

**State of Board of Health – Nominating Committee
Agenda
April 23, 2010 – 8:30 a.m.
Perimeter Center
9960 Mayland Drive
Richmond, Virginia 23233**

Welcome and Introductions	Dr. Craig Reed
Nominations	Committee Members
Adoption of Recommended Slate of Officers	Committee Members
Adjourn	

**State of Board of Health
Agenda
April 23, 2010 – 9:00 a.m.
Perimeter Center
9960 Mayland Drive
Richmond, Virginia 23233**

Welcome and Introductions	Fred Hannett, Chairman
Review of Agenda	Joseph Hilbert, Executive Advisor
Approval of January 2010 Minutes	Fred Hannett
Commissioner’s Report	Karen Remley, MD, MBA, FAAP State Health Commissioner
Budget Update	Michael McMahon, Deputy Director Office of Financial Management
Legislative Update	Joseph Hilbert
Break	
Federal Health Care Reform Update	Joseph Hilbert
Public Comment	
<u>Board Action Items</u>	
Nursing Home Request for Applications	Chris Durrer, Director Office of Licensure and Certification
Designation of Regional Emergency Medical Services Councils § 32.1-111.11, Code of Virginia	Gary Brown, Director Office of Emergency Medical Services

Statewide Prehospital and Interhospital
Stroke Triage Plan
§ 32.1-111.3, Code of Virginia

Gary Brown

Lunch

Luncheon Speaker – The Honorable William A. Hazel, Jr., M.D.
Secretary of Health and Human Resources

Board Regulatory Action Items

Disease Reporting and Control Regulations
12 VAC 5-90
(Proposed Amendments – expansion of healthcare
associated infection reporting requirements)

Dr. Keri Hall, Director
Office of Epidemiology

Disease Reporting and Control Regulations
12 VAC 5-90
(Final Amendments – to comply with
recent changes to Code of Virginia, and
updated disease control policies and practices)

Dr. Keri Hall

Virginia Immunization Information System
Regulations
12 VAC 5-115
(Proposed Regulations)

Dr. Keri Hall

Virginia Radiation Protection Regulations
12 VAC 5-481
(Notice of Intended Regulatory Action)

Dr. Keri Hall

Regulations for Licensure of Hospitals
12 VAC 5-410
(Exempt Regulatory Action)

Chris Durrer, Director
Office of Licensure and Certification

Regulations for Licensure of Nursing Facilities
12 VAC 5-371
(Exempt Regulatory Action)

Chris Durrer

Nominating Committee Report

Dr. Craig Reed

Member Reports

Other Business

Adjourn



COMMONWEALTH of VIRGINIA

Karen Remley, MD, MBA, FAAP
State Health Commissioner

Department of Health
P O BOX 2448
RICHMOND, VA 23218

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

March 19, 2010

MEMORANDUM

TO: The Board of Health

FROM: Christopher T. Durrer, FACHE 
Director

SUBJ: Request for Applications (RFA) for Nursing Facility Beds

Section 32.1-102.3:2 of the Code of Virginia stipulates that the State Health Commissioner, in consultation with the Department of Medical Assistance Services, issue a Request for Applications (RFA) in order to create opportunities for the submission and review of Certificate of Public Need (COPN) requests that propose increasing the number of nursing facility beds.

After approval by the Board, stakeholder response to the proposed RFA is sought through publication of the RFA in the Virginia Register. Sixty days after publication, the Commissioner may approve and formally issue the RFA. At that time, stakeholders can file letters of intent to file an application in response, starting the COPN review cycle for this RFA.

Thank you.

PROPOSED
NOTICE OF REQUEST FOR CERTIFICATE OF PUBLIC NEED APPLICATIONS
FOR DEVELOPMENT OF ADDITIONAL NURSING HOME BEDS
PLANNING TARGET YEAR 2013

THE VIRGINIA STATE BOARD OF HEALTH and
THE VIRGINIA DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

Legal Notice of Request for Certificate of Public Need Applications.

Pursuant to the authority vested in the State Board of Health ("Board") and the Department of Medical Assistance Services ("DMAS") by § 32.1-102.3:2 of the Code of Virginia, notice is hereby given of the *proposed* issuance of a Request for Applications ("RFA"). This RFA would be a request for certificate of public need ("COPN") applications for projects that would result in an increase in the number of beds in which nursing home services are provided in the Commonwealth of Virginia. The RFA process is outlined in 12 VAC 5-220-335 of the Virginia Medical Care Facilities Certificate of Public Need Rules and Regulations.

Eligible Planning District and Total Nursing Home Beds Available for Authorization.

In the review cycles that would be established by this RFA upon issuance of the final notice, the Commissioner of Health will consider requests for COPNs that propose an increase in nursing home beds in the planning districts ("PD") identified below and that propose an increase in beds no greater than the number of available beds shown below for that planning district. COPN requests that propose an increase in nursing home beds in any other planning district not identified below or propose an increase in beds greater than the number of available beds shown below for the eligible planning district will not be accepted for review.

Planning District 9, also known as the Rappahannock-Rapidan Planning District, consisting of the counties of Culpeper, Fauquier, Madison, Orange, and Rappahannock.

Total nursing home beds available for authorization: 60.

Planning District 10, also known as the Thomas Jefferson Planning District, consisting of the counties of Albemarle, Fluvanna, Greene, Louisa, and Nelson and the city of Charlottesville.

Total nursing home beds available for authorization: 60.

Planning District 18, also known as the Middle Peninsula Planning District, consisting of the counties of Essex, Gloucester, King and Queen, King William, Matthews, and Middlesex.

Total nursing home beds available for authorization: 30.

Evaluation of Need for Additional Nursing Home Beds.

The "Nursing Facilities" component of the *Virginia State Medical Facilities Plan* ("SMFP") contains a nursing home bed need forecasting method (12 VAC 5-230-610). This method has been employed by the Virginia Department of Health to compute a forecast of needed nursing home beds in 2013 in each of Virginia's twenty-two planning districts.¹

Consistent with the *Virginia State Medical Facilities Plan* (12 VAC 5-230-610 A), no planning district is considered to have a need for additional nursing home beds unless the average annual occupancy of all existing Medicaid-certified nursing home beds in the planning district was at least 93%, excluding the bed inventory and utilization of the Virginia Veterans Care Centers.

For purposes of this document, the annual occupancy of Medicaid-certified nursing home beds was determined from filings with Virginia Health Information made by Virginia nursing homes covering their fiscal year 2008. The average annual occupancy of one planning district was adjusted to take into account the fact that one nursing home in the planning district, although Medicaid-certified at the end of its fiscal year, had a substantial period of non-participation in the Medicaid program during the nursing home's fiscal year 2008.

