520-120. [Repealed]**

80 Part III

81 Scholarship and Loan Repayment Awards

82 **12VAC5-520-130. Eligible applicants.**

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

89 ~~B. Any graduate of an accredited dental school in the United States who is establishing a~~
90 ~~practice in general or specialty dentistry in an underserved area or practicing dentistry in a~~
91 ~~designated state facility shall be eligible to apply for the Virginia Dentist Loan Repayment~~
92 ~~Program. General practice dentists will be within five years of graduation from an accredited~~
93 ~~undergraduate dental program and have existing loans accumulated as a result of their~~
94 ~~undergraduate dental program. Specialty practice dentists will be within five years of completion~~
95 ~~of their specialty training and have existing loans accumulated as a result of their undergraduate~~

96 dental program. ~~Dentists who received Virginia scholarship awards or other scholarships that~~
97 ~~paid their full tuition and fees are not eligible for the Dentist Loan Repayment Program for the~~
98 ~~years they received those awards.~~

99 A. In order to be considered for the Virginia Dental Scholarship Program, an applicant shall:

100 1. Be a United States citizen, a United States national, or a qualified alien pursuant to 8
101 USC § 1621;

102 2. Be currently enrolled, in good standing and attend the Virginia Commonwealth University
103 School of Dentistry full time;

104 3. Not have entered the first year of an accredited residency;

105 4. Demonstrate financial need, which is verified by the school's financial aid officer or
106 authorized person as part of the application process;

107 5. Submit a completed application form and appropriate grade transcript prior to the
108 established deadline dates; and

109 6. Preference for scholarships shall be given to:

110 a. Bona fide residents of Virginia as evidenced by being domiciled in the Commonwealth for
111 at least one year as defined by § 23.1-502 of the Code of Virginia; and

112 b. Students who are residents of a dental underserved area, and students from
113 economically disadvantaged backgrounds.

114 B. In order to be considered for the Virginia Dentist Loan Repayment Program, an applicant
115 shall:

116 1. Be a United States citizen, a United States national, or a qualified alien pursuant to 8
117 USC §1621;

118 2. Be a graduate of an accredited dental school in the United States;

119 3. Be establishing a practice in general or specialty dentistry in a dental underserved area;

120 4. Be a general practice dentist within five years of graduation from an accredited dental
121 program or a specialty practice dentist within five years of completion of specialty training;

122 5. Have existing loans accumulated as a result of the applicant's dental program;

123 6. Not have received Virginia scholarship awards or other scholarships that paid the
124 applicant's full tuition and fees; and

125 7. Submit a completed application form prior to the established deadline dates.

126 8. Preference shall be given to Virginia Commonwealth University School of Dentistry
127 graduates.

128 **12VAC5-520-140. Scholarship and loan repayment award.**

129 A Virginia dental scholarship or loan repayment shall be awarded to the recipient upon or
130 following the recipient's execution of a contract with the commissioner for scholarship or loan
131 repayment by practicing dentistry in an dental underserved area ~~or designated state facility~~ as
132 defined in this chapter.

133 **12VAC5-520-150. Distribution of scholarships and loan repayment awards.**

134 The Virginia General Assembly establishes the total combined appropriation for the dental
135 scholarship and dentist loan repayment programs. Funds shall be awarded for these programs
136 based on the following criteria:

137 1. ~~The governing board of Virginia Commonwealth University School of Dentistry~~ shall
138 use the application procedure established by the commissioner and annually submit the
139 names of qualified students to receive scholarships in accordance with the criteria ~~for~~
140 ~~preference~~ enumerated in 12VAC5-520-130. The total number of scholarship
141 awards ~~will~~shall be based on availability of funds. Scholarship awards ~~will~~shall be made
142 annually by October 30 to third-year and fourth-year dental students. First-year and
143 second-year students ~~will~~shall be considered for an award only in the event of extreme
144 financial need. Individual scholarship recipients may receive a maximum of five
145 scholarship awards.

146 2. The application period for the Dentist Loan Repayment Program ~~will~~shall begin in
147 October with awards made by the end of each fiscal year. Preference for loan repayment
148 awards ~~will~~shall be given to graduates of Virginia Commonwealth University School of
149 Dentistry. Individual loan repayment recipients may receive a maximum of four awards
150 upon graduation from dental school. All awards ~~will~~shall be competitive and will be
151 based on availability of funds.

152 **12VAC5-520-160. Contractual practice obligation.**

153 ~~A. Prior to the payment of money to becoming~~ a scholarship or loan repayment recipient, the
154 applicant shall enter into a contract with the commissioner shall prepare and enter into a
155 contract with the recipient. The contract shall: agreeing to terms and conditions upon which the
156 scholarship or loan repayment is granted.

157 ~~1. Provide~~ B. The contract shall provide that the recipient of the scholarship award shall
158 pursue the dental course of Virginia Commonwealth University until graduation ~~and upon~~
159 ~~graduation or upon graduation from an accredited residency program that does not exceed four~~
160 years. For each scholarship received, the participant agrees to engage in the equivalent of one
161 year full-time dental practice in a dental underserved area of Virginia. The recipient shall notify

162 the ~~commissioner~~department, in writing ~~of his proposed practice location or intent to enter a~~
163 ~~residency not more than 30 days after graduation and begin his approved practice within 90~~
164 ~~days after completing dental school or residency, and thereafter, within 180 days of graduation~~
165 ~~from the dental course of Virginia Commonwealth University or upon graduation from an~~
166 ~~accredited residency program that does not exceed four years, of the type of dental practice to~~
167 ~~be performed or intent to enter a residency. The notice shall include the name and address of~~
168 ~~the employer for approval. Thereafter the recipient shall~~ continuously engage in full-time dental
169 practice in a dental underserved area of Virginia ~~or in a designated state facility~~ for a period of
170 years equal to the number of annual scholarships received. Dental practice in federal agencies,
171 military service or the U.S. Public Health Service may not be substituted for scholarship
172 obligation.

173 ~~2. Provide~~C. The contract shall provide that upon graduation from an accredited dental
174 ~~school and receiving notification of the dentist loan repayment award, the dentist shall begin his~~
175 ~~approved practice within 90~~180 days ~~and thereafter continuously engage in.~~ For each loan
176 repayment received, the participant agrees to engage in the equivalent of one year full-time
177 dental practice in an a dental underserved area of Virginia or in a designated state facility for a
178 period of years equal to the number of loan repayment awards receiveddesignated by the Board
179 of Health.

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

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

187 ~~5. Provide~~F. The contract shall provide that the recipient shall repay the scholarship or loan
188 repayment obligation by practicing dentistry on a full-time basis in a dental underserved area,
189 shall maintain office hours convenient for the population of the area to have access to the
190 recipient's services and shall participate in all government-sponsored insurance programs
191 designed to ensure access to dental services of recipients of public assistance, including but not
192 limited to programs established pursuant to §§ 32.1-325 and 32.1-351 of the Code of Virginia.
193 The recipient shall not ~~selectively~~ place limits on the numbers of such patients admitted to the
194 practice.

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

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

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

213 H. The recipient may be absent from the place of approved practice for a total of four weeks
214 in each 12-month period for personal reasons. Absence for a period in excess of four weeks
215 without the written permission of the commissioner shall result in proportional reduction of the
216 period of credit toward fulfillment of the contractual obligation.

217 Part IV

218 Special Requests

219 **12VAC5-520-170. Special requests for approval.**

220 Special requests for approval of the practice of dentistry in an area in which the ratio does
221 not meet the definition of an ~~area of need~~ dental underserved area shall be considered by the
222 Board of Health on an individual basis. To obtain the board's approval, the scholarship or loan
223 repayment recipient shall substantiate to the board's satisfaction that the ratio does not correctly
224 depict the provision of dental services in the city or county and that additional practitioners are
225 necessary. Examples of situations deserving special consideration may include topography, age
226 or physical health of dental practitioners in the area, and sub-areas of high density population
227 that can be geographically identified and shown to have a ratio less than the state ratio.

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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.

Part VI
Default-Breach of Contract

12VAC5-520-190. Default-Breach of contract.

~~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 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 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~~

262 proportionate amount of money, such proportion being determined as the ratio of the
263 number of whole months that a recipient has practiced dentistry in an approved location
264 to the total number of months of the contractual obligation the recipient has incurred.
265 The commissioner may waive all or part of the scholarship or loan repayment obligation
266 under application by the recipient or his estate under these conditions and consider
267 whole or partial forgiveness of payment or service in consideration of individual cases of
268 hardship or inability to pay.

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

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

- 276 1. The commissioner is notified in writing by the recipient that he does not intend to fulfill
277 his contractual obligation;
- 278 2. The recipient has not accepted a placement and commenced his period of obligated
279 practice as provided for in subdivisions 1 and 2 of 12VAC5-520-160; or
- 280 3. The recipient absents himself without the consent of the commissioner from the place
281 of dental practice that the commissioner has approved for fulfillment of his contractual
282 obligation.

283 A. A scholarship recipient shall be in breach of contract if:

- 284 1. The recipient fails to complete his dental studies;
- 285 2. The recipient fails to begin or complete the terms of obligated service under the terms
286 and conditions of the scholarship contract;
- 287 3. The recipient falsifies or misrepresents information on the program application, the
288 verification of employment forms, or other required documents; or
- 289 4. The recipient's employment is terminated for good cause as determined by the
290 employer and confirmed by the department. If employment is terminated for reasons
291 beyond the participant's control (e.g. closure of site), the participant shall transfer to
292 another site approved by the board in the Commonwealth within six months of
293 termination. Failure of participant to transfer to another site shall be deemed to be a
294 breach of the contract.

295 B. A loan repayment recipient shall be in breach of contract if:

- 296 1. The recipient fails to begin or complete the term of obligated service under the terms
297 and conditions of the loan repayment contract;
298 2. The recipient falsifies or misrepresents information on the program application, the
299 verification of employment forms, or other required documents; or
300 3. The recipient's employment is terminated for good cause as determined by the
301 employer and confirmed by the department. If employment is terminated for reasons
302 beyond the participant's control (e.g. closure of site), the participant shall transfer to
303 another site approved by the board in the Commonwealth within six months of
304 termination. Failure of the participant to transfer to another site shall be deemed to be a
305 breach of the contract.

306 **12VAC5-520-195. Deferment and waivers.**

307 A. For recipients completing part of the scholarship or loan obligation prior to becoming
308 permanently disabled or in the event of death, the total amount of the funds owed shall be
309 reduced by the proportion of obligated years served. The obligation to make restitution may be
310 waived by the board upon application of the participant or the participant's personal
311 representative to the board.

312 B. Individual cases of undue hardship may be considered for a variance by the board of
313 payment or service pursuant to § 32.1-12 of the Code of Virginia.

314 C. All requests for deferments, waivers or variances must be submitted in writing to the
315 department for consideration and final disposition by the board.

316 Part VII

317 Repayment

318 **12VAC5-520-200. Repayment.**

319 A. Repayment requirements for scholarship and loan repayment recipients are as follows:

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

322 2. The commissioner in his discretion shall permit extension of the period of repayment
323 for up to ~~24 months~~ 2 years from the date that the recipient ~~is deemed to be in~~ is
324 ~~default~~ completes postgraduate training or the recipient enters into the full-time practice
325 of dentistry, whichever is later.

326 3. Partial fulfillment of the recipient's contractual obligation by the practice of dentistry as
327 provided for in ~~this~~ the recipient's contract shall reduce the amount
328 of ~~restitution~~ repayment by a percentage based on the number of whole months that the

329 recipient has practiced dentistry in an approved location and the total number of months
330 of the contractual obligation the recipient has incurred.

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

335 B. A scholarship recipient who defaults while still in dental school by voluntarily notifying the
336 commissioner in writing that he will not practice dentistry in Virginia as required by his contract
337 shall repay the total amount of scholarship funds received plus interest to the Commonwealth of
338 Virginia. A scholarship recipient who commits a breach of contract after graduation shall pay a
339 penalty of three times the amount of all monetary scholarship awards paid to the scholarship
340 recipient plus interest to the Commonwealth of Virginia.

341 C. In the event that a recipient, in accordance with the terms of the contract, fully repays the
342 Commonwealth for part or all of any scholarship or loan repayment because of breach of
343 contract and later fulfills the terms of the contract after repayment, the Commonwealth shall
344 reimburse the award amount repaid by the recipient minus applicable interest and fees.

345 Part VIII

346 Records and Reporting

347 **12VAC5-520-210. Reporting requirements.**

348 A. Reporting requirements of Virginia Commonwealth University School of Dentistry
349 scholarship and loan repayment recipients are as follows:

350 1. Virginia Commonwealth University School of Dentistry shall maintain accurate records
351 of the enrollment and academic status of scholarship recipients until the recipient's
352 graduation from dental school. The dental school shall provide a report listing the status
353 of each recipient annually to the commissioner.

354 2. Each scholarship and loan repayment recipient shall at any time provide information
355 as requested by the commissioner to verify compliance with the practice requirements of
356 the scholarship or loan repayment contract.

357 ~~B. The recipient shall report any changes of mailing address, change of academic standing,~~
358 ~~change of intent to fulfill his contractual obligation and any other information that may be~~
359 ~~relevant to the contract at such time as changes or information may occur. The recipient shall~~
360 ~~respond within 30 days with such information as may be requested by the commissioner. notify~~
361 ~~the department in writing within 30 days if any of the following events occur:~~

362 1. Recipient changes name;

- 363 2. Recipient changes address;
- 364 3. Scholarship recipient changes dental program;
- 365 4. Recipient changes practice site (a recipient is required to request in writing and obtain
- 366 prior approval of changes in practice site);
- 367 5. Recipient no longer intends or is unable to fulfill service obligation as a dentist in the
- 368 Commonwealth;
- 369 6. Recipient ceases to practice as a dentist; or
- 370 7. Scholarship recipient ceases or no longer intends to complete his dental program.



COMMONWEALTH of VIRGINIA

Department of Health

Marissa J. Levine, MD, MPH, FAAFP
STATE HEALTH COMMISSIONER

P O BOX 2448
RICHMOND, VA 23218

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: February 22, 2017

TO: Virginia State Board of Health

FROM: Erik Bodin, Director, Office of Licensure and Certification

SUBJECT: Virginia's Rules and Regulations Governing Cooperative Agreements (12VAC5-221)

Enclosed for your review is a fast track action for the proposed permanent regulations for Virginia's Rules and Regulations Governing Cooperative Agreements (12VAC5-221) to replace the emergency regulations enacted in 2015.

House Bill 2316 enacted by the 2015 General Assembly mandates this regulatory action. HB2316 required the Board of Health to promulgate regulations that at a minimum address the review of applications for proposed cooperative agreements, the process by which applications for proposed cooperative agreements shall be approved or denied, post-approval monitoring and a fee schedule establishing the amount of the annual fee per cooperative agreement. HB2316 further specified that the regulations must be effective within 280 days of enactment. For that reason, the Board promulgated emergency regulations in 2015 utilizing the emergency rulemaking process authorized by the Administrative Process Act.

The proposed permanent regulations are, with one exception, identical to the emergency regulations, which were prepared with the assistance of a regulatory advisory panel. The regulatory advisory panel met twice in 2015 and panel members provided recommendations regarding regulatory language to the State Health Commissioner. VDH reviewed the recommendations of the regulatory advisory panel and regulations for similar programs within other jurisdictions. From that information, VDH created the language that was approved by the Board as the emergency regulations. These permanent regulations contain provisions pertaining to definitions, a fee schedule, and procedures for the Commissioner's request for information, the Commissioner's review, ongoing monitoring and annual reporting. These permanent regulations differ from the emergency regulations only in the change of the definition of "day."

The Board of Health is requested to approve the permanent regulations to replace the emergency regulations, which are set to expire on July 17, 2017. Should the Board of Health approve the regulations, they will be submitted to the Office of the Attorney General to begin the executive branch review process, as specified by the Administrative Process Act. Following executive branch review and approval, the regulations will be published in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall website. The regulations will become effective 45-days following publication in the Virginia Register of Regulations, following a 30-day public comment period.



townhall.virginia.gov

Fast-Track Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-221
Regulation title(s)	Virginia's Rules and Regulations Governing Cooperative Agreements
Action title	Establishes standards for the review of applications for proposed Cooperative Agreements and post-approval monitoring
Date this document prepared	February 22, 2017

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 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.