Also, no planning district will be considered to have a need for additional nursing home beds if there are uncompleted nursing home beds, for which Medicaid certification will be sought, that were authorized for the planning district within the three years prior to this notice of a proposed RFA. The following table displays, by planning district, the nursing home *gross* bed need forecast for 2013, the current licensed bed inventory plus uncompleted COPN-authorized additions of nursing home beds, and the *net* bed need forecast for 2013.

The table also shows the average annual occupancy rate of Medicaid-certified nursing home beds for each planning district for the 2008 reporting year and identifies the status of each planning district with respect to authorized but uncompleted nursing home beds. The final column of the table states whether the planning district qualifies for additional nursing home beds for 2013.

**Nursing Home Bed Need Forecast and
Whether a Planning District Qualifies for Additional Nursing Home Beds for 2013**

Planning District	Gross Bed Need Forecast For 2013	Existing Plus Authorized Beds	Projected Net Bed Need In 2013	Average Occupancy Medicaid Beds 2008	Authorized But Uncompleted Medicaid Beds	Planning District Qualifies for Additional NH Beds
1	511	641	(130)	88.4%	no	no--no need

¹ For conduct of the certificate of public need program, the Virginia Department of Health continues to recognize the former Planning District 20, Southeastern Virginia, and the former Planning District 21, Peninsula, rather than Planning District 23, Hampton Roads, which combined the former PD 20 and PD 21.

Proposed Notice of Request for Certificate of Public Need Applications
for Development of Additional Nursing Home Beds--Planning Target Year 2013

Page 3

Planning District	Gross Bed Need Forecast For 2013	Existing Plus Authorized Beds	Projected Net Bed Need In 2013	Average Occupancy Medicaid Beds 2008	Authorized But Uncompleted Medicaid Beds	Planning District Qualifies for Additional NH Beds
2	426	547	(121)	76.7%	no	no--no need
3	1,378	1,405	(27)	93.1%	no	no--no need
4	828	788	40	85.7%	no	no--low occu.
5	2,046	2,301	(255)	91.0%	no	no--no need
6	1,746	1,528	218	92.4%	no	no--low occu.
7	966	972	(6)	89.2%	no	no--no need
8	5,026	4,358	668	89.6%	no	no--low occu.
9	815	746	69	93.7%	no	yes--60 beds
10	1,081	1,007	74	93.4%	no	yes--60 beds
11	1,512	1,550	(38)	92.9%	no	no--no need
12	2,036	1,929	107	91.8%	no	no--low occu.
13	935	881	54	92.9%	yes	no--low occu.
14	638	665	(27)	95.4%	yes	no--no need
15	3,927	4,049	(122)	93.0%	yes	no--no need
16*	825	785	40	92.4%	no	no--low occu.
17	332	368	(36)	79.2%	no	no--no need.
18	593	550	43	93.0%	no	yes--30 beds
19	1,099	1,075	24	91.0%	no	no--low occu.
20	4,547	4,421	126	90.2%	no	no--low occu.
21	2,056	1,875	181	92.5%	no	no--low occu.
22	377	389	(12)	89.8%	no	no--no need
Total VA	33,700	32,830	870	91.0%		

Sources: *Virginia State Medical Facilities Plan* (12 VAC 5-230-610)
Virginia Employment Commission (population projections, 2007 edition)
2006 Virginia Nursing Home Patient Survey, Health Systems Agency of Northern Virginia (for age-specific nursing home use rates)
Office of Licensure and Certification, VDH (for bed inventory)

*Note to table: There are 90 authorized but uncompleted nursing home beds in PD 16 that are expected to be Medicaid-certified. However, by virtue of provisions of H 267 of the 2006 General Assembly (Chap. 816, Acts of Assembly), the existence of these uncompleted beds is not to keep PD 16 from being the subject of an RFA, if PD 16 otherwise qualifies for an RFA. Therefore, PD 16 is shown above as having no uncompleted beds expected to be certified for Medicaid.

Basis for Review.

The Commissioner, in her review of COPN requests submitted pursuant to this RFA, will consider each of the eight factors enumerated in § 32.1-102.3 B of the Code of Virginia, as applicable. She will also consider applicable standards of the State Medical Facilities Plan (12 VAC 5-230-600 et. seq.).

Projection of Potential Fiscal Impact.

The Department of Medical Assistance Services projects total additional expenditures for medical services provided to Medicaid recipients of approximately \$4.29 million (\$2.14 million of Commonwealth general funds) for the fiscal year ending June 30, 2014, if all 150 beds included in this RFA are authorized and available for occupancy by July 1, 2013. This

Proposed Notice of Request for Certificate of Public Need Applications
for Development of Additional Nursing Home Beds--Planning Target Year 2013

Page 4

projection is based on the following principal assumptions:

Average proportion of beds filled during FY 2014	90.69%
Assumed Medicaid proportion of bed-days of service	61.24%
Average estimated payment rate per day (net of patient co-payments)	\$140.69

Schedule for Review.

COPN requests filed in response to this RFA must be filed in accordance with the provisions of 12 VAC 5-220-355. The review schedules shown below will apply. Letters of intent and applications must be received by the Virginia Department of Health Division of COPN and by the applicable regional health planning agency, if one is then in operation, by the dates shown below in order to qualify for consideration in the specified review cycle.

Letter of intent must be received by (to be stated in the final notice)

Application must be received by (to be stated in the final notice)

Review cycle will begin on (to be stated in the final notice)

Application Fees.

The Virginia Department of Health shall collect fees for COPN applications filed in response to this RFA. No application may be deemed to be complete for review until the required application fee is paid. The fee is one percent of the proposed capital expenditure for the project, but not less than \$1,000 or more than \$20,000.



COMMONWEALTH of VIRGINIA
Department of Health
Office of Emergency Medical Services
P.O. Box 2448
Richmond, VA 23218-2448

Karen Remley, MD, MBA, FAAP
State Health Commissioner

Gary R. Brown
Director

P. Scott Winston
Assistant Director

109 Governor St., Suite UB-55
Richmond, Virginia 23219

1-800-523-6019 (VA only)
804-864-7600
FAX: 804-864-7580

April 4, 2010

Mr. Frederick J. Hannett, Chair
Virginia State Board of Health
109 Governor Street
Richmond, VA 23219

Dear Chairman Hannett:

In accordance with 12 VAC 5-31-2340 (Section N) of the Virginia Emergency Medical Services Regulations governing Regional EMS Councils, the Virginia Office of EMS (OEMS) is providing the Board of Health with information and recommendations for entities who have applied for designation as a Regional EMS Council in Virginia.