House Bill 2316 enacted by the 2015 General Assembly mandates the Board of Health to promulgate regulations that at a minimum address the review of applications for proposed cooperative agreements, the process by which applicants for proposed cooperative agreements shall be approved or denied, post-approval monitoring and a fee schedule establishing the amount of the annual fee per cooperative agreement. HB2316 further specified that the regulations must contain provisions pertaining to definitions, a fee schedule, procedures for the Commissioner's request for information, the Commissioner's review, ongoing monitoring and annual reporting. In drafting the Regulations the Virginia Department of Health consulted other jurisdictions, convened a regulatory advisory panel, and held a public hearing. Tennessee has a program which is similar to the program envisioned by HB2316 and is a neighboring jurisdiction to Southwest Virginia. For these reasons, the Virginia Department of Health utilized regulations issued by Tennessee as a framework to build upon in drafting the Regulations. The Virginia Department of Health convened a regulatory advisory panel of stakeholders consisting of hospital providers, health plans, physicians, and representatives from the Southwest Virginia Health Authority. The regulatory advisory

panel met twice and provided feedback to a framework document that the Virginia Department of Health incorporated into the Regulations. Finally the Virginia Department of Health held a public hearing in Abingdon, Virginia. Public comment received at the hearing was considered and where appropriate incorporated into the Regulations.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

No acronyms are utilized within this Agency Background Document.

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 taking the action; and 3) the title of the regulation.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

The regulatory chapter 12VAC5-221 is promulgated under the authority of HB 2316 of the 2015 General Assembly and § 32.1-12 of the Code of Virginia. HB2316 enacted as Chapter 741 of the 2015 Virginia Acts of Assembly contains an enactment clause which mandates the State Board of Health to promulgate regulations to implement the provisions of the Act and requires those regulations contain at a minimum provisions regarding i) the review of applications for proposed cooperative agreements; ii) the process by which applications for proposed cooperative agreements shall be approved or denied; iii) post-approval monitoring; and iv) a schedule establishing the amount of the annual fee that the Commissioner is authorized to assess from the parties to a cooperative agreement. Section 32.1-12 of the Code of Virginia authorizes the Board of Health to make, adopt, promulgate and enforce such regulations and provide for reasonable variances and exemptions therefrom as may be necessary to carry out the provisions of Title 32.1 of the Code and other laws of the Commonwealth administered by it, the Commissioner or the Department.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation 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.

In order to address the unique healthcare challenges that exist in the Southwest Virginia region, the General Assembly through HB2316 has authorized the Commissioner to approve Cooperative Agreements that are beneficial to individuals served by the Southwest Virginia Health Authority, and to actively supervise Cooperative Agreements to ensure compliance with the provisions that have been approved. The intent of this regulatory action is to promote and protect the health and safety of individuals within the Southwest Virginia Health Authority's geographic area by ensuring any Cooperative Agreements entered into by hospitals foster improvements in the quality of health care, moderate increases in health care cost, improve access to needed health care services, and promote improvements in population health status in the Southwest Virginia Health Authority's geographic area. HB2316 mandates that this regulatory action include at a minimum provisions regarding i) the review of applications for proposed cooperative agreements; ii) the process by which applications for proposed cooperative agreements shall be approved or denied; iii) post-approval monitoring; and iv) a schedule establishing the amount of the annual fee that the Commissioner is authorized to assess from the parties to a cooperative agreement. The proposed Regulations contain provisions which meet these requirements.

Rationale for using fast-track process

Please explain the rationale for using the fast-track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

HB2316 mandates the Board of Health to promulgate regulations that at a minimum address the review of applications for proposed cooperative agreements, the process by which applicants for proposed cooperative agreements shall be approved or denied, post-approval monitoring and a fee schedule establishing the amount of the annual fee per cooperative agreement within 280 days. The emergency regulations that were promulgated have been utilized since 2015. Furthermore, the Code of Virginia (§15.2-5384.1) is very specific in regards to the review of cooperative agreements, with the regulatory language closely tracking the statutory requirements. Therefore, the Virginia Department of Health believes the proposed regulation will be noncontroversial, allowing use of the fast-track process.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of changes" section below.

A chart describing the proposed new regulation

Section Number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
10 - Purpose	This section of the regulations lays out the purpose of the regulatory chapter which is derived from HB 2316 (2015) and § 15.2-5368 et.seq. of the Code of Virginia.	Any procedures and policies implemented by the Southwest Virginia Health Authority.	Intent: To provide members of the public a better understanding of the reason for the regulatory chapter and the program. Likely impact: Notice to the public and parties to a Cooperative Agreement.
20 - Definitions	This section of the regulations defines key terms utilized within the regulatory chapter.	Any procedures and policies implemented by the Southwest Virginia Health Authority.	Intent: To ensure members of the public and regulated entities have a clear understanding of the vocabulary utilized within the regulatory chapter. Likely impact: Clear understanding of terms used in the regulations.

<p>30 – Separate Applications</p>	<p>This section of the regulations requires that each cooperative agreement entered into requires its own Letter Authorizing Cooperative Agreement. The section states that amendments to existing Cooperative Agreements require submission of a new application.</p>	<p>Any procedures and policies implemented by the Southwest Virginia Health Authority.</p>	<p>Intent: To ensure the Commissioner and the Authority have notice of all activities taking place under the Cooperative Agreement program.</p> <p>Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.</p>
<p>40 – Application</p>	<p>This section of the regulations specifies the process for applying for a Letter Authorizing Cooperative Agreement. The section states that applications shall be submitted simultaneously to the Authority, Commissioner and the Office of the Attorney General. The section also lays out the method for submitting information considered to be confidential.</p>	<p>Any procedures and policies implemented by the Southwest Virginia Health Authority.</p>	<p>Intent: To ensure that applicants submit applications in the manner consistent with the Code of Virginia.</p> <p>Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.</p>
<p>50 – Fee Schedule</p>	<p>This section of the regulations lays out the method for submitting application fees, establishes the application fee, method for the Department to refund the applicant should it be necessary and establishes that the Department may charge additional fees beyond the application fee should the cost to the Department be greater than the application fee.</p>	<p>Any procedures and policies implemented by the Southwest Virginia Health Authority</p>	<p>Intent: To ensure that authorized fees are assessed and collected.</p> <p>Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.</p>
<p>60 – Public Hearing</p>	<p>This section of the regulations lays out the requirements of the public hearing required by § 15.2-5384.1 (D) of the Code of Virginia. This section states that the public hearing shall be held by the Authority in conjunction with the Virginia Department of Health, shall be open to the public and shall be recorded by the Virginia Department of Health.</p>	<p>Any procedures and policies implemented by the Southwest Virginia Health Authority</p>	<p>Intent: To establish the requirements of the public hearing which is a statutory mandate required by § 15.2- 5384.1 (D) of the Code of Virginia. Ensure the public and regulated entities are aware that public hearings held in accordance with this section shall be recorded.</p> <p>Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.</p>
<p>70 – The Commissioner's Request for Information</p>	<p>This section of the regulations lays out that information the Commissioner shall request from an applicant provided that information is not already included within the application. The Commissioner is permitted to request further information not specified by regulation.</p>	<p>Any procedures and policies implemented by the Southwest Virginia Health Authority</p>	<p>Intent: To ensure the applicants have adequate notice of the information to be requested by the Commissioner. Placing this information in regulation provides the applicant the opportunity to gather the listed information while the Authority is reviewing their application, provided any of the information is not included within the Authority's application process.</p> <p>Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement. Notice to the public and parties to a Cooperative Agreement.</p>

<p>80 – The Commissioner's Review</p>	<p>This section of the regulations lays out the process the Commissioner shall follow when reviewing an application for a Letter Authorizing Cooperative Agreement. The Commissioner shall Consult with the Attorney General's Office and other affected agencies of the Commonwealth and may consult with the Federal Trade Commission and other affected jurisdictions. This section specifies what materials the Commissioner shall consider, when the Commissioner shall issue his decision, and the circumstances under which the Commissioner shall approve an application.</p>	<p>Any procedures and policies implemented by the Southwest Virginia Health Authority</p>	<p>Intent: To ensure an applicant is notified of the method of the Commissioner's review. Transparency.</p> <p>Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement. Notice to the public and parties to a Cooperative Agreement.</p>
<p>90 - Action on an Application</p>	<p>This section of the regulations provides the framework for the Commissioner's decision including the timeframe a decision will be rendered, as required by § 15.2-5384.1 (F) of Virginia, and laying out potential conditions which may be placed on a Letter Authorizing Cooperative Agreement.</p>	<p>Any procedures and policies implemented by the Southwest Virginia Health Authority</p>	<p>Intent: To ensure an applicant is aware of the timeframe within which a decision will be rendered and aware prior to a decision that the Letter Authorizing Cooperative Agreement may have conditions. Also ensuring the applicant is aware of their rights under the Administrative Process Act.</p> <p>Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.</p>
<p>100 – Ongoing and Active Supervision</p>	<p>This section of the regulations lays out the process for ongoing monitoring should a Letter Authorizing Cooperative Agreement be issued, including ongoing reporting to the Department. Further, the section lays out how the Department will evaluate continued reporting to determine if the Letter Holder is compiling with the terms of the Letter Authorizing Cooperative Agreement including conditions. That process includes the creation of qualitative measures. The qualitative measures will be created utilizing the Technical Advisory Panel established in Section 120 of these Regulations. This section permits the Virginia Department of Health to make on-site inspections if necessary and requires an investigation of any complaints regarding noncompliance with the Cooperative Agreement or the Letter Authorizing Cooperative Agreement. The regulation also provides for other methods of monitoring</p>	<p>Any procedures and policies implemented by the Southwest Virginia Health Authority</p>	<p>Intent: To ensure that Letter Holders are aware of the requirements of ongoing supervision and the method the Department will use to evaluate ongoing supervision. This will ensure transparency.</p> <p>Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.</p>

	provided the Commissioner and the Department provides advance notice to the Parties.		
110 – Annual Reporting	This section of the regulations details the requirements of the annual report each Letter Holder is required to submit. This section lays out the fee due to be submitted with the annual report.	Any procedures and policies implemented by the Southwest Virginia Health Authority	Intent: Notice to Letter Holders regarding the requirements of Annual Reporting and the amount of the annual filing fee. Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.
120 – Technical Advisory Panel	This section of the regulations states that the Commissioner shall appoint a Technical Advisory Panel which will provide recommendations to the Commissioner regarding the creation of qualitative measures which will be utilized to track the benefits of a Cooperative Agreement. The section further lays out the requirements of the membership of the Technical Advisory Panel, when it shall meet and the metrics it shall identify.	Any procedures and policies implemented by the Southwest Virginia Health Authority	Intent: Specify the process for the appointment of a Technical Advisory Panel and the task of that panel. Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.
130 – Enforcement Procedures	This section of the regulations lays the procedures that the Commissioner is to follow should there be reason to believe that a Cooperative Agreement no longer meets the requirements of the Code of Virginia. The section also lays out the circumstances in which the Commissioner may revoke a Letter Authorizing Cooperative Agreement.	Any procedures and policies implemented by the Southwest Virginia Health Authority	Intent: Specify the process in the event the Letter Holder is no longer in compliance with the Letter Authorizing Cooperative Agreement. Transparency. Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.
140 – Voluntary Termination of Cooperative Agreement	This section of the regulations states that Letter Holder shall file notice with the Department should they terminate a Cooperative Agreement and return the Letter Authorizing Cooperative Agreement.	Any procedures and policies implemented by the Southwest Virginia Health Authority	Intent: Specify the process in the event the Letter Holder wishes to voluntarily terminate a Cooperative Agreement. Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.
150 – Official Records	This section of the regulations clarifies that the Commissioner and the Department shall maintain all Cooperative Agreements, all records collected pursuant to the regulatory chapter and all annual reports as official records. The section also states which records shall be available on the Department's website.	Any procedures and policies implemented by the Southwest Virginia Health Authority	Intent: Specify requirements regarding records collected by the Department and the Commissioner in administering the program. Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.

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 primary advantages to the public, the agency and the Commonwealth is in meeting the stated policy of the Commonwealth as included in Va Code §15.2-5384.1 “to encourage cooperative, collaborative, and integrative arrangements, including mergers and acquisitions among hospitals, health centers, or health providers who might otherwise be competitors. To the extent such cooperative agreements, or the planning and negotiations that precede such cooperative agreements, might be anticompetitive within the meaning and intent of state and federal antitrust laws, the intent of the Commonwealth with respect to each participating locality is to supplant competition with a regulatory program to permit cooperative agreements that are beneficial to citizens served by the Authority, and to invest in the Commissioner the authority to approve cooperative agreements recommended by the Authority and the duty of active supervision to ensure compliance with the provisions of the cooperative agreements that have been approved.” The proposed regulatory action poses no disadvantage to the public or the Commonwealth.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need 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 requirements in this proposal that exceed 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.

Those localities within the jurisdiction of the Southwest Virginia Health Authority, specifically those with the Lenowisco and Cumberland Plateau Planning District Commissions, as well as the Counties of Smyth and Washington, and the City of Bristol.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, 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.

HB2316 mandates the Board of Health to promulgate regulations governing cooperative agreements. The regulations are mandated by law and there are no viable alternatives to the proposed regulatory action to achieve the necessary regulatory changes mandated by HB2316.

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 requirement creates the anticipated economic impact.

<p>Projected cost to the state to implement and enforce the proposed regulation, including: a) fund source / fund detail; and b) a delineation of one-time versus on-going expenditures</p>	<p>A minimum \$87,000 for the initial review of a cooperative agreement, with the likelihood that this is a conservative estimate. A minimum of \$75,000 annually for ongoing, active State supervision and monitoring of the cooperative agreement, with the likelihood that this is a conservative estimate. A maximum of \$75,000 for initial review and \$75,000 annually for supervision is authorized, by statute, for reimbursement from the applicants.</p>
<p>Projected cost of the new regulations or changes to existing regulations on localities.</p>	<p>None</p>
<p>Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.</p>	<p>Wellmont Health System, Mountain States Health Alliance, as well as all competitors, health insurance carriers and consumers of health care services in those localities within the jurisdictions of the Southwest Virginia Health Authority.</p>
<p>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: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>258,101 health care consumers. 3,253 physicians. 11 hospitals. At least 8 health insurance carriers plus Medicare and Medicaid.</p>
<p>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 including: a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and b) 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.</p>	<p>Beyond the \$75,000 reimbursements to the State it is unknown and impossible to estimate the cost applicants may incur to apply for a cooperative agreement as allowed in the regulations, to maintain records and to comply with annual record keeping and reporting and any other requirements of active supervision by the State.</p>
<p>Beneficial impact the regulation is designed to produce.</p>	<p>Provides the criteria by which cooperative agreements are to be considered, approved or denied, and continuously supervised.</p>

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.

HB 2316 enacted by the 2015 General Assembly mandates that the Board of Health promulgate these regulations. Therefore, there are no alternatives to this regulatory action.

Public participation notice

If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register; and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

Family impact

Please assess the impact of this 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.

It is not anticipated that the proposed regulatory action will have any direct impact on the institution of the family and family stability.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please list separately: (1) all differences between the pre-emergency regulation and this proposed regulation; and 2) only changes made since the publication of the emergency regulation.

Current Section Number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
	12VAC5-221-10. Purpose		To address the unique healthcare challenges that exist in the Southwest Virginia community, the General Assembly authorized the Commissioner

			<p>to approve or deny an Application for a Cooperative Agreement following receipt of a recommendation for approval by the Authority. To the extent an approved Cooperative Agreement might be anticompetitive within the meaning and intent of state and federal antitrust laws, it is the intent of the Commonwealth with respect to each Participating Locality to supplant competition with a regulatory program to permit Cooperative Agreements that are beneficial to citizens served by the Authority. The Commissioner is authorized to issue a Letter Authorizing Cooperative Agreement if he determines by a preponderance of the evidence that the benefits likely to result from the Cooperative Agreement outweigh the disadvantages likely to result from a reduction in competition. The Commissioner is responsible for actively supervising the Parties that receive the Letter Authorizing Cooperative Agreement to ensure compliance with the provisions that have been approved. Such intent is within the public policy of the Commonwealth to facilitate the provision of quality, cost-efficient medical care to residents of a Participating Locality.</p> <p>Intent: To provide members of the public a better understanding of the reason for the regulatory chapter and the program.</p> <p>Likely impact: Notice to the public and parties to a Cooperative Agreement.</p>
	<p>12VAC5-221-20. Definitions</p>		<p>"Applicant" means a Party to a proposed Cooperative Agreement who submits an Application to the Authority pursuant to § 15.2-5384.1 of the Code of Virginia.</p> <p>"Application" means the written materials submitted to the Authority and the Department in accordance with § 15.2-5384.1 of the Code of Virginia by Applicants.</p> <p>"Authority" means the political subdivision organized and operated pursuant to Chapter 53.1 of Title 15.2 of the Code of Virginia, or if such Authority is abolished, the board, body, authority, Department, or officer succeeding to the principal functions thereof or to whom the powers given by Chapter 53.1 of Title 15.2 of the Code of Virginia are given by law.</p> <p>"Attorney General" means the Attorney General for the Commonwealth of Virginia.</p> <p>"Commissioner" means the State Health Commissioner.</p> <p>"Cooperative Agreement" means an agreement among two or more hospitals for the sharing, allocation, consolidation by merger or other combination of assets, or referral of patients, personnel, instructional programs, support services, and facilities or medical, diagnostic, or laboratory facilities or procedures or other services traditionally offered by hospitals.</p> <p>"Day" or "Days" means calendar days.</p> <p>"Department" means the Virginia Department of Health.</p> <p>"Hospital" includes any health center and health provider under common ownership with the hospital and means any and all providers of dental, medical, and mental health services, including all related facilities and approaches thereto and appurtenances thereof. Dental, medical, and mental health facilities includes any</p>

		<p>and all facilities suitable for providing hospital, dental, medical, and mental health care, including any and all structures, buildings, improvements, additions, extensions, replacements, appurtenances, lands, rights in lands, franchises, machinery, equipment, furnishing, landscaping, approaches, roadways, and other facilities necessary or desirable in connection therewith or incidental thereto (including, without limitation, hospitals, nursing homes, assisted living facilities, continuing care facilities, self-care facilities, mental health facilities, wellness and health maintenance centers, medical office facilities, clinics, outpatient surgical centers, alcohol, substance abuse and drug treatment centers, dental care clinics, laboratories, research facilities, sanitariums, hospices, facilities for the residence or care of the elderly, the handicapped or the chronically ill, residential facilities for nurses, interns, and physicians and any other kind of facility for the diagnosis, treatment, rehabilitation, prevention, or palliation of any human illness, injury, disorder, or disability), together with all related and supporting facilities and equipment necessary and desirable in connection therewith or incidental thereto, or equipment alone, including, without limitation, kitchen, laundry, laboratory, wellness, pharmaceutical, administrative, communications, computer and recreational facilities and equipment, storage space, mobile medical facilities, vehicles and other equipment necessary or desirable for the transportation of medical equipment or the transportation of patients. Dental, medical, and mental health facilities also includes facilities for graduate-level instruction in medicine or dentistry and clinics appurtenant thereto offering free or reduced rate dental, medical, or mental health services to the public.</p> <p><u>"Letter Authorizing Cooperative Agreement"</u> means a document that is issued by the Commissioner approving a Cooperative Agreement.</p> <p><u>"Measure"</u> means some number of factors or benchmarks, which may be binary, a range or continuous factors.</p> <p><u>"Participating Locality"</u> means any county or city in the LENOWISCO or Cumberland Plateau Planning District Commissions and the Counties of Smyth and Washington and the City of Bristol with respect to which an authority may be organized and in which it is contemplated that the Authority will function.</p> <p><u>"Party"</u> means a hospital entering into a Cooperative Agreement.</p> <p><u>"Plan of Separation"</u> means the written proposal submitted with an Application to return the parties to a pre-consolidation state, which includes a plan for separation of any combined assets, offering, provision, operation, planning, funding, pricing, contracting, utilization review or management of health services or any combined sharing, allocation, or referral of patients, personnel, instructional programs, support services and facilities or medical, diagnostic or laboratory facilities or procedures or other services traditionally offered by hospitals, including any parent or subsidiary at the time the consolidation occurs or thereafter.</p> <p><u>"Primary Service Area"</u> or <u>"PSA"</u> means the</p>
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			<p><u>geographic area from which a hospital draws 75% of its patients as measured by the residential zip code of each patient.</u> <u>"Secondary Service Area" or "SSA" means the geographic area from which a hospital draws an additional 15% of its patients, as measured by the residential zip code of each patient.</u></p> <p>Intent: To ensure members of the public and regulated entities have a clear understanding of the vocabulary utilized within the regulatory chapter.</p> <p>Likely impact: Clear understanding of terms used in the regulations.</p>
	<p>12VAC5-221-30. Separate Applications</p>		<p><u>A Party shall submit an Application for a Letter Authorizing Cooperative Agreement for each Cooperative Agreement the Party is applying to enter into. This provision applies even in the event that the Parties have an existing Letter Authorizing Cooperative Agreement issued by the Commissioner. An amendment to a Cooperative Agreement shall require submission of a new Application.</u></p> <p>Intent: To ensure the Commissioner and the Authority have notice of all activities taking place under the Cooperative Agreement program.</p> <p>Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.</p>
	<p>12VAC5-221-40. Application</p>		<p><u>A. Parties within any Participating Locality may submit an Application for a Letter Authorizing Cooperative Agreement to the Authority. Information regarding the requirements of an Application for a Letter Authorizing Cooperative Agreement submitted to the Authority should be obtained through the Authority.</u> <u>B. At the time of submission to the Authority, Parties shall simultaneously submit a copy of the Application to the Commissioner and the Attorney General.</u> <u>C. If the Authority requires the Applicant to submit additional information before determining that the Application is complete, the Parties shall simultaneously submit a copy of the additional information to the Authority, the Commissioner, and the Attorney General.</u> <u>D. If the applicants believe the materials submitted contain proprietary information that are required to remain confidential, such information must be clearly identified and the applicants shall submit duplicate applications, one with full information for the Commissioner's use and one redacted application available for release to the public. Proprietary information that is clearly identified by the Applicants will be kept confidential by the Department pursuant to § 2.2-3705.6 (3) of the Code of Virginia.</u></p> <p>Intent: To ensure that applicants submit applications in the manner consistent with the Code of Virginia.</p> <p>Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.</p>

	<p>12VAC5-221-50. Fee Schedule</p>		<p><u>A. Fees shall be remitted only by certified check, cashier's check, bank money order or other methods approved by the department. Fees shall be made payable to the Department.</u> <u>B. The Application fee shall be \$50,000 and shall be due to the Department upon its receipt of a recommendation for approval from the Authority.</u> <u>C. If the Commissioner should determine after review of the Application that the actual cost incurred by the Department is less than \$50,000, the Applicant shall be reimbursed the amount that is greater than the actual cost. If the Commissioner should determine that the actual cost incurred by the Department is greater than \$50,000, the Applicant shall pay any additional amounts due as instructed by the Department. The Application fee shall not exceed \$75,000.</u></p> <p>Intent: To ensure that the application and monitoring fee structure is clear in the manner consistent with the Code of Virginia.</p> <p>Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.</p>
	<p>12VAC5-221-60. Public Hearing</p>		<p><u>A. The Authority shall, in conjunction with the Commissioner, schedule a public hearing for each completed Application submitted. The hearing shall be held no later than 45 days after the receipt of a complete Application by the Authority.</u> <u>B. The Authority will publish and issue notice of the hearing in accordance with § 15.2-5384.1 (C) of the Code of Virginia.</u> <u>C. The public hearing shall be open to the public in accordance with the provisions of the Virginia Freedom of Information Act (§ 2.2-3700 et. seq.) of the Code of Virginia.</u> <u>D. The public hearing shall be recorded by the Virginia Department of Health.</u></p> <p>Intent: To establish the requirements of the public hearing which is a statutory mandate required by § 15.2- 5384.1 (D) of the Code of Virginia. Ensure the public and regulated entities are aware that public hearings held in accordance with this section shall be recorded.</p> <p>Likely impact: Effective oversight of Letters authorizing Cooperative Agreements.</p>
	<p>12VAC5-221-65. Public Comment to the Commissioner</p>		<p><u>The public may submit written comments regarding the Application to the Commissioner. To ensure consideration by the Commissioner, written comments must be received no later than 14 days after the Authority adopts its recommendation on the Application.</u></p> <p>Intent: Assure public participation is the cooperative agreement review process.</p> <p>Likely impact: Improved information and transparency in the review of requests for letters authorizing Cooperative Agreements.</p>
	<p>12VAC5-221-70. The Commissioner's Request for Information</p>		<p><u>A. Upon receipt of the Authority's recommendation for approval, the Commissioner and Department may request supplemental information from the Applicants.</u> <u>B. To the extent the information is not present within the Application, the Commissioner shall request the following information:</u></p>

		<p>1. A report(s) used for public information and education about the proposed Cooperative Agreement prior to the Parties' submission of the Application. The Applicants shall document the efforts used to disseminate the report(s). The report(s) shall include, but are not limited to:</p> <ul style="list-style-type: none"> a. A description of the proposed Primary Service Area (PSA) and Secondary Service Areas (SSA) and the services and facilities to be included in the Cooperative Agreement; b. A description of how health services will change if the Letter Authorizing Cooperative Agreement is issued; c. A description of improvements in patient access to health care including prevention services for all categories of payers and advantages patients will experience across the entire service area regarding costs, availability, and accessibility upon implementation of the Cooperative Agreement and/or findings from studies conducted by hospitals and other external entities, including health economists, and clinical services and population health experts, that describe how implementation of the proposed Cooperative Agreement will be effective with respect to resource allocation implications; efficient with respect to fostering cost containment, including, but not limited to, eliminating duplicative services; and equitable with respect to maintaining quality and competition in health services within the service area and assuring patient access to and choice of insurers and providers within the health care system; d. A description of any plans by the Parties regarding existing or planned facilities that will impact access for patients to the services currently offered by the Parties at their respective facilities, including expansions, closures, reductions in capacity, consolidation, and reduction or elimination of any services; e. A description of the findings from community or population health assessments for the service areas regarding major health issues, trends, and health disparities, including comparisons to measures for the state and similar regional areas, and a description of how the health of the population will change if the Letter Authorizing Cooperative Agreement is issued; and f. A description of the impact on the health professions workforce including long-term employment, wage levels, recruitment, and retention of health professionals. <p>2. A record of community stakeholder and consumer views of the proposed Cooperative Agreement collected through a public participatory process including meetings and correspondence. Transcripts or minutes of any meetings held during the public participatory process shall be included in the report.</p> <p>3. A summary of the nature of the proposed Cooperative Agreement between the parties;</p> <p>4. A signed copy of the Cooperative Agreement and a copy of the following:</p> <ul style="list-style-type: none"> a. A description of any consideration passing to any Party, individual or entity under the Cooperative Agreement including the amount, nature, source, and recipient; b. A detailed description of any merger, lease, operating or management contract, change of control or other acquisition or change, direct or
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		<p>indirect, in ownership of any Party or of the assets of any Party to the Cooperative Agreement;</p> <p>c. A list of all services and products and of all hospitals and other service locations that are a subject of the Cooperative Agreement including those not located or provided within the boundaries of the Commonwealth of Virginia, and including, but not limited to, hospitals or other inpatient facilities, insurance products, physician practices, pharmacies, accountable care organizations, psychiatric facilities, nursing homes, physical therapy and rehabilitation units, home care agencies, wellness centers or services, surgical centers or services, dialysis centers or services, cancer centers or services, imaging centers or services, support services, and any other product, facility, or service; and</p> <p>d. A description of each Party's contribution of capital, equipment, labor, services, or other contribution of value to the transaction.</p> <p>5. A detailed description of the current and proposed PSA and SSA for the Parties, including the PSA and SSA of each of the Parties' hospitals, not limited to the boundaries of the Commonwealth of Virginia. If the proposed PSA and SSA differ from the service areas where the Parties have conducted business over the five (5) years preceding the Application, a description of how and why the proposed PSA or SSA differ and why changes are proposed;</p> <p>6. A description of the prior history of dealings between the Parties for the last five (5) years, including but not limited to, their relationship as competitors and any prior joint ventures, affiliations or other collaborative agreements between the Parties.</p> <p>7. Documents sufficient to show the financial performance of each Party to the transaction for each of the preceding five (5) fiscal years including tax returns, debt, bond rating, and debt service, and copies of offering materials, subsequent filings such as continuing disclosure agreements and material event disclosures, and financial statements prepared by external certified public accountants, including management reports;</p> <p>8. A copy of the current annual budget and budgets for the last five (5) years for each Party to the Cooperative Agreement. The budgets shall be in sufficient detail so as to determine the fiscal impact of the Cooperative Agreement on each Party. The budgets shall be prepared in conformity with generally accepted accounting principles (GAAP) and all assumptions used shall be documented;</p> <p>9. Projected budgets, including project costs, revenues, profit margins, and operating ratios, of each Party for each year for a period of five years after a Letter Authorizing Cooperative Agreement is issued. The budgets shall be prepared in conformity with generally accepted accounting principles (GAAP) and all assumptions used shall be documented;</p> <p>10. A detailed explanation of the projected effects including expected change in volume, price, and revenue as a result of the Cooperative Agreement, including:</p> <p>a. Identification of all insurance contracts and payer agreements in place at the time of the Application and a description of pending or</p>
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		<p>a. <u>The identity of any non-Party hospital located in the PSA and SSA and any non-Party hospital outside of the PSA and SSA that also serves patients in the Parties' PSA and SSA;</u></p> <p>b. <u>Estimates of the share of hospital services furnished by each of the Parties and any non-Party hospitals;</u></p> <p>c. <u>Identification of whether any services or products of the proposed Cooperative Agreement are currently being offered or capable of being offered by any non-Party hospitals in the PSA and SSA and a description of how the proposed Cooperative Agreement will not exclude such non-Party hospitals from continued competitive and independent operation in the PSA and SSA;</u></p> <p>d. <u>A listing of the physicians employed by or under contract with each of the Parties' hospitals in the PSA and SSA, including their specialty and office location(s);</u></p> <p>e. <u>The identity of any potential entrants in the Parties' PSA and SSA and the basis for any belief that such entry is likely within the two calendar years immediately following the date of the Letter Authorizing Cooperative Agreement is issued by the Department; and</u></p> <p>f. <u>A list of each Party's top 10 commercial insurance payers by revenue within the PSA and SSA.</u></p> <p>15. <u>A detailed description of each of the benefits that the Parties propose will be achieved through the Cooperative Agreement. For each benefit include:</u></p> <p>a. <u>A description specifically describing how the Parties intend to achieve the benefit;</u></p> <p>b. <u>A description of what the Parties have done in the past with respect to achieving or attempting to achieve the benefits independently or through collaboration and how this may change if the Cooperative Agreement is granted;</u></p> <p>c. <u>An explanation of why the benefit can only be achieved through a Cooperative Agreement and not through other less restrictive arrangements; and</u></p> <p>d. <u>A description of how the Parties propose that the Commissioner measure and monitor achievement of the proposed benefit including:</u></p> <p>(1) <u>Proposed measures and suggested baseline values with rationale for each measure to be considered by the Commissioner in developing a plan to monitor achievement of the benefit;</u></p> <p>(2) <u>The current and projected levels, and the trajectory, for each measure that would be achieved over the next five years under the Cooperative Agreement;</u></p> <p>(3) <u>The projected levels for each measure in five years in the absence of the Cooperative Agreement; and</u></p> <p>(4) <u>A plan for how the requisite data for assessing the benefit will be obtained.</u></p> <p>16. <u>A description of any potential adverse impact of the proposed Cooperative Agreement on population health, or quality, availability, cost, or price of health care services to patients or payers;</u></p> <p>17. <u>A description of any commitments the Parties are willing to make to address any potential adverse impacts resulting from the Cooperative Agreement. Each such commitment shall at a minimum include:</u></p> <p>a. <u>The Parties' proposed benchmarks and metrics</u></p>
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			<p>to measure achievement of the proposed commitments;</p> <p>b. The Parties' proposed plan to obtain and analyze data to evaluate the extent to which the commitments have been met, including how data shall be obtained from entities other than the Parties; and</p> <p>c. The Parties' proposed consequences if they do not meet a commitment.</p> <p>18. A Plan of Separation. The parties shall provide an independent opinion from a qualified organization verifying the Plan of Separation can be operationally implemented without undue disruption to essential health services provided by the Parties.</p> <p>19. A statement regarding the requirements for any Certificate(s) of Public Need resulting from the Cooperative Agreement;</p> <p>20. A detailed description of the total cost to the Parties resulting from the Application for the Cooperative Agreement. Cost estimates should include costs for consultant, legal and professional services, capital costs, financing costs, and management costs. The description should identify costs associated with the implementation of the Cooperative Agreement, including documentation of the availability of necessary funds. The description should identify which costs will be borne by each Party.</p> <p>21. An explanation of the reasons for the exclusion of any information set forth in this section. If the Parties exclude an item because it is not applicable to the proposed Cooperative Agreement, an explanation of why the item is not applicable shall be provided;</p> <p>22. A timetable for implementing all components of the proposed Cooperative Agreement and contact information for the person(s) authorized to receive notices, reports, and communications with respect to the Letter Authorizing Cooperative Agreement;</p> <p>23. Records, reports, and documentation to support the information submitted pursuant to this section, including any additional supplemental information requested by the Commissioner.</p> <p>C. All supplemental information submitted to the Commissioner shall be accompanied by a verified statement signed by the Chairperson of the Board of Directors and Chief Executive Officer of each Party; or if one or more of the Parties is an individual, signed by the individual attesting to the accuracy and completeness of the enclosed information.</p> <p>Intent: To ensure the applicants have adequate notice of the information to be requested by the Commissioner. Placing this information in regulation provides the applicant the opportunity to gather the listed information while the Authority is reviewing their application, provided any of the information is not included within the Authority's application process.</p> <p>Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement. Notice to the public and parties to a Cooperative Agreement.</p>
	<p>12VAC5-221-80. The Commissioner's Review</p>		<p>A. The Commissioner shall consult with the Attorney General when reviewing an Application. B. The Commissioner may consult with the</p>