Applications for designation as Regional EMS Councils were received by OEMS in October of 2009. Upon verification of completion of those applications, OEMS forwarded those applications on to Regional EMS Council designation site reviewers, to provide an objective evaluation of the information supplied by the applicant in the submitted materials, as well as conduct a review of the physical location of the applicant, and conduct interviews of the applicant organization's staff, officers, and other system stakeholders.

The site review team consisted of the following individuals:

Randy P. Abernathy
Deputy Chief, Hanover County Fire & EMS
Past Vice-chair, State EMS Advisory Board.

Donald R. Barklage, Jr.
Battalion Chief (Retired) City of Fairfax Fire & Rescue Services
Past Chair, State EMS Advisory Board
Past Chair, Northern Virginia EMS Council

Raphael M. Barishansky
Program Chief – Public Health, Emergency Preparedness, Prince George’s County, MD
Past Executive Director, Hudson Valley (NY) EMS Council
Site Reviewer – Commission on Accreditation of Ambulance Services
Robert A. Brown
Assistant Chief, Albemarle County Fire & Rescue
Past Training Coordinator, Peninsulas EMS Council

William Bullock
Battalion Chief (Retired) County of Fairfax Department of Fire & EMS
Past Member, State EMS Advisory Board

Kenneth G. Cook
Technical Assistance Director, Virginia Rural Health Resource Center
Past Regional Training Coordinator, Western Virginia EMS Council

David P. Edwards
EMS for Children Coordinator, Virginia Department of Health, Office of EMS
Site Reviewer – Commission on Accreditation of Ambulance Services

Glenn H. Luedtke
EMS Director (Retired), Sussex County, DE
Past Member, Arlington Volunteer Fire Dept, Arlington, VA

Karen Wagner
Site Supervisor, Valley Medical Transport, Winchester, VA
Past Chair, State EMS Advisory Board

Site reviews of all applicant entities were conducted between February 17 and March 23, 2010. A copy of each reviewer report accompanies this cover. In addition, a copy of the site review checklist, with comments as applicable, and the site review evaluation criteria also accompany this cover.

Based on the applications received, as well as the site reviewer reports, the OEMS recommends designation of Regional EMS Councils and in specified service areas as follows:

Blue Ridge EMS Council – Service area including the counties of Amherst, Appomattox, Bedford and Campbell, and the cities of Bedford and Lynchburg.

Central Shenandoah EMS Council – Service area including the counties of Augusta, Bath, Highland, Rockbridge and Rockingham, and the cities of Buena Vista, Harrisonburg, Lexington, Staunton and Waynesboro.

Lord Fairfax EMS Council – Service area including the counties of Clarke, Frederick, Page, Shenandoah, Warren, and the city of Winchester.

Old Dominion EMS Alliance – Service area including the counties of Amelia, Brunswick, Buckingham, Charles City, Charlotte, Chesterfield, Cumberland, Dinwiddie, Halifax, Hanover, Henrico, Goochland, Greensville, Lunenburg, Mecklenburg, New Kent, Nottoway, Powhatan, Prince Edward, Prince George, Surry, Sussex; the cities of Colonial Heights, Emporia, Hopewell, Petersburg, Richmond, and South Boston; and the towns of Ashland, Farmville and South Hill.

Peninsulas EMS Council – Service area including the counties of Essex, Gloucester, James City, King and Queen, King William, Lancaster; Mathews, Middlesex, Northumberland, Richmond, Westmoreland, York, and the cities of cities of Poquoson, Hampton, Newport News and Williamsburg.

Rappahannock EMS Council – Service area including the counties of Caroline, Culpeper, Fauquier, King George, Orange, Rappahannock, Spotsylvania, and Stafford; the town of Colonial Beach and the city of Fredericksburg.

Southwest Virginia EMS Council – Service area including the counties of Bland, Buchanan, Carroll, Dickenson, Grayson, Lee, Russell, Scott, Smyth, Tazewell, Washington, Wise and Wythe and the cities of Bristol, Galax, and Norton.

Thomas Jefferson EMS Council – Service area including the counties of Albemarle, Fluvanna, Greene, Louisa, Madison, Nelson, and the City of Charlottesville.

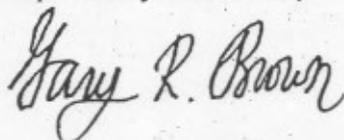
Tidewater EMS Council – Service area including the counties of Accomack, Isle of Wight, Northampton, and Southampton, and the cities of Chesapeake, Franklin, Norfolk, Portsmouth, Suffolk, and Virginia Beach.

Western Virginia EMS Council – Service area including the counties of Alleghany, Craig, Botetourt, Floyd, Franklin, Giles, Henry, Montgomery, Roanoke, Patrick, Pittsylvania, and Pulaski; and the cities of Covington, Manville, Martinsville, Radford, Roanoke, and Salem.

A map outlining the recommended service areas accompanies this cover. OEMS recommends a designation term of no less than three (3) years, commencing on July 1, 2010.

OEMS staff is prepared to answer any questions of the Board related to Regional EMS Council designation, and anticipates the Board approval of the recommendation as specified above.