		<p>Federal Trade Commission when reviewing an Application.</p> <p>C. The Commissioner may consult and coordinate with other affected jurisdictions when reviewing an Application.</p> <p>D. The Commissioner shall consult with all other affected agencies of the Commonwealth when reviewing an Application.</p> <p>E. The Commissioner in his review shall examine the record developed by the Authority, the Authority's recommendation for approval, and any additional information received from the Parties. In addition, the Commissioner may consider any other data, information, or advice available to him.</p> <p>F. The Commissioner shall not render a decision on the Application until all supplemental information requested has been received.</p> <p>G. The Commissioner shall consider the following factors when conducting a review of an Application:</p> <p>1. Advantages:</p> <p>a. Enhancement of the quality of hospital and hospital-related care, including mental health services and treatment of substance abuse, provided to citizens served by the Authority, resulting in improved patient satisfaction;</p> <p>b. Enhancement of population health status consistent with the regional health goals established by the Authority;</p> <p>c. Preservation of hospital facilities in geographical proximity to the communities traditionally served by those facilities to ensure access to care;</p> <p>d. Gains in the cost-efficiency of services provided by the hospitals involved;</p> <p>e. Improvements in the utilization of hospital resources and equipment;</p> <p>f. Avoidance of duplication of hospital resources;</p> <p>g. Participation in the state Medicaid program; and</p> <p>h. Total cost of care.</p> <p>2. Disadvantages:</p> <p>a. The extent of any likely adverse impact of the proposed Cooperative Agreement on the ability of health maintenance organizations, preferred provider organizations, managed health care organizations, or other health care payers to negotiate reasonable payment and service arrangements with hospitals, physicians, allied health care professionals, or other health care providers;</p> <p>b. The extent of any reduction in competition among physicians, allied health care professionals, other health care providers, or other persons furnishing goods or services to, or in competition with, hospitals that is likely to result directly or indirectly from the proposed Cooperative Agreement;</p> <p>c. The extent of any likely adverse impact on patients in the quality, availability, and price of health care services; and</p> <p>d. The availability of arrangements that are less restrictive to competition and achieve the same benefits or a more favorable balance of benefits over disadvantages attributable to any reduction in competition likely to result from the proposed Cooperative Agreement.</p> <p>H. The Commissioner shall approve the Application if he finds by a preponderance of the evidence that the benefits likely to result from the proposed Cooperative Agreement outweigh the</p>
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			<p><u>disadvantages likely to result from a reduction in competition from the proposed Cooperative Agreement.</u></p> <p><u>1. In the selection and application of the measures for reviewing the proposed benefits of the Cooperative Agreement, as well as during the monitoring and active supervision of any approved Cooperative Agreement, the Commissioner shall:</u></p> <p><u>1. Draw from consensus health and health care metrics, such as those being developed pursuant to the Virginia state innovation model development initiative and state population health improvement plan, to ensure the validity and consistency of the measure;</u></p> <p><u>2. Use historical actual experience in the region to establish baseline performance and evaluate progress over time;</u></p> <p><u>3. Consider recommendations on the measures and goals from the Technical Advisory Panel pursuant to 12VAC5-221-120; and</u></p> <p><u>4. Allow for flexibility, to the extent quantifiable goals or targets are specified, should environmental factors that are outside the control of the Parties change significantly.</u></p> <p>Intent: To ensure an applicant is notified of the method of the Commissioner's review. Transparency.</p> <p>Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement. Notice to the public and parties to a Cooperative Agreement.</p>
	<p>12VAC5-221-90. Action on an application</p>		<p><u>A. The Commissioner shall issue his decision in writing within 45 days of receipt of the Authority's recommendation. However, if the Commissioner has requested supplemental information from the Applicants, the Commissioner shall have 15 days, following receipt of the supplemental information, to issue a decision.</u></p> <p><u>B. At the request of the Applicants, the Commissioner may delay issue of his decision to provide additional time to review the record.</u></p> <p><u>C. The Commissioner may condition approval of the Letter Authorizing Cooperative Agreement upon the Applicants' commitment to achieving the improvements in population health, access to health care services, quality, and cost efficiencies identified by the Applicant in support of their Application. Such conditions may include, but are not limited to:</u></p> <p><u>1. A cap on the negotiated case-mix adjusted revenue per discharge by payer by product. The method for calculating such a case-mix shall be published on the Virginia Department of Health's Office of Licensure and Certification's website in a guidance document. The Department may rely on third-party auditors to assist in determining the method for determining such caps, their level, and a plan for monitoring compliance;</u></p> <p><u>2. A commitment to return a portion of the cost savings and efficiencies gained through the Cooperative Agreement to residents in the Participating Localities through specific proposed mechanisms;</u></p> <p><u>3. An agreement that the Parties shall not prevent or discourage health plans from directing or incentivizing patients to choose certain providers; the Parties shall not have any contractual clauses or provisions which prevent health plans from</u></p>

		<p><u>directing or incentivizing patients;</u> <u>4. An agreement that the Parties shall not engage in the tying of sales of the health system's services with the health plan's purchase of other services from the health system;</u> <u>5. An agreement that the Parties shall not restrict a health plan's ability to make available to its health plan enrollees cost, quality, efficiency, and performance information to aid enrollees in evaluating and selecting providers in the health plan; and</u> <u>6. A commitment that the Parties shall not refuse to include certain provisions in contracts with health plans that have been utilized in health plan contracts in other parts of the Commonwealth in order to promote value-based health care, including but not limited to, bundled payments, pay for performance, utilization management, and other processes that reward improvements in quality and efficiency.</u> <u>D. The Commissioner's decision to approve or deny an Application shall constitute a case decision pursuant to the Virginia Administrative Process Act (§ 2.2-4000 et. seq.).</u></p> <p>Intent: To ensure an applicant is aware of the timeframe a decision will be rendered and to be aware prior to a decision that the Letter Authorizing Cooperative Agreement may have conditions. Also ensuring the applicant is aware of their rights under the Administrative Process Act.</p> <p>Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.</p>
	<p>12VAC5-221-100. Ongoing and Active Supervision</p>	<p><u>A. The Commissioner shall maintain active and continuing supervision of the Parties in accordance with the terms under this subsection and to ensure compliance with the Cooperative Agreement and the Letter Authorizing Cooperative Agreement.</u> <u>B. Any Party who receives a Letter Authorizing Cooperative Agreement shall submit any additional information that is requested by the Department to establish benchmarks for ongoing monitoring and supervision. The Department's request may include, but is not limited to, information on patient satisfaction, employee satisfaction, a charge master, and information reflecting the contracted rates negotiated with non-physician providers, allied health professionals, and other providers.</u> <u>C. The Department shall establish quantitative measures that will be used to evaluate the proposed and continuing benefits of the Cooperative Agreement.</u> <u>1. The quantitative measures shall include measures of the cognizable benefits from the Cooperative Agreement in at least the following categories:</u> <u>a. Population health;</u> <u>b. Access to health services;</u> <u>c. Economic;</u> <u>d. Patient safety;</u> <u>e. Patient satisfaction; and</u> <u>f. Other cognizable benefits.</u> <u>2. Each category may be comprised of measures for subcategories.</u> <u>3. The Technical Advisory Panel and the Parties to the Cooperative Agreement may make</u></p>

			<p><u>recommendations for the creation and evaluation of quantitative measures, but the Department shall have the exclusive authority to add, modify, accept, or reject recommendations when creating or interpreting the quantitative measures.</u></p> <p><u>D. A Department representative may make periodic unannounced on-site inspections of the Parties' facilities as necessary. If the Department finds, after inspection, noncompliance with any provision of this chapter, any applicable state regulations, or the elements of the Cooperative Agreement or the Letter Authorizing Cooperative Agreement, the Commissioner shall begin enforcement procedures in accordance with 12VAC5-221-130.</u></p> <p><u>E. The Parties shall make available to the Department representative any requested records and shall allow access to interview the agents, employees, contractors, and any other person under the Parties' control, direction, or supervision.</u></p> <p><u>F. Complaints received by the Department with regard to noncompliance with the Cooperative Agreement or the Letter Authorizing Cooperative Agreement shall be investigated. When the investigation is complete, the Parties, and the complainant, if known, shall be notified of the findings of the investigation.</u></p> <p><u>G. The Commissioner may develop other mechanisms of monitoring the Parties to determine compliance with the Cooperative Agreement and whether compliance continues to meet the requirements of Code of Virginia § 15.2-5384.1. The Commissioner may modify the mechanisms of monitoring the Parties upon notice to the Parties.</u></p> <p>Intent: To ensure that Letter Holders are aware of the requirements of ongoing supervision and the method the Department will use to evaluate ongoing supervision. This will ensure transparency.</p> <p>Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.</p>
	<p>12VAC5-221-110. Annual Reporting</p>		<p><u>A. Parties shall report annually to the Commissioner on the extent of the benefits realized and compliance with any terms and conditions placed on their Letter Authorizing Cooperative Agreement. The report shall:</u></p> <ol style="list-style-type: none"> <u>1. Describe the activities conducted pursuant to the Cooperative Agreement;</u> <u>2. Include any actions taken in furtherance of commitments made by the Parties or terms imposed by the Commissioner as a condition for approval of the Cooperative Agreement;</u> <u>3. Include information related to changes in price, cost, quality, access to care, and population health improvement;</u> <u>4. Include actual costs, revenues, profit margins, and operating costs;</u> <u>5. Include a charge master;</u> <u>6. Include information reflecting the contracted rates negotiated with non-physician providers, allied health professionals, and others;</u> <u>7. Include any measures requested by the Department based on the recommendations of the Technical Advisory Panel appointed pursuant to 12VAC5-221-120; and</u>

		<p><u>8. Include the current status of the quantitative measures established under 12VAC5-221-100(C) and the information requested by the Department for benchmarks established in 12VAC5-221-100(B).</u></p> <p><u>B. The Parties shall be required to update the Parties' Plan for Separation annually and submit the updated Plan of Separation to the Department. The Parties shall provide an independent opinion from a qualified organization that states the Plan of Separation may be operationally implemented without undue disruption to essential health services provided by the Parties.</u></p> <p><u>C. The Commissioner may require the Parties to supplement the annual report with additional information to the extent necessary to ensure compliance with the Cooperative Agreement and the Letter Authorizing Cooperative Agreement.</u></p> <p><u>D. All annual reports submitted pursuant to this subsection shall be certified audited by a third-party auditor.</u></p> <p><u>E. The fee due with the filing of the annual report shall be \$20,000. If the Commissioner should determine that the actual cost incurred by the Department is greater than \$20,000, the Parties shall pay any additional amounts due as instructed by the Department. The annual filing fee shall not exceed \$75,000.</u></p> <p><u>F. The Commissioner shall issue a written decision and the basis for the decision on an annual basis as to whether the benefits of the Cooperative Agreement continue to outweigh any disadvantages attributable to a reduction in competition that have resulted from the Cooperative Agreement.</u></p> <p>Intent: Notice to Letter Holders regarding the requirements of Annual Reporting and the amount of the annual filing fee.</p> <p>Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.</p>
	<p>12VAC5-221-120. Technical Advisory Panel</p>	<p><u>A. The Commissioner shall appoint a Technical Advisory Panel to provide initial recommendations to the Commissioner as to the quality, cost, and access measures and benchmarks to be considered to objectively track the benefits and disadvantages of a Cooperative Agreement, and to provide ongoing input to the Commissioner on the evolution of these and other new measures and the progress of the Parties with respect to achievement of commitments with respect to these measures.</u></p> <p><u>B. The Technical Advisory Panel shall consist of:</u></p> <ol style="list-style-type: none"> <u>1. A representative of the Commissioner of Health who shall serve as Chair of the panel;</u> <u>2. The Chief Medical or Quality Officer(s) of the Parties;</u> <u>3. A Chief Medical or Quality Officer of a hospital or health system from other state market areas with no affiliation with the Parties;</u> <u>4. A Chief Medical or Quality Officer of a health plan that has subscribers in the affected area;</u> <u>5. Experts in the area of health quality measurement and performance;</u> <u>6. A consumer and employer representative from the affected area;</u> <u>7. A representative from the Board of Insurance;</u> <u>8. The Chief Financial Officer(s) of the Parties;</u>

		<p>9. A Chief Financial Officer of a hospital or health system from other state market areas with no affiliation with the Parties; and</p> <p>10. A Chief Financial Officer of a health plan that has subscribers in the affected area.</p> <p>C. The Technical Advisory Panel shall meet at least on an annual basis.</p> <p>D. The Technical Advisory Panel shall identify evidence-based cost, quality, and access measures in areas including, but not limited to, population health, patient safety, health outcomes, patient satisfaction, access to care, and any other areas identified by the panel. The panel shall also make recommendations regarding how to best report performance on quality metrics.</p> <p>E. The Technical Advisory Panel meetings shall be staffed by the Virginia Department of Health Office of Licensure and Certification.</p> <p>Intent: Specify the process for the appointment of a Technical Advisory Panel and the task of that panel.</p> <p>Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.</p>
	<p>12VAC5-221-130. Enforcement Procedures</p>	<p>A. If the Commissioner has reason to believe that compliance with a Cooperative Agreement no longer meets the requirements of the Code of Virginia § 15.2-5384.1 or this chapter, the Commissioner shall initiate a proceeding to determine whether compliance with the Cooperative Agreement no longer meets the requirements of Code of Virginia § 15.2-5384.1 or this chapter.</p> <p>B. In the course of such a proceeding, the Commissioner is authorized to seek reasonable modifications to a Letter Authorizing Cooperative Agreement. Such modifications shall be with the consent of the Parties.</p> <p>C. The Commissioner may revoke a Letter Authorizing Cooperative Agreement upon a finding that:</p> <ol style="list-style-type: none"> 1. The Parties are not complying with the terms or conditions of the Cooperative Agreement or the Letter Authorizing Cooperative Agreement; 2. The Cooperative Agreement is not in substantial compliance with the terms of the Parties' Application or the Letter Authorizing Cooperative Agreement; 3. The benefits resulting from the Cooperative Agreement no longer outweigh the disadvantages attributable to the reduction in competition resulting from the Cooperative Agreement; 4. The Commissioner's approval was obtained as a result of intentional material misrepresentation to the Commissioner or as the result of coercion, threats, or intimidation toward any Party to the Cooperative Agreement; or 5. The Parties have failed to pay any fee required by the Department or the Authority. <p>D. The proceeding initiated by the Commissioner under this section, and any judicial review thereof, shall be held in accordance with and governed by the Virginia Administrative Process Act (§ 2.2-4000).</p> <p>Intent: Specify the process in the event the Letter Holder is no longer in compliance with the Letter</p>

			<p>Authorizing Cooperative Agreement. Transparency.</p> <p>Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.</p>
	12VAC5-221-140. Voluntary Termination of Cooperative Agreement		<p><u>A. Any Party shall file notice with the Department within 30 days after terminating its participation in a Cooperative Agreement. The notice shall be sent in writing to the attention of the director of the Office of Licensure and Certification.</u></p> <p><u>B. In the event of a termination of a Cooperative Agreement, the Parties shall return the Letter Authorizing Cooperative Agreement to the Office of Licensure and Certification.</u></p> <p>Intent: Specify the process in the event the Letter Holder wishes to voluntarily terminate a Cooperative Agreement.</p> <p>Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.</p>
	12VAC5-221-150. Official Records		<p><u>A. The Commissioner shall maintain on file all Cooperative Agreements that the Commissioner has approved.</u></p> <p><u>B. All records collected pursuant to this regulatory chapter shall be maintained in accordance with the Virginia Freedom of Information Act (§ 2.2-3700 et. seq.) and the Library of Virginia's record management program (§ 42.1-85).</u></p> <p><u>C. All approved Cooperative Agreements and Letters Authorizing Cooperative Agreement shall be published on the Virginia Department of Health's Office of Licensure and Certification website.</u></p> <p><u>D. All reports collected pursuant to 12VAC5-221-110 shall be published on the Virginia Department of Health's Office of Licensure and Certification website.</u></p> <p><u>E. The Commissioner shall make public his annual determination of compliance with a Letter Authorizing the Cooperative Agreement.</u></p> <p>Intent: Specify requirements regarding records collected by the Department and the Commissioner in administering the program.</p> <p>Likely impact: Effective oversight of Letters Authorizing Cooperative Agreement.</p>

Changes from the Emergency Regulations:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12VAC5-221-20. Definitions		<p><u>"Applicant" means a Party to a proposed Cooperative Agreement who submits an Application to the Authority pursuant to § 15.2-5384.1 of the Code of Virginia.</u></p> <p><u>"Application" means the written materials submitted to the Authority and the Department in accordance</u></p>	<p>"Day" or "Days" means calendar days.</p> <p>The Intent: Clarify that since the Code of Virginia does not specify business days, "days" is read to mean calendar days.</p> <p>Likely Impact: The definition will mean the total time of review will be shortened.</p>

		<p>with § 15.2-5384.1 of the Code of Virginia by Applicants.</p> <p><u>"Authority" means the political subdivision organized and operated pursuant to Chapter 53.1 of Title 15.2 of the Code of Virginia, or if such Authority is abolished, the board, body, authority, Department, or officer succeeding to the principal functions thereof or to whom the powers given by Chapter 53.1 of Title 15.2 of the Code of Virginia are given by law.</u></p> <p><u>"Attorney General" means the Attorney General for the Commonwealth of Virginia.</u></p> <p><u>"Commissioner" means the State Health Commissioner.</u></p> <p><u>"Cooperative Agreement" means an agreement among two or more hospitals for the sharing, allocation, consolidation by merger or other combination of assets, or referral of patients, personnel, instructional programs, support services, and facilities or medical, diagnostic, or laboratory facilities or procedures or other services traditionally offered by hospitals.</u></p> <p><u>"Day" or "Days" means business days.</u></p> <p><u>"Department" means the Virginia Department of Health.</u></p> <p><u>"Hospital" includes any health center and health provider under common ownership with the hospital and means any and all providers of dental, medical, and mental health services, including all related facilities and approaches thereto and appurtenances thereof. Dental, medical, and mental health facilities includes any and all facilities suitable for providing hospital, dental, medical, and mental health care, including any and all structures, buildings, improvements, additions, extensions, replacements, appurtenances, lands, rights in lands, franchises, machinery, equipment, furnishing, landscaping, approaches, roadways, and other facilities necessary or desirable in connection therewith or incidental thereto (including, without limitation, hospitals, nursing homes, assisted living facilities, continuing care facilities, self-care facilities, mental health facilities, wellness and health maintenance centers, medical office facilities, clinics, outpatient surgical centers, alcohol, substance abuse and drug treatment centers, dental care clinics, laboratories, research facilities, sanitariums, hospices, facilities for the residence or care of the elderly, the handicapped or the chronically ill, residential facilities for nurses, interns, and physicians and</u></p>	
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		<p><u>any other kind of facility for the diagnosis, treatment, rehabilitation, prevention, or palliation of any human illness, injury, disorder, or disability), together with all related and supporting facilities and equipment necessary and desirable in connection therewith or incidental thereto, or equipment alone, including, without limitation, kitchen, laundry, laboratory, wellness, pharmaceutical, administrative, communications, computer and recreational facilities and equipment, storage space, mobile medical facilities, vehicles and other equipment necessary or desirable for the transportation of medical equipment or the transportation of patients. Dental, medical, and mental health facilities also includes facilities for graduate-level instruction in medicine or dentistry and clinics appurtenant thereto offering free or reduced rate dental, medical, or mental health services to the public.</u></p> <p><u>"Letter Authorizing Cooperative Agreement" means a document that is issued by the Commissioner approving a Cooperative Agreement.</u></p> <p><u>"Measure" means some number of factors or benchmarks, which may be binary, a range or continuous factors.</u></p> <p><u>"Participating Locality" means any county or city in the LENOWISCO or Cumberland Plateau Planning District Commissions and the Counties of Smyth and Washington and the City of Bristol with respect to which an authority may be organized and in which it is contemplated that the Authority will function.</u></p> <p><u>"Party" means a hospital entering into a Cooperative Agreement.</u></p> <p><u>"Plan of Separation" means the written proposal submitted with an Application to return the parties to a pre-consolidation state, which includes a plan for separation of any combined assets, offering, provision, operation, planning, funding, pricing, contracting, utilization review or management of health services or any combined sharing, allocation, or referral of patients, personnel, instructional programs, support services and facilities or medical, diagnostic or laboratory facilities or procedures or other services traditionally offered by hospitals, including any parent or subsidiary at the time the consolidation occurs or thereafter.</u></p> <p><u>"Primary Service Area" or "PSA" means the geographic area from which a hospital draws 75% of its</u></p>	
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		<p><u>patients as measured by the residential zip code of each patient. "Secondary Service Area" or "SSA" means the geographic area from which a hospital draws an additional 15% of its patients, as measured by the residential zip code of each patient.</u></p>	
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DEPARTMENT OF HEALTH
Regulations Governing Cooperative Agreements

CHAPTER 221

VIRGINIA'S RULES AND REGULATIONS GOVERNING COOPERATIVE AGREEMENTS

1 **12VAC5-221-10. Purpose.**

2 To address the unique healthcare challenges that exist in the Southwest Virginia
3 community, the General Assembly authorized the Commissioner to approve or deny an
4 Application for a Cooperative Agreement following receipt of a recommendation for approval by
5 the Authority. To the extent an approved Cooperative Agreement might be anticompetitive
6 within the meaning and intent of state and federal antitrust laws, it is the intent of the
7 Commonwealth with respect to each Participating Locality to supplant competition with a
8 regulatory program to permit Cooperative Agreements that are beneficial to citizens served by
9 the Authority. The Commissioner is authorized to issue a Letter Authorizing Cooperative
10 Agreement if he determines by a preponderance of the evidence that the benefits likely to result
11 from the Cooperative Agreement outweigh the disadvantages likely to result from a reduction in
12 competition. The Commissioner is responsible for actively supervising the Parties that receive
13 the Letter Authorizing Cooperative Agreement to ensure compliance with the provisions that
14 have been approved. Such intent is within the public policy of the Commonwealth to facilitate
15 the provision of quality, cost-efficient medical care to residents of a Participating Locality.

16 **12VAC5-221-20. Definitions.**

17 "Applicant" means a Party to a proposed Cooperative Agreement who submits an
18 Application to the Authority pursuant to § 15.2-5384.1 of the Code of Virginia.

19 "Application" means the written materials submitted to the Authority and the Department in
20 accordance with § 15.2-5384.1 of the Code of Virginia by Applicants.

21 "Authority" means the political subdivision organized and operated pursuant to Chapter 53.1
22 of Title 15.2 of the Code of Virginia, or if such Authority is abolished, the board, body, authority,
23 Department, or officer succeeding to the principal functions thereof or to whom the powers given
24 by Chapter 53.1 of Title 15.2 of the Code of Virginia are given by law.

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

26 "Commissioner" means the State Health Commissioner.

27 "Cooperative Agreement" means an agreement among two or more hospitals for the
28 sharing, allocation, consolidation by merger or other combination of assets, or referral of

29 patients, personnel, instructional programs, support services, and facilities or medical,
30 diagnostic, or laboratory facilities or procedures or other services traditionally offered by
31 hospitals.

32 "Day" or "Days" means calendar days.

33 "Department" means the Virginia Department of Health.

34 "Hospital" includes any health center and health provider under common ownership with the
35 hospital and means any and all providers of dental, medical, and mental health services,
36 including all related facilities and approaches thereto and appurtenances thereof. Dental,
37 medical, and mental health facilities includes any and all facilities suitable for providing hospital,
38 dental, medical, and mental health care, including any and all structures, buildings,
39 improvements, additions, extensions, replacements, appurtenances, lands, rights in lands,
40 franchises, machinery, equipment, furnishing, landscaping, approaches, roadways, and other
41 facilities necessary or desirable in connection therewith or incidental thereto (including, without
42 limitation, hospitals, nursing homes, assisted living facilities, continuing care facilities, self-care
43 facilities, mental health facilities, wellness and health maintenance centers, medical office
44 facilities, clinics, outpatient surgical centers, alcohol, substance abuse and drug treatment
45 centers, dental care clinics, laboratories, research facilities, sanitariums, hospices, facilities for
46 the residence or care of the elderly, the handicapped or the chronically ill, residential facilities for
47 nurses, interns, and physicians and any other kind of facility for the diagnosis, treatment,
48 rehabilitation, prevention, or palliation of any human illness, injury, disorder, or disability),
49 together with all related and supporting facilities and equipment necessary and desirable in
50 connection therewith or incidental thereto, or equipment alone, including, without limitation,
51 kitchen, laundry, laboratory, wellness, pharmaceutical, administrative, communications,
52 computer and recreational facilities and equipment, storage space, mobile medical facilities,
53 vehicles and other equipment necessary or desirable for the transportation of medical
54 equipment or the transportation of patients. Dental, medical, and mental health facilities also
55 includes facilities for graduate-level instruction in medicine or dentistry and clinics appurtenant
56 thereto offering free or reduced rate dental, medical, or mental health services to the public.

57 "Letter Authorizing Cooperative Agreement" means a document that is issued by the
58 Commissioner approving a Cooperative Agreement.

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

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

65 "Party" means a hospital entering into a Cooperative Agreement.

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

73 "Primary Service Area" or "PSA" means the geographic area from which a hospital draws
74 75% of its patients as measured by the residential zip code of each patient.

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

77 **12VAC5-221-30. Separate Applications.**

78 A Party shall submit an Application for a Letter Authorizing Cooperative Agreement for each
79 Cooperative Agreement the Party is applying to enter into. This provision applies even in the
80 event that the Parties have an existing Letter Authorizing Cooperative Agreement issued by the
81 Commissioner. An amendment to a Cooperative Agreement shall require submission of a new
82 Application.

83 **12VAC5-221-40. Application.**

84 A. Parties within any Participating Locality may submit an Application for a Letter Authorizing
85 Cooperative Agreement to the Authority. Information regarding the requirements of an
86 Application for a Letter Authorizing Cooperative Agreement submitted to the Authority should be
87 obtained through the Authority.

88 B. At the time of submission to the Authority, Parties shall simultaneously submit a copy of
89 the Application to the Commissioner and the Attorney General.

90 C. If the Authority requires the Applicant to submit additional information before determining
91 that the Application is complete, the Parties shall simultaneously submit a copy of the additional
92 information to the Authority, the Commissioner, and the Attorney General.

93 D. If the applicants believe the materials submitted contain proprietary information that are
94 required to remain confidential, such information must be clearly identified and the applicants
95 shall submit duplicate applications, one with full information for the Commissioner's use and one
96 redacted application available for release to the public. Proprietary information that is clearly
97 identified by the Applicants will be kept confidential by the Department pursuant to § 2.2-3705.6
98 (3) of the Code of Virginia.

99 **12VAC5-221-50. Fee Schedule.**

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

102 B. The Application fee shall be \$50,000 and shall be due to the Department upon its receipt
103 of a recommendation for approval from the Authority.

104 C. If the Commissioner should determine after review of the Application that the actual cost
105 incurred by the Department is less than \$50,000, the Applicant shall be reimbursed the amount
106 that is greater than the actual cost. If the Commissioner should determine that the actual cost
107 incurred by the Department is greater than \$50,000, the Applicant shall pay any additional
108 amounts due as instructed by the Department. The Application fee shall not exceed \$75,000.

109 **12VAC5-221-60. Public Hearing.**

110 A. The Authority shall, in conjunction with the Commissioner, schedule a public hearing for
111 each completed Application submitted. The hearing shall be held no later than 45 days after the
112 receipt of a complete Application by the Authority.

113 B. The Authority will publish and issue notice of the hearing in accordance with § 15.2-
114 5384.1 (C) of the Code of Virginia.

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

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

118 **12VAC5-221-65. Public Comment to the Commissioner.**

119 The public may submit written comments regarding the Application to the Commissioner. To
120 ensure consideration by the Commissioner, written comments must be received no later than 14
121 days after the Authority adopts its recommendation on the Application.

122 **12VAC5-221-70. The Commissioner's Request for Information.**

123 A. Upon receipt of the Authority's recommendation for approval, the Commissioner and
124 Department may request supplemental information from the Applicants.

125 B. To the extent the information is not present within the Application, the Commissioner shall
126 request the following information:

127 1. A report(s) used for public information and education about the proposed Cooperative
128 Agreement prior to the Parties' submission of the Application. The Applicants shall
129 document the efforts used to disseminate the report(s). The report(s) shall include, but
130 are not limited to:

131 a. A description of the proposed Primary Service Area (PSA) and Secondary Service
132 Areas (SSA) and the services and facilities to be included in the Cooperative
133 Agreement;

134 b. A description of how health services will change if the Letter Authorizing
135 Cooperative Agreement is issued;

136 c. A description of improvements in patient access to health care including
137 prevention services for all categories of payers and advantages patients will
138 experience across the entire service area regarding costs, availability, and
139 accessibility upon implementation of the Cooperative Agreement and/or findings from
140 studies conducted by hospitals and other external entities, including health
141 economists, and clinical services and population health experts, that describe how
142 implementation of the proposed Cooperative Agreement will be effective with respect
143 to resource allocation implications; efficient with respect to fostering cost
144 containment, including, but not limited to, eliminating duplicative services; and
145 equitable with respect to maintaining quality and competition in health services within
146 the service area and assuring patient access to and choice of insurers and providers
147 within the health care system;

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

152 e. A description of the findings from community or population health assessments for
153 the service areas regarding major health issues, trends, and health disparities,
154 including comparisons to measures for the state and similar regional areas, and a
155 description of how the health of the population will change if the Letter Authorizing
156 Cooperative Agreement is issued; and

- 157 f. A description of the impact on the health professions workforce including long-term
158 employment, wage levels, recruitment, and retention of health professionals.
- 159 2. A record of community stakeholder and consumer views of the proposed Cooperative
160 Agreement collected through a public participatory process including meetings and
161 correspondence. Transcripts or minutes of any meetings held during the public
162 participatory process shall be included in the report.
- 163 3. A summary of the nature of the proposed Cooperative Agreement between the
164 parties;
- 165 4. A signed copy of the Cooperative Agreement and a copy of the following:
- 166 a. A description of any consideration passing to any Party, individual or entity under
167 the Cooperative Agreement including the amount, nature, source, and recipient;
- 168 b. A detailed description of any merger, lease, operating or management contract,
169 change of control or other acquisition or change, direct or indirect, in ownership of
170 any Party or of the assets of any Party to the Cooperative Agreement;
- 171 c. A list of all services and products and of all hospitals and other service locations
172 that are a subject of the Cooperative Agreement including those not located or
173 provided within the boundaries of the Commonwealth of Virginia, and including, but
174 not limited to, hospitals or other inpatient facilities, insurance products, physician
175 practices, pharmacies, accountable care organizations, psychiatric facilities, nursing
176 homes, physical therapy and rehabilitation units, home care agencies, wellness
177 centers or services, surgical centers or services, dialysis centers or services, cancer
178 centers or services, imaging centers or services, support services, and any other
179 product, facility, or service; and
- 180 d. A description of each Party's contribution of capital, equipment, labor, services, or
181 other contribution of value to the transaction.
- 182 5. A detailed description of the current and proposed PSA and SSA for the Parties,
183 including the PSA and SSA of each of the Parties' hospitals, not limited to the
184 boundaries of the Commonwealth of Virginia. If the proposed PSA and SSA differ from
185 the service areas where the Parties have conducted business over the five (5) years
186 preceding the Application, a description of how and why the proposed PSA or SSA differ
187 and why changes are proposed;

188 6. A description of the prior history of dealings between the Parties for the last five (5)
189 years including but not limited to, their relationship as competitors and any prior joint
190 ventures, affiliations or other collaborative agreements between the Parties.