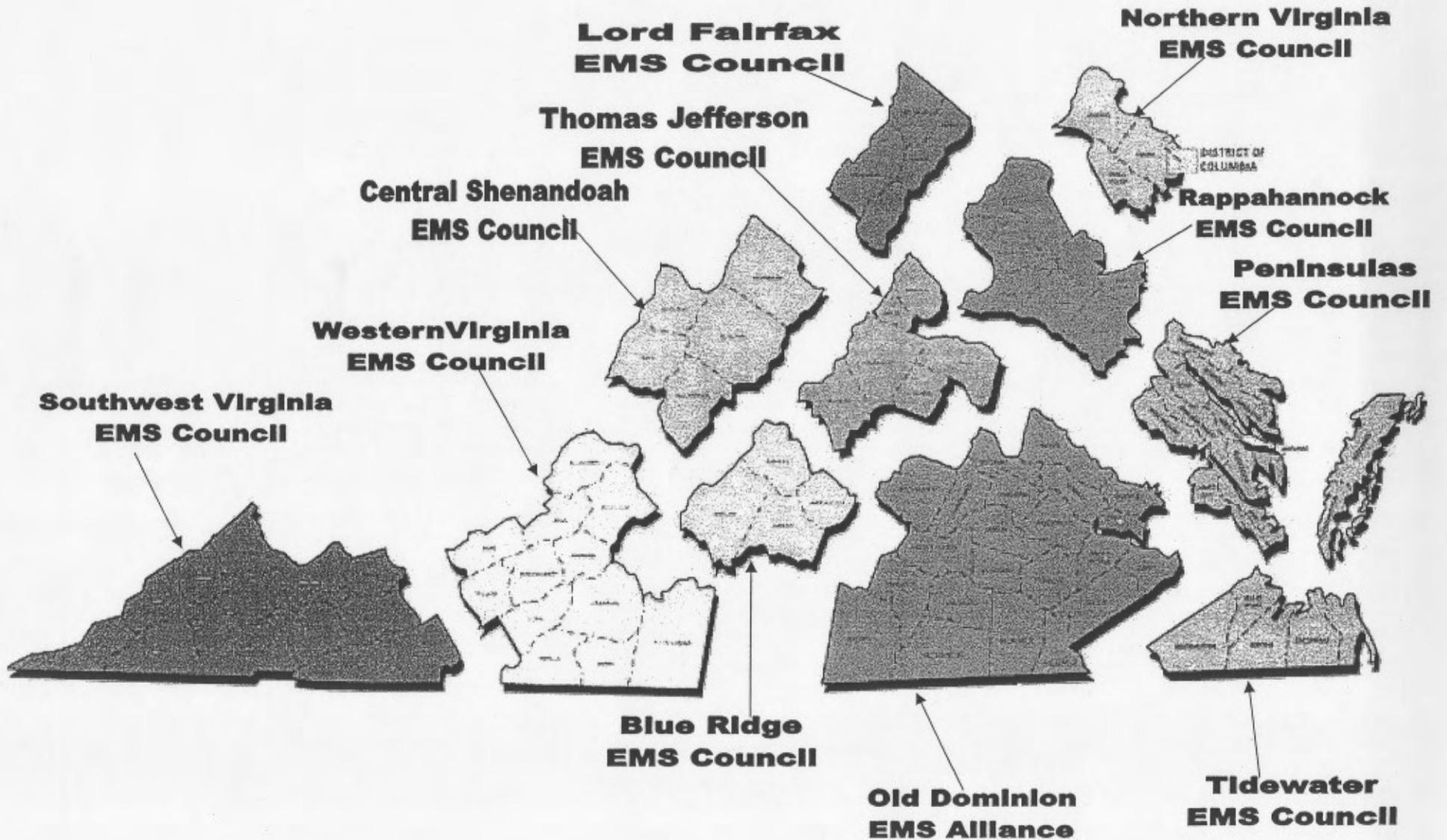
Respectfully submitted,



Gary R. Brown, Director
Virginia Department of Health
Office of EMS

Designated Regional EMS Council Map

July 1, 2010



April 1, 2010

Introduction

As pursuant to 12 VAC 5-31-2340 (H-J) of the Virginia Emergency Medical Services Regulations Governing Regional Emergency Medical Services Councils, I Karen D. Wagner, participated as a member of a site review team, tasked with evaluation of the Central Shenandoah EMS Council on March 2, 2010.

Purpose

The purpose of the review was to provide an objective evaluation of the applicant for designation as a Regional EMS Council, including a review of the submitted application, a visit of the physical location of the applicant, and conducting interviews of applicant organization staff, members of the applicant organization board of directors, and system stakeholders. This evaluation was performed to determine the applicant organization's ability to provide services to the regional EMS system, as outlined in Part VII of Virginia Emergency Medical Services Regulations.

Site Review

On March 2, 2010, the review team traveled to the Central Shenandoah EMS Council office, located at 2312 West Beverley Street, Staunton VA 24401. During the site visit, the review team evaluated the applicant in the following areas:

- * Regional EMS Council Designation Requirements
- * Site Visit/Inspection
- * Composition of Regional EMS Council
- * Governing Body of Regional EMS Council
- * Regional Planning
- * Financial Assistance for EMS Services
- * Base Funding of Regional EMS Councils
- * Experience in Development and/or Coordination
- * Accountability for public funds

In addition, interviews were conducted with the applicant organization Executive Director, members of the applicant organization board of directors, financial officers, and system stakeholders. We met with Dave Cullen, Matt Lawler, Gary Critzer and Amanda McComas.

Summary and Recommendation

Based on the evaluation of the applicant organization's application for designation, as well as information received during the site visit of the applicant organization, no deficiencies were noted/the following deficiencies were noted. As such, I recommend that the Central Shenandoah EMS Council be designated by the Virginia Board of Health as a Regional EMS Council for a term of three (3) years.

Respectfully submitted,

Karen D Wagner

February 26, 2010

Introduction

As pursuant to 12 VAC 5-31-2340 (H-J) of the Virginia Emergency Medical Services Regulations Governing Regional Emergency Medical Services Councils, I, Don Barklage, participated as a member of a site review team, tasked with evaluation of the Central Shenandoah EMS Council on February 26, 2010.

Purpose

The purpose of the review was to provide an objective evaluation of the applicant for designation as a Regional EMS Council, including a review of the submitted application, a visit of the physical location of the applicant, and conducting interviews of applicant organization staff, members of the applicant organization board of directors, and system stakeholders. This evaluation was performed to determine the applicant organization's ability to provide services to the regional EMS system, as outlined in Part VII of Virginia Emergency Medical Services Regulations.

Site Review

On 2/26/10, the review team traveled to the CSEMSC office, located at 2312 West Beverley St., Staunton, VA. During the site visit, the review team evaluated the applicant in the following areas:

- * Regional EMS Council Designation Requirements
- * Site Visit/Inspection
- * Composition of Regional EMS Council
- * Governing Body of Regional EMS Council
- * Regional Planning
- * Financial Assistance for EMS Services
- * Base Funding of Regional EMS Councils
- * Experience in Development and/or Coordination
- * Accountability for public funds

In addition, interviews were conducted with the applicant organization Executive Director, members of the applicant organization board of directors, financial officers, and system stakeholders, to include: Dave Cullen, Executive Director; Gary Critzer, President; and Matt Lawler, Assistant Director.

Summary and Recommendation

Based on the evaluation of the applicant organization's application for designation, as well as information received during the site visit of the applicant organization, no deficiencies were noted/the following deficiencies were noted. As such, I recommend that the CSEMSC be designated by the Virginia Board of Health as a Regional EMS Council for a term of three (3) years.

Respectfully submitted,

Donald R. Barklage Jr.

VIRGINIA REGIONAL EMS COUNCIL DESIGNATION SITE REVIEW CHECK LIST

Name of Organization : Central Shenandoah EMS Council

Name of Review Team Leader: Don Barklage

Date of Review: 2/26/10

Criteria Met	I. Designation Process	Comments*
<input checked="" type="checkbox"/>	1. Current roster of the organization's board of directors.	
<input checked="" type="checkbox"/>	2. Current approved bylaws of the organization.	
<input checked="" type="checkbox"/>	3. Scope of Services	
<input checked="" type="checkbox"/>	4. Proposed budget for the first year of operations.	
<input checked="" type="checkbox"/>	5. Documentation of interaction with agencies in region.	
<input checked="" type="checkbox"/>	6. Current operational policies and guidelines for organization.	
<input checked="" type="checkbox"/>	7. Comprehensive directory of localities and agencies	
<input checked="" type="checkbox"/>	8. Hospital catchment area	
<input checked="" type="checkbox"/>	9. Demonstrated capability to establish programs	
<input checked="" type="checkbox"/>	10. Evaluation of prior performance as a Regional EMS Council.**	
<input checked="" type="checkbox"/>	11. Proof of articles of incorporation.	
<input checked="" type="checkbox"/>	12. Copy of letter verifying tax exempt status from IRS.	
*Comments should be placed at the end of the review checklist.		
**If applicable		

Criteria Met	II. Designated Regional EMS Council Standards	Comments
	1. Regional Structure and the Board	
<input checked="" type="checkbox"/>	a. The regional EMS council is organizationally independent of any other entity.	
<input checked="" type="checkbox"/>	b. One regional governing board oversees the EMS council, and represents the entire designated service area.	
<input checked="" type="checkbox"/>	c. Bylaws are in force for the governing board which specify:	
<input checked="" type="checkbox"/>	i. Governing Board membership and representation.	
<input checked="" type="checkbox"/>	ii. Method of board member appointment or election.	
<input checked="" type="checkbox"/>	iii. Tenure of members.	
<input checked="" type="checkbox"/>	iv. Officers, and their roles, responsibilities and terms of office.	
<input checked="" type="checkbox"/>	v. Quorum requirements.	Vague
<input checked="" type="checkbox"/>	vi. Meeting attendance requirements and enforcement policies.	
<input checked="" type="checkbox"/>	vii. Indemnification of officers and directors.	
<input checked="" type="checkbox"/>	viii. Dissolution of assets.	
<input checked="" type="checkbox"/>	d. There is a minimum of five (5) members with full voting privileges comprising a governing board.	
<input checked="" type="checkbox"/>	e. Staff members of the applicant organization do not serve in a voting capacity on the governing board.	
<input checked="" type="checkbox"/>	f. Proof of board member orientation program for Council Board members.	
<input checked="" type="checkbox"/>	g. Clear structure to accomplish Regional Council goals and objectives identified.	
<input checked="" type="checkbox"/>	h. Proof of governing board and standing committees meeting a minimum of four times each year.	
<input checked="" type="checkbox"/>	i. Written minutes of all governing board and standing committee meetings.	
<input checked="" type="checkbox"/>	j. Proof of provision of filing, security and control of regional office files (hard copy and electronic).	
<input checked="" type="checkbox"/>	k. Current roster of council governing board, council office staff, and standing committee/members and current bylaws. This information shall be updated as necessary.	
<input checked="" type="checkbox"/>	l. The governing board compliance with requirements of the Virginia Freedom of Information Act.	
<input checked="" type="checkbox"/>	m. Proof of provision of professional development and management training for its members.	
<input checked="" type="checkbox"/>	n. Program reports developed and provided to the board, and other interested parties on a quarterly basis including a yearly final report, reflecting progress related to the Regional Council Strategic Plan. The final report includes, but not be limited to: a concise narrative description of activities, achievements, completed objectives and explanations for failure to achieve any objectives as defined in the contract with OEMS.	
<input checked="" type="checkbox"/>	o. The final report includes a report of all unexpended funds and documentation of satisfaction of matching funds requirement (percentage match required for state contract monies). The final report shall define the source and amount of matching funds.	
<input checked="" type="checkbox"/>	p. All materials, newsletters, software, etc. whether purchased or developed, in whole or in part, with state funds compliance with all United States copyright laws.	
<input checked="" type="checkbox"/>	q. The regional EMS council implementation and compliance with Virginia's record retention program.	
<input checked="" type="checkbox"/>	r. The regional EMS council must have proof of a currently updated Business Resumption Plan in place.	
*Comments should be placed at the end of the review checklist		

Criteria Met	2. Financial Administration	Comments*
<input checked="" type="checkbox"/>	a. Current operating statement, reflecting revenue and expenditures, available for review.	
<input checked="" type="checkbox"/>	b. Current income and expenditure statement shall be available at all governing board meetings.	
<input checked="" type="checkbox"/>	c. Proof of an independent audit of financial records with management letters as required by OEMS.	
<input checked="" type="checkbox"/>	d. A Certified Professional Accountant (CPA) upon change of an Executive Director may perform an audit of financial records.	
<input checked="" type="checkbox"/>	e. Proof of all financial management following generally accepted accounting principles.	
<input checked="" type="checkbox"/>	f. Proof of governing board approval of an annual budget.	
<input checked="" type="checkbox"/>	g. Proof of appropriate federal and state tax-related reporting.	
<input type="checkbox"/>	h. As applicable, proof of appropriate registration for solicitation with the Office of Consumer Affairs.	Exempt
<input checked="" type="checkbox"/>	i. Fund raising activities compliance with all applicable state and federal laws.	
<input checked="" type="checkbox"/>	j. Written policy indication by position, signatories of executed financial and contractual instruments.	
<input checked="" type="checkbox"/>	k. Proof of written policies concerning procurement and travel.	
*Comments should be placed at the end of the review checklist		