191 7. Documents sufficient to show the financial performance of each Party to the
192 transaction for each of the preceding five (5) fiscal years including tax returns, debt,
193 bond rating, and debt service, and copies of offering materials, subsequent filings such
194 as continuing disclosure agreements and material event disclosures, and financial
195 statements prepared by external certified public accountants, including management
196 reports;

197 8. A copy of the current annual budget and budgets for the last five (5) years for each
198 Party to the Cooperative Agreement. The budgets shall be in sufficient detail so as to
199 determine the fiscal impact of the Cooperative Agreement on each Party. The budgets
200 shall be prepared in conformity with generally accepted accounting principles (GAAP)
201 and all assumptions used shall be documented;

202 9. Projected budgets, including project costs, revenues, profit margins, and operating
203 ratios, of each Party for each year for a period of five years after a Letter Authorizing
204 Cooperative Agreement is issued. The budgets shall be prepared in conformity with
205 generally accepted accounting principles (GAAP) and all assumptions used shall be
206 documented;

207 10. A detailed explanation of the projected effects including expected change in volume,
208 price, and revenue as a result of the Cooperative Agreement, including:

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

213 b. A description of how pricing for provider insurance contracts are calculated and
214 the financial advantages accruing to insurers, insured consumers and the parties to
215 the Cooperative Agreement, if the Letter Authorizing Cooperative Agreement is
216 issued including changes in percentage of risk-bearing contracts; and

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

219 (1) Discuss each Party's projected performance in the market, business strategies,
220 capital investment plans, competitive analyses, and financial projections, including
221 any documents prepared in anticipation of the Cooperative Agreement; and
222 (2) Identify plans that will be altered, eliminated, or combined under the Cooperative
223 Agreement.

224 11. A copy of the following policies under the proposed Cooperative Agreement:

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

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

227 c. Policies for bad debt write-off; and

228 d. Policies that require the Parties to the Cooperative Agreement to maintain or

229 exceed the existing level of charitable programs and services.

230 12. A description of the plan to systematically integrate health care and preventive health
231 services among the Parties to the Cooperative Agreement in the proposed geographic
232 service area that addresses the following:

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

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

237 c. Clinical standardization;

238 d. Alignment of the cultural identities of the Parties to the Cooperative Agreement

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

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

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

244 13. A description of the plan, including economic metrics, that details anticipated
245 efficiencies in operating costs and shared services that can be gained only through the
246 Cooperative Agreement including:

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

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

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

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

255 a. The identity of any non-Party hospital located in the PSA and SSA and any non-
256 Party hospital outside of the PSA and SSA that also serves patients in the Parties'
257 PSA and SSA;

258 b. Estimates of the share of hospital services furnished by each of the Parties and
259 any non-Party hospitals;

260 c. Identification of whether any services or products of the proposed Cooperative
261 Agreement are currently being offered or capable of being offered by any non-Party
262 hospitals in the PSA and SSA and a description of how the proposed Cooperative
263 Agreement will not exclude such non-Party hospitals from continued competitive and
264 independent operation in the PSA and SSA;

265 d. A listing of the physicians employed by or under contract with each of the Parties'
266 hospitals in the PSA and SSA, including their specialty and office location(s);

267 e. The identity of any potential entrants in the Parties' PSA and SSA and the basis
268 for any belief that such entry is likely within the two calendar years immediately
269 following the date of the Letter Authorizing Cooperative Agreement is issued by the
270 Department; and

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

273 15. A detailed description of each of the benefits that the Parties propose will be
274 achieved through the Cooperative Agreement. For each benefit include:

275 a. A description specifically describing how the Parties intend to achieve the benefit;
276 b. A description of what the Parties have done in the past with respect to achieving
277 or attempting to achieve the benefits independently or through collaboration and how
278 this may change if the Cooperative Agreement is granted;

279 c. An explanation of why the benefit can only be achieved through a Cooperative
280 Agreement and not through other less restrictive arrangements; and

281 d. A description of how the Parties propose that the Commissioner measure and
282 monitor achievement of the proposed benefit including:
283 (1) Proposed measures and suggested baseline values with rationale for each
284 measure to be considered by the Commissioner in developing a plan to monitor
285 achievement of the benefit;
286 (2) The current and projected levels, and the trajectory, for each measure that would
287 be achieved over the next five years under the Cooperative Agreement;
288 (3) The projected levels for each measure in five years in the absence of the
289 Cooperative Agreement; and
290 (4) A plan for how the requisite data for assessing the benefit will be obtained.
291 16. A description of any potential adverse impact of the proposed Cooperative
292 Agreement on population health, or quality, availability, cost, or price of health care
293 services to patients or payers;
294 17. A description of any commitments the Parties are willing to make to address any
295 potential adverse impacts resulting from the Cooperative Agreement. Each such
296 commitment shall at a minimum include:
297 a. The Parties' proposed benchmarks and metrics to measure achievement of the
298 proposed commitments;
299 b. The Parties' proposed plan to obtain and analyze data to evaluate the extent to
300 which the commitments have been met, including how data shall be obtained from
301 entities other than the Parties; and
302 c. The Parties' proposed consequences if they do not meet a commitment.
303 18. A Plan of Separation. The parties shall provide an independent opinion from a
304 qualified organization verifying the Plan of Separation can be operationally implemented
305 without undue disruption to essential health services provided by the Parties.
306 19. A statement regarding the requirements for any Certificate(s) of Public Need
307 resulting from the Cooperative Agreement;
308 20. A detailed description of the total cost to the Parties resulting from the Application for
309 the Cooperative Agreement. Cost estimates should include costs for consultant, legal
310 and professional services, capital costs, financing costs, and management costs. The
311 description should identify costs associated with the implementation of the Cooperative

312 Agreement, including documentation of the availability of necessary funds. The
313 description should identify which costs will be borne by each Party.

314 21. An explanation of the reasons for the exclusion of any information set forth in this
315 section. If the Parties exclude an item because it is not applicable to the proposed
316 Cooperative Agreement, an explanation of why the item is not applicable shall be
317 provided;

318 22. A timetable for implementing all components of the proposed Cooperative
319 Agreement and contact information for the person(s) authorized to receive notices,
320 reports, and communications with respect to the Letter Authorizing Cooperative
321 Agreement;

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

325 C. All supplemental information submitted to the Commissioner shall be accompanied by a
326 verified statement signed by the Chairperson of the Board of Directors and Chief Executive
327 Officer of each Party; or if one or more of the Parties is an individual, signed by the
328 individual attesting to the accuracy and completeness of the enclosed information.

329 **12VAC5-221-80. The Commissioner's Review.**

330 A. The Commissioner shall consult with the Attorney General when reviewing an
331 Application.

332 B. The Commissioner may consult with the Federal Trade Commission when reviewing an
333 Application.

334 C. The Commissioner may consult and coordinate with other affected jurisdictions when
335 reviewing an Application.

336 D. The Commissioner shall consult with all other affected agencies of the Commonwealth
337 when reviewing an Application.

338 E. The Commissioner in his review shall examine the record developed by the Authority, the
339 Authority's recommendation for approval, and any additional information received from the
340 Parties. In addition, the Commissioner may consider any other data, information, or advice
341 available to him.

342 F. The Commissioner shall not render a decision on the Application until all supplemental
343 information requested has been received.

344 G. The Commissioner shall consider the following factors when conducting a review of an
345 Application:

346 1. Advantages:

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

350 b. Enhancement of population health status consistent with the regional health goals
351 established by the Authority;

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

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

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

356 f. Avoidance of duplication of hospital resources;

357 g. Participation in the state Medicaid program; and

358 h. Total cost of care.

359 2. Disadvantages:

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

365 b. The extent of any reduction in competition among physicians, allied health care
366 professionals, other health care providers, or other persons furnishing goods or
367 services to, or in competition with, hospitals that is likely to result directly or indirectly
368 from the proposed Cooperative Agreement;

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

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

375 H. The Commissioner shall approve the Application if he finds by a preponderance of the
376 evidence that the benefits likely to result from the proposed Cooperative Agreement outweigh
377 the disadvantages likely to result from a reduction in competition from the proposed Cooperative
378 Agreement.

379 I. In the selection and application of the measures for reviewing the proposed benefits of the
380 Cooperative Agreement, as well as during the monitoring and active supervision of any
381 approved Cooperative Agreement, the Commissioner shall:

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

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

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

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

392 **12VAC5-221-90. Action on an application.**

393 A. The Commissioner shall issue his decision in writing within 45 days of receipt of the
394 Authority's recommendation. However, if the Commissioner has requested supplemental
395 information from the Applicants, the Commissioner shall have 15 days, following receipt of the
396 supplemental information, to issue a decision.

397 B. At the request of the Applicants, the Commissioner may delay issue of his decision to
398 provide additional time to review the record.

399 C. The Commissioner may condition approval of the Letter Authorizing Cooperative
400 Agreement upon the Applicants' commitment to achieving the improvements in population
401 health, access to health care services, quality, and cost efficiencies identified by the Applicant in
402 support of their Application. Such conditions may include, but are not limited to:

403 1. A cap on the negotiated case-mix adjusted revenue per discharge by payer by
404 product. The method for calculating such a case-mix shall be published on the Virginia
405 Department of Health's Office of Licensure and Certification's website in a guidance

406 document. The Department may rely on third-party auditors to assist in determining the
407 method for determining such caps, their level, and a plan for monitoring compliance;

408 2. A commitment to return a portion of the cost savings and efficiencies gained through
409 the Cooperative Agreement to residents in the Participating Localities through specific
410 proposed mechanisms;

411 3. An agreement that the Parties shall not prevent or discourage health plans from
412 directing or incentivizing patients to choose certain providers; the Parties shall not have
413 any contractual clauses or provisions which prevent health plans from directing or
414 incentivizing patients;

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

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

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

426 D. The Commissioner's decision to approve or deny an Application shall constitute a case
427 decision pursuant to the Virginia Administrative Process Act (§ 2.2-4000 et. seq.).

428 **12VAC5-221-100. Ongoing and Active Supervision.**

429 A. The Commissioner shall maintain active and continuing supervision of the Parties in
430 accordance with the terms under this subsection and to ensure compliance with the Cooperative
431 Agreement and the Letter Authorizing Cooperative Agreement. .

432 B. Any Party who receives a Letter Authorizing Cooperative Agreement shall submit any
433 additional information that is requested by the Department to establish benchmarks for ongoing
434 monitoring and supervision. The Department's request may include, but is not limited to,
435 information on patient satisfaction, employee satisfaction, a charge master, and information
436 reflecting the contracted rates negotiated with non-physician providers, allied health
437 professionals, and other providers.

438 C. The Department shall establish quantitative measures that will be used to evaluate the
439 proposed and continuing benefits of the Cooperative Agreement.

440 1. The quantitative measures shall include measures of the cognizable benefits from the
441 Cooperative Agreement in at least the following categories:

442 a. Population health;

443 b. Access to health services;

444 c. Economic;

445 d. Patient safety;

446 e. Patient satisfaction; and

447 f. Other cognizable benefits.

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

449 3. The Technical Advisory Panel and the Parties to the Cooperative Agreement may
450 make recommendations for the creation and evaluation of quantitative measures, but the
451 Department shall have the exclusive authority to add, modify, accept, or reject
452 recommendations when creating or interpreting the quantitative measures.

453 D. A Department representative may make periodic unannounced on-site inspections of the
454 Parties' facilities as necessary. If the Department finds, after inspection, noncompliance with
455 any provision of this chapter, any applicable state regulations, or the elements of the
456 Cooperative Agreement or the Letter Authorizing Cooperative Agreement, the Commissioner
457 shall begin enforcement procedures in accordance with 12VAC5-221-130.

458 E. The Parties shall make available to the Department representative any requested records
459 and shall allow access to interview the agents, employees, contractors, and any other person
460 under the Parties' control, direction, or supervision.

461 F. Complaints received by the Department with regard to noncompliance with the
462 Cooperative Agreement or the Letter Authorizing Cooperative Agreement shall be investigated.
463 When the investigation is complete, the Parties, and the complainant, if known, shall be notified
464 of the findings of the investigation.

465 G. The Commissioner may develop other mechanisms of monitoring the Parties to
466 determine compliance with the Cooperative Agreement and whether compliance continues to
467 meet the requirements of Code of Virginia § 15.2-5384.1. The Commissioner may modify the
468 mechanisms of monitoring the Parties upon notice to the Parties.

469 **12VAC5-221-110. Annual Reporting.**

470 A. Parties shall report annually to the Commissioner on the extent of the benefits realized
471 and compliance with any terms and conditions placed on their Letter Authorizing Cooperative
472 Agreement. The report shall:

- 473 1. Describe the activities conducted pursuant to the Cooperative Agreement;
- 474 2. Include any actions taken in furtherance of commitments made by the Parties or terms
475 imposed by the Commissioner as a condition for approval of the Cooperative
476 Agreement;
- 477 3. Include information related to changes in price, cost, quality, access to care, and
478 population health improvement;
- 479 4. Include actual costs, revenues, profit margins, and operating costs;
- 480 5. Include a charge master;
- 481 6. Include information reflecting the contracted rates negotiated with non-physician
482 providers, allied health professionals, and others;
- 483 7. Include any measures requested by the Department based on the recommendations
484 of the Technical Advisory Panel appointed pursuant to 12VAC5-221-120; and
- 485 8. Include the current status of the quantitative measures established under 12VAC5-
486 221-100(C) and the information requested by the Department for benchmarks
487 established in 12VAC5-221-100(B).

488 B. The Parties shall be required to update the Parties' Plan for Separation annually and
489 submit the updated Plan of Separation to the Department. The Parties shall provide an
490 independent opinion from a qualified organization that states the Plan of Separation may be
491 operationally implemented without undue disruption to essential health services provided by the
492 Parties.

493 C. The Commissioner may require the Parties to supplement the annual report with
494 additional information to the extent necessary to ensure compliance with the Cooperative
495 Agreement and the Letter Authorizing Cooperative Agreement.

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

498 E. The fee due with the filing of the annual report shall be \$20,000. If the Commissioner
499 should determine that the actual cost incurred by the Department is greater than \$20,000, the

500 Parties shall pay any additional amounts due as instructed by the Department. The annual filing
501 fee shall not exceed \$75,000.

502 F. The Commissioner shall issue a written decision and the basis for the decision on an
503 annual basis as to whether the benefits of the Cooperative Agreement continue to outweigh any
504 disadvantages attributable to a reduction in competition that have resulted from the Cooperative
505 Agreement.

506 **12VAC5-221-120. Technical Advisory Panel.**

507 A. The Commissioner shall appoint a Technical Advisory Panel to provide initial
508 recommendations to the Commissioner as to the quality, cost, and access measures and
509 benchmarks to be considered to objectively track the benefits and disadvantages of a
510 Cooperative Agreement, and to provide ongoing input to the Commissioner on the evolution of
511 these and other new measures and the progress of the Parties with respect to achievement of
512 commitments with respect to these measures.