Criteria Met	3. Personnel Administration	Comments*
<input checked="" type="checkbox"/>	a. Proof of governing board adoption of written personnel policies which include:	
<input checked="" type="checkbox"/>	i. Position classification and salary schedule.	
<input checked="" type="checkbox"/>	ii. Affirmative action and nondiscrimination policies.	
<input checked="" type="checkbox"/>	iii. Current position descriptions of staff and volunteers.	
<input checked="" type="checkbox"/>	iv. Annual personnel performance evaluation.	
<input checked="" type="checkbox"/>	v. Initial administrative and programmatic orientation for the region and state.	
<input checked="" type="checkbox"/>	vi. Employee development.	
<input checked="" type="checkbox"/>	vii. Conflict of interest statement.	
<input checked="" type="checkbox"/>	viii. Outside employment.	
<input checked="" type="checkbox"/>	ix. Employment benefits.	
<input checked="" type="checkbox"/>	x. Enforcement procedures.	
<input checked="" type="checkbox"/>	xi. Grievance procedures.	
<input checked="" type="checkbox"/>	xii. Termination procedures.	
<input checked="" type="checkbox"/>	xiii. Code of ethics/standards of conduct	
<input checked="" type="checkbox"/>	xiv. Substance abuse policy	
<input checked="" type="checkbox"/>	xv. Record management and security	
<input checked="" type="checkbox"/>	b. Proof of personnel record management which includes, but not limited to:	
<input checked="" type="checkbox"/>	i. Employment application and letter of offer/agreement.	
<input checked="" type="checkbox"/>	ii. Leave records.	
<input checked="" type="checkbox"/>	iii. Employee performance records/correspondence.	
<input checked="" type="checkbox"/>	iv. Required employment forms (W-4, I-9, etc.).	
<input checked="" type="checkbox"/>	v. Promotion or salary adjustment.	
<input checked="" type="checkbox"/>	vi. Exit interview documentation.	
*Comments should be placed at the end of the review checklist		

Comments:**I. Designation Process:**

CSEMSC site review went very well. All documents had been presented. Staff very knowledgeable.

II. Regional EMS Council Standards**1. Regional Structure and Board Composition**

Reviewer believes that a more detailed policy on the requirements of a quorum for both the Executive Board and the full Board is necessary. Current policy stipulates a majority of the members present; this does not require a minimum number of people present to conduct business. Reviewer believes a number, or percentage, should be stipulated.

2. Financial Administration

Clear records, well documented.

3. Personnel Administration

Clear Personnel policies.

REGIONAL EMS COUNCIL EVALUATION CRITERIA

Central Shenandoah EMS Council - Don Barklage, Site Reviewer

Items	Item In Code	Score	Comments
Section One: Regional EMS Council Designation Requirements			
Completed Application	12.1-1	3	
Completed Self Assessment Checklist		3	
Complete Roster of Board of Directors		3	
Scope of Services Statement/Plan/Etc.		3	
Budget		3	
Documentation of EMS involvement		3	
Policies/Guidelines		3	
Locality directory		3	
Geographic Outline of Hospital Catchment Area		3	
Demonstration of capability of applicant to establish programs		3	
30 points maximum		30	
Section Two: Site Visit/Inspection			
Fixed Place of Operation		3	
Maintenance of records		3	
Inspection of vehicles and equipment		3	
9 points maximum		9	
Section Three: Composition of Regional EMS Council			
Appropriate representation of regional EMS stakeholders		3	
3 points maximum		3	
Section Four: Governing body of Regional EMS Council			
Council is governed by a board		3	Council should consider development of clearer quorum policies.
Articles of Incorporation and bylaws in force:		3	
Designated representation		3	
Method of appointment or election		3	
Governing board representation		3	
Tenure of representatives		3	
Roles and responsibilities, term limits of Board Officers		3	
Quorum requirements		2	
Meeting attendance requirements and enforcement policies		3	
Indemnification of officers and directors		3	
Dissolution of assets		3	
Minimum of 5 members with full voting privileges		3	
36 points maximum		35	
Section Five: Regional Planning			
Council develops, maintains and distributes the following:			
Regional EMS Plan	32.1-111.3/32.1-111.11	3	
Regional Trauma Triage Plan	32.1-111.3/32.1-111.11	3	
6 points maximum		6	
Section Six: Financial assistance for EMS Services			
Participation in the financial assistance for EMS program		3	

REGIONAL EMS COUNCIL EVALUATION CRITERIA

Written guidelines and procedures for program	6 points maximum	3	
		6	

Section Seven: Base funding of Regional EMS Councils		Score	Comments
Submission of 25% match of base funding	32.1-111.11	3	
	3 points maximum	3	

Section Eight: Experience in Development and/or Coordination		Score	Comments
Regional training plan		3	
Regional MCI plan		3	
Regional Medical Protocols		3	
Regional medication kit restocking procedures		3	
Regional hospital diversion plan		3	
Designates a Regional Medical Director		3	
Develop and implement ALS Coordinator endorsement process			Exempt
Establish a regional medical direction committee		3	
<i>Develops regional medical protocols</i>		3	
<i>Develops process for provision of medical direction</i>		3	
<i>Develops recommendations initial qualifications for prehospital personnel</i>		3	
<i>Develops and implements a PI program</i>		3	
	24 points maximum	21	

Section Nine: Accountability for public funds		Score	Comments
Council maintains operating statement, available for review		3	
Income and Expense Statement reported at each board meeting		3	
Annual independent audit with management letters		3	
Audit of financials upon change of Ex. Director		3	
Maintain financial records for minimum of 5 years		3	
Council utilizes general accounting principles		3	
Governing board approves annual fiscal budget by each 7/15		3	
Council compliance with federal and state tax reporting		3	
Council compliance with fund raising practices		3	
Written policies for financial and contractual instruments		3	
	30 points maximum	30	
TOTAL SCORE (147 POINTS Maximum)		143	

Section Scoring Key:

- 3 - Exceptional - Exceeds regulatory requirements. One or more strengths, with no significant weaknesses.
- 2 - Acceptable - Meets regulatory requirements, with strengths outweighing weaknesses found.
- 1 - Marginal - May not meet regulatory requirements, weaknesses outweigh strengths, and may be difficult to overcome.
- 0 - Unacceptable - Does not meet regulatory requirements, one or more significant weaknesses exist, which may be difficult or impossible to correct.

Section Scoring Percentages (Based on 100% of the nine sections):

- Section One: 20%
- Section Two: 3%
- Section Three: 5%
- Section Four: 20%
- Section Five: 15%

REGIONAL EMS COUNCIL EVALUATION CRITERIA

Section Six: 2%
Section Seven: 20%
Section Eight: 10%
Section Nine: 5%

April 1, 2010

Introduction

As pursuant to 12 VAC 5-31-2340 (H-J) of the Virginia Emergency Medical Services Regulations Governing Regional Emergency Medical Services Councils, I Kenneth G. Cook, Jr., participated as a member of a site review team, tasked with evaluation of the Blue Ridge Emergency Medical Services Council, Inc. on March 19, 2010.

Purpose

The purpose of the review was to provide an objective evaluation of the applicant for designation as a Regional EMS Council, including a review of the submitted application, a visit of the physical location of the applicant, and conducting interviews of applicant organization staff, members of the applicant organization board of directors, and system stakeholders. This evaluation was performed to determine the applicant organization's ability to provide services to the regional EMS system, as outlined in Part VII of Virginia Emergency Medical Services Regulations.

Site Review

On March 19, 2010, the review team traveled to the Blue Ridge EMS Council office, located at 1900 Tate Springs Road, Lynchburg. During the site visit, the review team evaluated the applicant in the following areas:

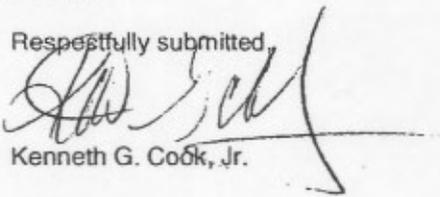
- * Regional EMS Council Designation Requirements
- * Site Visit/Inspection
- * Composition of Regional EMS Council
- * Governing Body of Regional EMS Council
- * Regional Planning
- * Financial Assistance for EMS Services
- * Base Funding of Regional EMS Councils
- * Experience in Development and/or Coordination
- * Accountability for public funds

In addition, interviews were conducted with the applicant organization Executive Director, members of the applicant organization board of directors, financial officers, and system stakeholders. These included Connie Purvis, Executive Director; Tom Scruggs, BREMS Treasurer and Board member representing Bedford County; Brad Ferguson, BREMS President, and Chief of the Lynchburg Fire Department; Mary Kathryn Allen, BREMS Assistant Director; and Steve Wade, BREMS Regional Training Coordinator.

Summary and Recommendation

Based on the evaluation of the applicant organization's application for designation, as well as information received during the site visit of the applicant organization, no significant deficiencies were noted. As such, I recommend that the Blue Ridge Emergency Medical Services Council, Inc. be designated by the Virginia Board of Health as a Regional EMS Council for a term of three (3) years.

Respectfully submitted,


Kenneth G. Cook, Jr.

Introduction

April 1, 2010

As pursuant to 12 VAC 5-31-2340 (H-J) of the Virginia Emergency Medical Services Regulations Governing Regional Emergency Medical Services Councils, I, David P. Edwards, participated as a member of a site review team tasked with evaluation of the Blue Ridge EMS Council on March 19, 2010.

Purpose

The purpose of the review was to provide an objective evaluation of the applicant for designation as a Regional EMS Council, including a review of the submitted application, a visit of the physical location of the applicant, and conducting interviews of applicant organization staff, members of the applicant organization board of directors, and system stakeholders. This evaluation was performed to determine the applicant organization's ability to provide services to the regional EMS system, as outlined in Part VII of Virginia Emergency Medical Services Regulations.

Site Review

On March 19, 2010, the review team traveled to the Blue Ridge EMS Council offices, located at 1900 Tate Springs Road, Suite 14, Lynchburg, VA 24501. During the site visit, the review team evaluated the applicant in the following areas:

- Regional EMS Council Designation Requirements
- Site Visit/Inspection
- Composition of Regional EMS Council
- Governing Body of Regional EMS Council
- Regional Planning
- Financial Assistance for EMS Services
- Base Funding of Regional EMS Councils
- Experience in Development and/or Coordination
- Accountability for Public Funds

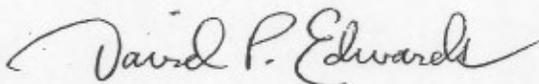
In addition, interviews were conducted with the applicant organization Executive Director, members of the applicant organization board of directors, financial officers, and system stakeholders. A partial list of those interviewed includes:

- Connie Purvis (Executive Director)
- Tom Scruggs (BREMS Treasurer, and Board Member representing Bedford County)
- Brad Ferguson (BREMS President, and Chief of Lynchburg FD)
- Mary Kathryn Allen (BREMS Assistant Director)
- Steve Wade (BREMS Regional Training Coordinator)

Summary and Recommendation

Based on the evaluation of the applicant organization's application for designation, as well as information received during the site visit of the applicant organization, no serious deficiencies were noted. As such, I recommend that the Blue Ridge EMS Council be designated by the Virginia Board of Health as a Regional EMS Council for a term of three (3) years.

Respectfully submitted,



David P. Edwards, MBA

March 17, 2010

Introduction

As pursuant to 12 VAC 5-31-2340 (H-J) of the Virginia Emergency Medical Services Regulations Governing Regional Emergency Medical Services Councils, I Raphael M. Barishansky, participated as a member of a site review team, tasked with evaluation of the Lord Fairfax EMS Council on March 10th, 2010.

Purpose

The purpose of the review was to provide an objective evaluation of the applicant for designation as a Regional EMS Council, including a review of the submitted application, a visit of the physical location of the applicant, and conducting interviews of applicant organization staff, members of the applicant organization board of directors, and system stakeholders. This evaluation was performed to determine the applicant organization's ability to provide services to the regional EMS system, as outlined in Part VII of Virginia Emergency Medical Services Regulations.

Site Review

On March 10th, the review team traveled to the Lord Fairfax EMS Council office, located at 190 Prosperity Drive, Suite 4 in Winchester, VA 22602. During the site visit, the review team evaluated the applicant in the following areas:

- * Regional EMS Council Designation Requirements
- * Site Visit/Inspection
- * Composition of Regional EMS Council
- * Governing Body of Regional EMS Council
- * Regional Planning
- * Financial Assistance for EMS Services
- * Base Funding of Regional EMS Councils
- * Experience in Development and/or Coordination
- * Accountability for public funds

In addition, interviews were conducted with the applicant organization Executive Director, members of the applicant organization board of directors, financial officers, and system stakeholders. These include various staffers of the Lord Fairfax EMS Council and:

- Tracey McLaurin – Executive Director
- Eddie McClellan – LFEMS Board President & City of Winchester Fire
- Chris Rucker – LFEMS Board Secretary & Valley Medical Transport
- Vince McGregor – Lord Fairfax Community College EMS Education Program
- Ron Sticklely – LFEMS EMS Planner
- Larry Oliver – LFEMS Vice President & LFEMS representative to the Governor's Advisory Board & Frederick County Fire & Rescue
- Dr. Jack Potter – Regional Medical Director

Summary and Recommendation

Based on the evaluation of the applicant organization's application for designation, as well as information received during the site visit of the applicant organization, no deficiencies

were noted/the following deficiencies were noted. As such, I recommend that the Lord Fairfax EMS Council be designated by the Virginia Board of Health as a Regional EMS Council for a term of three (3) years.