513 B. The Technical Advisory Panel shall consist of:

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

515 2. The Chief Medical or Quality Officer(s) of the Parties;

516 3. A Chief Medical or Quality Officer of a hospital or health system from other state
517 market areas with no affiliation with the Parties;

518 4. A Chief Medical or Quality Officer of a health plan that has subscribers in the affected
519 area;

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

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

522 7. A representative from the Board of Insurance;

523 8. The Chief Financial Officer(s) of the Parties;

524 9. A Chief Financial Officer of a hospital or health system from other state market areas
525 with no affiliation with the Parties; and

526 10. A Chief Financial Officer of a health plan that has subscribers in the affected area.

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

528 D. The Technical Advisory Panel shall identify evidence-based cost, quality, and access
529 measures in areas including, but not limited to, population health, patient safety, health
530 outcomes, patient satisfaction, access to care, and any other areas identified by the panel. The

531 panel shall also make recommendations regarding how to best report performance on quality
532 metrics.

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

535 **12VAC5-221-130. Enforcement Procedures.**

536 A. If the Commissioner has reason to believe that compliance with a Cooperative
537 Agreement no longer meets the requirements of the Code of Virginia § 15.2-5384.1 or this
538 chapter, the Commissioner shall initiate a proceeding to determine whether compliance with the
539 Cooperative Agreement no longer meets the requirements of Code of Virginia § 15.2-5384.1 or
540 this chapter.

541 B. In the course of such a proceeding, the Commissioner is authorized to seek reasonable
542 modifications to a Letter Authorizing Cooperative Agreement. Such modifications shall be with
543 the consent of the Parties.

544 C. The Commissioner may revoke a Letter Authorizing Cooperative Agreement upon a
545 finding that:

- 546 1. The Parties are not complying with the terms or conditions of the Cooperative
547 Agreement or the Letter Authorizing Cooperative Agreement;
- 548 2. The Cooperative Agreement is not in substantial compliance with the terms of the
549 Parties' Application or the Letter Authorizing Cooperative Agreement;
- 550 3. The benefits resulting from the Cooperative Agreement no longer outweigh the
551 disadvantages attributable to the reduction in competition resulting from the Cooperative
552 Agreement;
- 553 4. The Commissioner's approval was obtained as a result of intentional material
554 misrepresentation to the Commissioner or as the result of coercion, threats, or
555 intimidation toward any Party to the Cooperative Agreement; or
- 556 5. The Parties have failed to pay any fee required by the Department or the Authority.

557 D. The proceeding initiated by the Commissioner under this section, and any judicial review
558 thereof, shall be held in accordance with and governed by the Virginia Administrative Process
559 Act (§ 2.2-4000).

560 **12VAC5-221-140. Voluntary Termination of Cooperative Agreement.**

561 A. Any Party shall file notice with the Department within 30 days after terminating its
562 participation in a Cooperative Agreement. The notice shall be sent in writing to the attention of
563 the director of the Office of Licensure and Certification.

564 B. In the event of a termination of a Cooperative Agreement, the Parties shall return the
565 Letter Authorizing Cooperative Agreement to the Office of Licensure and Certification.

566 **12VAC5-221-150. Official Records.**

567 A. The Commissioner shall maintain on file all Cooperative Agreements that the
568 Commissioner has approved.

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

572 C. All approved Cooperative Agreements and Letters Authorizing Cooperative Agreement
573 shall be published on the Virginia Department of Health's Office of Licensure and Certification
574 website.

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

577 E. The Commissioner shall make public his annual determination of compliance with a Letter
578 Authorizing the Cooperative Agreement.



COMMONWEALTH of VIRGINIA

Department of Health

Marissa J. Levine, MD, MPH, FAAFP
STATE HEALTH COMMISSIONER

P O BOX 2448
RICHMOND, VA 23218

TTY 7-1-1 OR
1-800-828-1120

MEMORANDUM

DATE: February 21, 2017

TO: Virginia State Board of Health

FROM: Erik Bodin, Director, Office of Licensure and Certification

SUBJECT: Virginia's Regulations for the Licensure of Nursing Facilities (12VAC5-371)
Electronic Monitoring

Enclosed for your review are fast track Amendments to Virginia's Regulations for the Licensure of Nursing Facilities (12VAC5-371).

Senate Bill 553 enacted by the 2016 General Assembly mandates this regulatory action. SB553 requires the Board of Health to promulgate regulations that at a minimum address the audio-visual recording of residents in nursing facilities. SB553 requires that such regulations shall include provisions related to (i) resident privacy, (ii) notice and disclosure, (iii) liability, (iv) ownership and maintenance of equipment, (v) cost, (vi) recording and data security, and (vii) nursing facility options for both nursing facility-managed recording and resident-managed recording. SB553 required the convening of a workgroup that included representatives of nursing facilities, advocates for residents of nursing facilities, and other stakeholders to make recommendations to the Board on such regulations. The workgroup built on the regulatory language that had previously come before the Board and the language of the 2004 Virginia Department of Health (VDH) Guidance Document. For that reason, the Board is requested to approve the utilization of the fast track process authorized by the Administrative Process Act. The amendments contain provisions pertaining to definitions, a framework to address policies and procedures, informed consent, admission, discharge or transfer, the equipment request process, notice procedures, retention and ownership of tapes or recordings, and reporting suspected abuse, neglect, accident or injury discovered through electronic monitoring.

In drafting the amendments VDH convened a workgroup pursuant to SB553. The workgroup met several times and workgroup members provided recommendations regarding regulatory language. VDH reviewed the recommendations of the workgroup and from that information, VDH drafted the amending language, which is presented to the Board.

The Board of Health is requested to approve the fast track amendments. Should the Board of Health approve the amendments, they will be submitted to the Office of the Attorney General to begin the executive branch review process, as specified by the Administrative Process Act. Following executive branch review and approval, the amendments will be published in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall website. The amendments will become effective 45-days following publication in the Virginia Register of Regulations.



townhall.virginia.gov

Fast-Track Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation(s)	12VAC5-371
Regulation title(s)	Regulations for the Licensure of Nursing Facilities
Action title	Amend regulations to address implementation of voluntary electronic monitoring
Date this document prepared	February 21, 2017

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 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.

Senate Bill 553 enacted by the 2016 General Assembly mandates the Board of Health to promulgate regulations governing the implementation of voluntary electronic monitoring in the rooms of residents of nursing homes. SB553 requires that the Board utilize existing policies and procedures set forth in the Board's 2004 Guideline "Electronic Monitoring of Residents' Rooms" in the promulgation of the regulations. The proposed amendments subject to this fast track action are a combination of the 2004 guidelines which were developed to assist facilities with the privacy issues that may arise when installing electronic monitoring equipment and the work of a workgroup assembled pursuant to SB553. Installing such equipment is not mandatory on the nursing home; however, if installed, facilities must safeguard resident's autonomy and rights according to current federal and state privacy laws and regulations. This regulatory action provides the framework to address policies and procedures, informed consent,

admission, discharge or transfer. The amendments include the equipment request process and notice procedures, retention and ownership of tapes or recordings, and reporting suspected abuse, neglect, accident or injury discovered through electronic monitoring.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

The acronyms that appear in this document are as follows:

OLC means the Office of Licensure and Certification

VDH means the Virginia Department of Health

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 taking the action; and 3) the title of the regulation.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

SB553 enacted by the 2016 General Assembly mandates the Board of Health to promulgate regulations governing the implementation of voluntary electronic monitoring in the rooms of residents of nursing homes. SB553 required that the Board convene a workgroup that includes representatives of nursing facilities, advocates for residents of nursing facilities, and other stakeholders to make recommendations to the Board on such regulations. Therefore, this regulatory action is mandated by law.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation 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.

SB553 enacted by the 2016 General Assembly mandates the Board of Health to promulgate regulations governing the implementation of voluntary electronic monitoring in the rooms of residents of nursing homes. Installing such equipment is not mandatory; however, if installed, facilities must safeguard

resident's autonomy and rights according to current federal and state privacy laws and regulations. This regulatory action provides the framework to address policies and procedures, informed consent, admission, discharge or transfer. The regulation includes the equipment request process and notice procedures, retention and ownership of tapes or recordings, and reporting suspected abuse, neglect, accident or injury discovered through electronic monitoring. The regulation will protect and promote public health, safety and welfare of citizens through the establishment of a framework which would set standards regarding electronic monitoring in nursing facility resident rooms. This framework will ensure that resident privacy and autonomy is paramount when electronic monitoring is utilized.

Rationale for using fast-track process

Please explain the rationale for using the fast-track process in promulgating this regulation. Why do you expect this rulemaking to be noncontroversial?

SB553 mandates the Board of Health to promulgate regulations governing the implementation of voluntary electronic monitoring in the rooms of residents of nursing homes. The regulation was developed cooperatively with the assistance of a workgroup convened pursuant to SB553 and relied heavily on language included in a Guidance Document in use since 2004. Therefore, VDH believes the proposed amendments will be noncontroversial, allowing use of the fast-track process.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of changes" section below.

The substantive provisions pertain to electronic monitoring in resident rooms. The provisions provide the framework for policies and procedures, informed consent, right of implementation/refusal, retention of tapes and recordings, and reporting of abuse, neglect, accident or injury discovered via electronic monitoring.

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 primary advantages of the regulatory action to the public are increased safety of nursing facility residents. There are no known disadvantages to the public. The primary advantages to the Agency and the Commonwealth are increased care and safety for citizens throughout the Commonwealth who chose to utilize electronic monitoring. There are no known disadvantages to the Commonwealth.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need 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 requirements in this proposal that exceed 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.

No locality will be particularly affected by the proposed regulatory action.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, 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.

SB553 mandates the Board of Health to promulgate regulations governing the implementation of voluntary electronic monitoring in the rooms of residents of nursing homes. The regulations are mandated by law and there are no viable alternatives to the proposed regulatory action to achieve the necessary regulatory changes mandated by SB553.

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 requirement creates the anticipated economic impact.

<p>Projected cost to the state to implement and enforce the proposed regulation, including: a) fund source / fund detail; and b) a delineation of one-time versus on-going expenditures</p>	<p>None</p>
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Projected cost of the new regulations or changes to existing regulations on localities.	None
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	The 281 licensed nursing facilities within the Commonwealth of Virginia, patients or residents of those facilities and their family members or legal representatives.
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: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.	All 281 licensed nursing facilities within the Commonwealth of Virginia must comply with 12VAC5-371. A majority of the licensed nursing facilities within the Commonwealth of Virginia qualify as small businesses.
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 including: a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and b) 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.	None, there are no costs unless the facility receives a request to install equipment. The regulation provides that such costs can be charged to the family, patient or resident seeking implementation of the electronic monitoring. Those individuals (patients, residents, family members) who wish to avail themselves of electronic monitoring will have a cost.
Beneficial impact the regulation is designed to produce.	Provides the controls necessary to assure that resident autonomy and rights to personal privacy are not violated.

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.

SB553 mandates the Board of Health to promulgate regulations governing the implementation of voluntary electronic monitoring in the rooms of residents of nursing homes. The regulations are mandated by law and there are no viable alternatives to the proposed regulatory action to achieve the necessary regulatory changes mandated by SB553.

Public participation notice

If an objection to the use of the fast-track process is received within the 30-day public comment period from 10 or more persons, any member of the applicable standing committee of either house of the General Assembly or of the Joint Commission on Administrative Rules, the agency shall: 1) file notice of the objections with the Registrar of Regulations for publication in the Virginia Register; and 2) proceed with the normal promulgation process with the initial publication of the fast-track regulation serving as the Notice of Intended Regulatory Action.

Family impact

Please assess the impact of this 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.

VDH anticipates the amendments will strengthen the family and family stability through increased involvement in nursing home resident’s care and greater assurance for family members that residents are being well cared for.

Detail of changes

*Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please list separately: (1) all differences between the **pre-emergency** regulation and this proposed regulation; and 2) only changes made since the publication of the emergency regulation.*

For changes to existing regulation(s), use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12VAC5-371-10		Definitions. Current definitions all remain unchanged.	Defined terms to be added: <u>“Electronic monitoring” means an unmanned video recording system, with or without audio capability, installed in the room of a resident.</u> <u>“Facility-managed” is an electronic monitoring system that is installed, controlled, and maintained by the nursing facility in accordance with the facility’s policies.</u> <u>“Resident-managed” is an electronic monitoring system that is installed, controlled, and maintained by the resident with the permission of the nursing facility.</u> Intent: Provides definition to terms and phrases used in 12VAC5-371-191. Likely impact: provides clarity to the new regulatory section.

<p>N/A</p>	<p>12VAC5-371-191- Electronic monitoring in resident rooms.</p>	<p>N/A</p>	<p><u>A. All requests for electronic monitoring shall be made in writing and signed by the resident or the resident's responsible party or legally authorized representative, if the resident has been properly assessed incapable of requesting and authorizing the monitoring.</u></p> <p><u>B. Only electronic monitoring authorized by 12VAC5-371-191 (A) is permitted under a facility-managed or resident-managed program if permitted by the facility. Audio monitoring, if authorized and allowed by the facility, shall be governed by the facility's policies and procedures as allowed by state and federal laws.</u></p> <p><u>C. A facility shall not refuse to admit an individual and shall not discharge or transfer a resident due to a request to conduct authorized electronic monitoring.</u></p> <p><u>D. Family members cannot obtain electronic monitoring over the objections of the resident or the resident's roommate. No equipment may be installed pursuant to 12VAC5-371-191 (Q) over the objections of the resident or the resident's roommate. Facilities shall not use monitoring equipment in violation of the law based solely on a family member's request or approval.</u></p> <p><u>E. Authorization for electronic monitoring shall be kept in the resident's medical record.</u></p> <p><u>F. Facilities shall designate one staff person to be responsible for managing the electronic monitoring program.</u></p> <p><u>G. Facilities may designate custodial ownership of any recordings from monitoring devices to the resident, the resident's responsible party or legal guardian. Facility retained recordings shall be considered part of the resident's medical record and shall be retained for no less than two years or as required by state and federal laws.</u></p> <p><u>H. If a facility chooses to retain ownership of recordings, the facility shall not permit viewings of recordings without the resident's, the resident's responsible party or legal guardian's approval. Should a resident, a resident's responsible party or legal guardian approve viewing, the facility shall accommodate viewing of any</u></p>
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			<p><u>recordings, including, but not limited to providing:</u></p> <ol style="list-style-type: none"> <u>1. Appropriate playing/viewing equipment;</u> <u>2. Privacy during viewing; and</u> <u>3. Viewing times convenient to the resident, the resident's responsible party, legal guardian or designees.</u> <p><u>I. Any incidences regarding safety or quality of care discovered as a result of viewing a recording shall be reported immediately to the facility administrator and to the OLC. Facilities shall instruct the resident, the resident's responsible party or legal guardian of this reporting requirement and shall provide the resident, the resident's responsible party or legal guardian with the OLC's Complaint Hotline telephone number.</u></p> <p><u>J. A facility shall have no obligation to seek access to a recording in its possession or to have knowledge of a recording's content, unless the facility is aware of a recorded incident of suspected abuse, neglect, accident or injury; or the resident or the resident's responsible party or legal guardian, or a government agency, seeks to use a recording in any way that affects the facility. Facilities shall immediately report suspected abuse and neglect, discovered as a result of using monitoring devices, as required by law.</u></p> <p><u>K. A facility may require the resident, the resident's responsible party or legal guardian to be responsible for all aspects of the operation of the monitoring equipment, including the removal and replacement of recordings, and for firewall protections to prevent images that would violate obscenity laws from being inadvertently shown on the Internet.</u></p> <p><u>L. Facility staff shall not refuse to enter a monitored room.</u></p> <p><u>M. Any electronic monitoring equipment shall be installed in a manner that is safe for residents, employees, or visitors who may be moving about the resident's room.</u></p> <p><u>N. A facility shall make reasonable physical accommodation for monitoring equipment including:</u></p> <ol style="list-style-type: none"> <u>1. Providing a reasonably secure place to mount the device; and</u>
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			<p><u>2. Providing access to power sources for the device.</u></p> <p><u>O. A facility may require a resident, a resident's responsible party or legal guardian, to pay for all costs, other than the cost of electricity, associated with installing electronic monitoring equipment. Such costs shall be reasonable and may include, but are not limited to: equipment, recording media and installation, compliance with life safety and building/electrical codes, maintenance or removal of the equipment, posting and removal of any public notices, or structural repairs to the building resulting from the removal of the equipment. Facilities shall give 45 days notice of an increase in monthly monitoring fees.</u></p> <p><u>P. Any equipment installed for the purpose of monitoring a resident room shall be fixed and unable to rotate.</u></p> <p><u>Q. The informed consent of all residents assigned to the monitoring room shall be obtained prior to any electronic monitoring equipment being installed.</u></p> <p><u>R. A facility may require that the resident, a resident's responsible party or legal guardian, obtain the necessary signed consent of other residents in the room.</u></p> <p><u>S. A copy of any signed consent form shall be kept in the resident's medical record as well as on file with the facility's designated electronic monitoring coordinator.</u></p> <p><u>T. Any resident of a monitored room may condition his or her consent for use of monitoring devices. Such conditions may be, but are not limited to, pointing the camera away or limiting or prohibiting the use of certain devices. If conditions are placed on consent, then electronic monitoring shall be conducted according to those conditions.</u></p> <p><u>U. The facility shall conspicuously post and maintain a notice at the entrance to the resident's room stating that an electronic monitoring device is in operation.</u></p> <p><u>V. Facilities shall notify all staff and their VDH OLC Long Term Care Supervisor that electronic monitoring is in use.</u></p>
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			<p><u>W. Covert monitoring is prohibited and any breach of this prohibition shall be governed by the facility's policies and procedures as allowed by state and federal laws.</u></p> <p><u>X. If covert monitoring is discovered, the facility may require a resident, a resident's responsible party or legal guardian, to meet all the requirements for authorized monitoring prior to the continuation of monitoring.</u></p> <p><u>Y. Each nursing facility, including those that choose not to offer electronic monitoring, shall adopt policies and procedures for electronic monitoring. These policies and procedures shall address all the elements of this section, 12VAC5-371-191.</u></p> <p><u>Z. Tampering with electronic monitoring with the intent to violate these regulations shall be prohibited.</u></p> <p>Intent: Providing assurance that a resident's dignity and right to personal, bodily privacy and autonomy are not violated should electronic monitoring be implemented within their room with their consent. These provisions largely already exist in a Guidance document published by VDH OLC in 2004, the Department is simply placing those provisions, updated with input from the workgroup, into the regulations as required by SB553.</p> <p>Likely impact: Greater patient safety, more comprehensive regulations.</p>
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Project 4519 - none

DEPARTMENT OF HEALTH
CH371- Amend regulations related to electronic monitoring

1 **12VAC5-371-191. Electronic monitoring in resident rooms.**

2 12VAC5-371-10. Definitions

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

5 "Abuse" means the willful infliction of injury, unreasonable confinement, intimidation, or
6 punishment with resulting physical harm, pain or mental anguish, or deprivation by an
7 individual, including caretaker, of goods or services that are necessary to attain or maintain
8 physical, mental, and psychosocial well-being. This includes verbal, sexual, physical or mental
9 abuse.

10 "Administrator" means the individual licensed by the Virginia Board of Long-Term Care
11 Administrators and who has the necessary authority and responsibility for management of the
12 nursing facility.

13 "Admission" means the process of acceptance into a nursing facility, including orientation, rules
14 and requirements, and assignment to appropriate staff. Admission does not include readmission
15 to the facility after a temporary absence.

16 "Advance directive" means (i) a witnessed written document, voluntarily executed by the
17 declarant in accordance with the requirements of § 54.1-2983 of the Code of Virginia, or (ii) a
18 witnessed oral statement, made by the declarant subsequent to the time he is diagnosed as
19 suffering from a terminal condition and in accordance with the provision of § 54.1-2983 of the
20 Code of Virginia.

21 "Assessment" means the process of evaluating a resident for the purpose of developing a profile
22 on which to base services. Assessment includes information gathering, both initially and on an
23 ongoing basis, designed to assist the multi-disciplinary staff in determining the resident's need
24 for care, and the collection and review of resident-specific data.

25 "Attending physician" means a physician currently licensed by the Virginia Board of Medicine
26 and identified by the resident, or legal representative, as having the primary responsibility in
27 determining the delivery of the resident's medical care.

28 "Board" means the Board of Health.

29 "Certified nurse aide" means the title that can only be used by individuals who have met the
30 requirements to be certified, as defined by the Virginia Board of Nursing, and who are listed in
31 the nurse aide registry.

32 "Chemical restraint" means a psychopharmacologic drug (a drug prescribed to control mood,
33 mental status, or behavior) that is used for discipline or convenience and not required to treat
34 medical symptoms or symptoms from mental illness or mental retardation that prohibit an
35 individual from reaching his highest level of functioning.

36 "Clinical record" means the documentation of health care services, whether physical or mental,
37 rendered by direct or indirect resident-provider interactions. An account compiled by physicians
38 and other health care professionals of a variety of resident health information, such as
39 assessments and care details, including testing results, medicines, and progress notes.

40 "Commissioner" means the State Health Commissioner.

41 "Complaint" means any allegation received by the Department of Health other than an incident
42 reported by the facility staff. Such allegations include, but are not limited to, abuse, neglect,
43 exploitation, or violation of state or federal laws or regulations.

44 "Comprehensive plan of care" means a written action plan, based on assessment data, that
45 identifies a resident's clinical and psychosocial needs, the interventions to meet those needs,
46 treatment goals that are measurable and that documents the resident's progress toward meeting
47 the stated goals.

48 "Construction" means the building of a new nursing facility or the expansion, remodeling, or
49 alteration of an existing nursing facility and includes the initial and subsequent equipping of the
50 facility.

51 "Department" means the Virginia Department of Health.

52 "Dignity" means staff, in their interactions with residents, carry out activities which assist a
53 resident in maintaining and enhancing the resident's self-esteem and self-worth.

54 "Discharge" means the process by which the resident's services, delivered by the nursing facility,
55 are terminated.

56 "Discharge summary" means the final written summary of the services delivered, goals achieved
57 and post-discharge plan or final disposition at the time of discharge from the nursing facility. The
58 discharge summary becomes a part of the clinical record.

59 "Drug" means (i) articles or substances recognized in the official United States "Drug"
60 Pharmacopoeia National Formulary or official Homeopathic Pharmacopoeia of the United
61 States, or any supplement to any of them; (ii) articles or substances intended for the use in the
62 diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animal; (iii)
63 articles or substances, other than food, intended to affect the structure or any function of the body
64 of man or other animal; and (iv) articles or substances intended for use as a component of any
65 article specified in clause (i), (ii), or (iii). This does not include devices or their components,
66 parts or accessories.

67 "Electronic monitoring" means an unmanned video recording system, with or without audio
68 capability, installed in the room of a resident.

69 "Emergency preparedness plan" means a component of a nursing facility's safety management
70 program designed to manage the consequences of natural disasters or other emergencies that
71 disrupt the nursing facility's ability to provide care.

72 "Employee" means a person who performs a specific job function for financial remuneration on a
73 full-time or part-time basis.

74 "Facility-managed" is an electronic monitoring system that is installed, controlled, and
75 maintained by the nursing facility in accordance with the facility's policies.

76 "Full-time" means a minimum of 35 hours or more worked per week in the nursing facility.

77 "Guardian" means a person legally invested with the authority and charged with the duty of
78 taking care of the resident, managing his property and protecting the rights of the resident who
79 has been declared by the circuit court to be incapacitated and incapable of administering his own
80 affairs. The powers and duties of the guardian are defined by the court and are limited to matters
81 within the areas where the resident in need of a guardian has been determined to be
82 incapacitated.

83 "Medication" means any substance, whether prescription or over-the-counter drug, that is taken
84 orally or injected, inserted, topically applied, or otherwise administered.

85 "Neglect" means a failure to provide timely and consistent services, treatment or care to a
86 resident or residents that are necessary to obtain or maintain the resident or residents' health,
87 safety or comfort; or a failure to provide timely and consistent goods and services necessary to
88 avoid physical harm, mental anguish, or mental illness.

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

90 "OLC" means the Office of Licensure and Certification of the Virginia Department of Health.
91 "Person" means any individual, corporation, partnership, association, trust, or other legal entity,
92 whether governmental or private, owning, managing, or operating a nursing facility.
93 "Physical restraint" means any manual method or physical or mechanical device, material, or
94 equipment attached or adjacent to the resident's body that the individual cannot remove easily
95 which restricts freedom of movement or normal access to one's own body.
96 "Policy" means a written statement that describes the principles and guides and governs the
97 activities, procedures and operations of the nursing facility.
98 "Procedures" means a series of activities designed to implement program goals or policy, which
99 may or may not be written, depending upon the specific requirements within this chapter. For
100 inspection purposes, there must be evidence that procedures are actually implemented.
101 "Progress note" means a written statement, signed and dated by the person delivering the care,
102 consisting of a pertinent, chronological report of the resident's care. A progress note is a
103 component of the clinical record.
104 "Qualified" means meeting current legal requirements of licensure, registration or certification in
105 Virginia; having appropriate training and experience commensurate with assigned
106 responsibilities; or, if referring to a professional, possessing an appropriate degree or having
107 documented equivalent education, training or experience.
108 "Quality assurance" means systematic activities performed to determine the extent to which
109 clinical practice meets specified standards and values with regard to such things as
110 appropriateness of service assignment and duration, appropriateness of facilities and resources
111 utilized, adequacy and clinical soundness of care given. Such activities should also assure
112 changes in practice that do not meet accepted standards. Examples of quality assurance activities
113 include the establishment of facility-wide goals for resident care, the assessment of the
114 procedures used to achieve the goals, and the proposal of solutions to problems in attaining those
115 goals.
116 "Readmission" means a planned return to the nursing facility following a temporary absence for
117 hospitalization, off-site visit or therapeutic leave, or a return stay or confinement following a
118 formal discharge terminating a previous admission.
119 "Resident" means the primary service recipient, admitted to the nursing facility, whether that
120 person is referred to as a client, consumer, patient, or other term.

121 “Resident-managed” is an electronic monitoring system that is installed, controlled, and
122 maintained by the resident with the permission of the nursing facility.
123 "Responsible person or party" means an individual authorized by the resident to act for him as an
124 official delegate or agent. The responsible person may be a guardian, payee, family member or
125 any other individual who has arranged for the care of the resident and assumed this
126 responsibility. The responsible person or party may or may not be related to the resident. A
127 responsible person or party is not a guardian unless so appointed by the court.
128 "Supervision" means the ongoing process of monitoring the skills, competencies and
129 performance of the individual supervised and providing regular, face-to-face guidance and
130 instruction.
131 "Volunteer" means a person who, without financial remuneration, provides services to the
132 nursing facility.

133 **12VAC5-371-191. Electronic monitoring in resident rooms.**

134 A. All requests for electronic monitoring shall be made in writing and signed by the resident
135 or the resident’s responsible party or legally authorized representative, if the resident has been
136 properly assessed incapable of requesting and authorizing the monitoring.

137 B. Only electronic monitoring authorized by 12VAC5-371-191 (A) is permitted under a
138 facility-managed or resident-managed program if permitted by the facility. Audio monitoring, if
139 authorized and allowed by the facility, shall be governed by the facility’s policies and procedures
140 as allowed by state and federal laws.

141 C. A facility shall not refuse to admit an individual and shall not discharge or transfer a
142 resident due to a request to conduct authorized electronic monitoring.

143 D. Family members cannot obtain electronic monitoring over the objections of the resident or
144 the resident's roommate. No equipment may be installed pursuant to 12VAC5-371-191 (Q) over
145 the objections of the resident or the resident's roommate. Facilities shall not use monitoring
146 equipment in violation of the law based solely on a family member's request or approval.

147 E. Authorization for electronic monitoring shall be kept in the resident's medical record.

148 F. Facilities shall designate one staff person to be responsible for managing the electronic
149 monitoring program.

150 G. Facilities may designate custodial ownership of any recordings from monitoring devices
151 to the resident, the resident's responsible party or legal guardian. Facility retained recordings
152 shall be considered part of the resident's medical record and shall be retained for no less than two
153 years or as required by state and federal laws.

154 H. If a facility chooses to retain ownership of recordings, the facility shall not permit
155 viewings of recordings without the resident's, the resident's responsible party or legal guardian's
156 approval. Should a resident, a resident's responsible party or legal guardian approve viewing, the
157 facility shall accommodate viewing of any recordings, including, but not limited to providing:

- 158 1. Appropriate playing/viewing equipment;
- 159 2. Privacy during viewing; and
- 160 3. Viewing times convenient to the resident, the resident's responsible party, legal
161 guardian or designees.

162 I. Any incidences regarding safety or quality of care discovered as a result of viewing a
163 recording shall be reported immediately to the facility administrator and to the OLC. Facilities
164 shall instruct the resident, the resident's responsible party or legal guardian of this reporting
165 requirement and shall provide the resident, the resident's responsible party or legal guardian with
166 the OLC's Complaint Hotline telephone number.

167 J. A facility shall have no obligation to seek access to a recording in its possession or to have
168 knowledge of a recording's content, unless the facility is aware of a recorded incident of
169 suspected abuse, neglect, accident or injury; or the resident or the resident's responsible party or
170 legal guardian, or a government agency, seeks to use a recording in any way that affects the
171 facility. Facilities shall immediately report suspected abuse and neglect, discovered as a result of
172 using monitoring devices, as required by law.

173 K. A facility may require the resident, the resident's responsible party or legal guardian to be
174 responsible for all aspects of the operation of the monitoring equipment, including the removal
175 and replacement of recordings, and for firewall protections to prevent images that would violate
176 obscenity laws from being inadvertently shown on the Internet.

177 L. Facility staff shall not refuse to enter a monitored room.

178 M. Any electronic monitoring equipment shall be installed in a manner that is safe for
179 residents, employees, or visitors who may be moving about the resident's room.

180 N. A facility shall make reasonable physical accommodation for monitoring equipment
181 including:

182 1. Providing a reasonably secure place to mount the device; and

183 2. Providing access to power sources for the device.

184 O. A facility may require a resident, a resident's responsible party or legal guardian, to pay
185 for all costs, other than the cost of electricity, associated with installing electronic monitoring
186 equipment. Such costs shall be reasonable and may include, but are not limited to: equipment,
187 recording media and installation, compliance with life safety and building/electrical codes,
188 maintenance or removal of the equipment, posting and removal of any public notices, or
189 structural repairs to the building resulting from the removal of the equipment. Facilities shall
190 give 45 days notice of an increase in monthly monitoring fees.

191 P. Any equipment installed for the purpose of monitoring a resident room shall be fixed and
192 unable to rotate.

193 Q. The informed consent of all residents assigned to the monitoring room shall be obtained
194 prior to any electronic monitoring equipment being installed.

195 R. A facility may require that the resident, a resident's responsible party or legal guardian,
196 obtain the necessary signed consent of other residents in the room.

197 S. A copy of any signed consent form shall be kept in the resident's medical record as well as
198 on file with the facility's designated electronic monitoring coordinator.

199 T. Any resident of a monitored room may condition his or her consent for use of monitoring
200 devices. Such conditions may be, but are not limited to, pointing the camera away or limiting or
201 prohibiting the use of certain devices. If conditions are placed on consent, then electronic
202 monitoring shall be conducted according to those conditions.

203 U. The facility shall conspicuously post and maintain a notice at the entrance to the resident's
204 room stating that an electronic monitoring device is in operation.

205 V. Facilities shall notify all staff and their VDH OLC Long Term Care Supervisor that
206 electronic monitoring is in use.

207 W. Covert monitoring is prohibited and any breach of this prohibition shall be governed by
208 the facility's policies and procedures as allowed by state and federal laws.

209 X. If covert monitoring is discovered, the facility may require a resident, a resident's
210 responsible party or legal guardian, to meet all the requirements for authorized monitoring prior
211 to the continuation of monitoring.

212 Y. Each nursing facility, including those that choose not to offer electronic monitoring, shall
213 adopt policies and procedures for electronic monitoring. These policies and procedures shall
214 address all the elements of this section, 12VAC5-371-191.

215 Z. Tampering with electronic monitoring with the intent to violate these regulations shall be
216 prohibited.