Respectfully submitted,
Raphael M. Barishansky

March 31, 2010

Introduction

As pursuant to 12 VAC 5-31-2340 (H-J) of the Virginia Emergency Medical Services Regulations Governing Regional Emergency Medical Services Councils, I **Robert A. Brown**, participated as a member of a site review team, tasked with evaluation of the **Lord Fairfax EMS Council** on **March 10, 2010**.

Purpose

The purpose of the review was to provide an objective evaluation of the applicant for designation as a Regional EMS Council, including a review of the submitted application, a visit of the physical location of the applicant, and conducting interviews of applicant organization staff, members of the applicant organization board of directors, and system stakeholders. This evaluation was performed to determine the applicant organization's ability to provide services to the regional EMS system, as outlined in Part VII of Virginia Emergency Medical Services Regulations.

Site Review

On 3/10/2010, the review team traveled to the Lord Fairfax EMS Council office, located at Winchester, Virginia. During the site visit, the review team evaluated the applicant in the following areas:

- * Regional EMS Council Designation Requirements
- * Site Visit/Inspection
- * Composition of Regional EMS Council
- * Governing Body of Regional EMS Council
- * Regional Planning
- * Financial Assistance for EMS Services
- * Base Funding of Regional EMS Councils
- * Experience in Development and/or Coordination
- * Accountability for public funds

In addition, interviews were conducted with the applicant organization members of the applicant organization board of directors, financial officers, and system stakeholders – including:

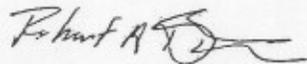
Tracey McLaurin, LFEMS Council Executive Director
Eddie McClellan, LFEMS Board President, Deputy Chief, City of Winchester Fire Department
Chris Rucker, LFEMS Board Secretary and Valley Medical Transport
Vince McGregor, Lord Fairfax Community College EMS Education Program
Ron Stickley, LFEMS Planner
Larry Oliver, LFEMS Vice President & LFEMS representative to the Governor's Advisory Board, and Frederick County Fire Rescue
Doctor Jack Potter, Regional Medical Director

Summary and Recommendation

Based on the evaluation of the applicant organization's application for designation, as well as information received during the site visit of the applicant organization, no deficiencies were noted/the following deficiencies were noted. As such, I recommend that the Lord Fairfax EMS Council be designated by the Virginia Board of Health as a Regional EMS Council

for a term of three (3) years.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Robert A. Brown", with a long horizontal flourish extending to the right.

Robert A. Brown

March 31, 2010

Introduction

As pursuant to 12 VAC 5-31-2340 (H-J) of the Virginia Emergency Medical Services Regulations Governing Regional Emergency Medical Services Councils, I **Robert A. Brown**, participated as a member of a site review team, tasked with evaluation of the **Northern Virginia EMS Council** on **March 2, 2010**.

Purpose

The purpose of the review was to provide an objective evaluation of the applicant for designation as a Regional EMS Council, including a review of the submitted application, a visit of the physical location of the applicant, and conducting interviews of applicant organization staff, members of the applicant organization board of directors, and system stakeholders. This evaluation was performed to determine the applicant organization's ability to provide services to the regional EMS system, as outlined in Part VII of Virginia Emergency Medical Services Regulations.

Site Review

On 3/02/2010, the review team traveled to the Northern Virginia EMS Council office, located at Gainesville, Virginia. During the site visit, the review team evaluated the applicant in the following areas:

- * Regional EMS Council Designation Requirements
- * Site Visit/Inspection
- * Composition of Regional EMS Council
- * Governing Body of Regional EMS Council
- * Regional Planning
- * Financial Assistance for EMS Services
- * Base Funding of Regional EMS Councils
- * Experience in Development and/or Coordination
- * Accountability for public funds

In addition, interviews were conducted with the applicant organization members of the applicant organization board of directors, financial officers, and system stakeholders – including:

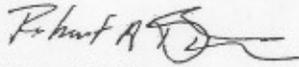
Melinda Duncan, NOVA EMS Council Executive Director
Byron Andrews, Past President and EMS Chief, Sterling Volunteer Rescue Squad
Linda Hale, EMS Division Chief, Loudon Co. Fire Rescue, NOVA BOD Member
Greg Rauch, Captain Fairfax City Fire Department, NOVA BOD Member
Jeannie Collins, Battalion Chief, Prince William Co. Fire Department, NOVA BOD Member, Chair of the Governor's EMS Advisory Board
Kate Passow, Physicians' Medical Transport and NOVA BOD Member
Ray Whatley, Alexandria Fire Department and NOVA CTC Coordinator
NOVA Office Staff

Summary and Recommendation

Based on the evaluation of the applicant organization's application for designation, as well as information received during the site visit of the applicant organization, no deficiencies were noted. As such, I recommend that the Northern Virginia EMS Council be designated by the Virginia Board of Health as a Regional EMS Council

for a term of three (3) years.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Robert A. Brown", with a stylized flourish at the end.

Robert A. Brown

April 1, 2010

Introduction

As pursuant to 12 VAC 5-31-2340 (H-J) of the Virginia Emergency Medical Services Regulations Governing Regional Emergency Medical Services Councils, I Karen D. Wagner, participated as a member of a site review team, tasked with evaluation of the Old Dominion EMS Alliance on March 12, 2010.

Purpose

The purpose of the review was to provide an objective evaluation of the applicant for designation as a Regional EMS Council, including a review of the submitted application, a visit of the physical location of the applicant, and conducting interviews of applicant organization staff, members of the applicant organization board of directors, and system stakeholders. This evaluation was performed to determine the applicant organization's ability to provide services to the regional EMS system, as outlined in Part VII of Virginia Emergency Medical Services Regulations.

Site Review

On March 12, 2010, the review team traveled to the ODEMSEA office located at 1463 Johnson-Willis Drive, Richmond VA. During the site visit, the review team evaluated the applicant in the following areas:

- * Regional EMS Council Designation Requirements
- * Site Visit/Inspection
- * Composition of Regional EMS Council
- * Governing Body of Regional EMS Council
- * Regional Planning
- * Financial Assistance for EMS Services
- * Base Funding of Regional EMS Councils
- * Experience in Development and/or Coordination
- * Accountability for public funds

In addition, interviews were conducted with the applicant organization Executive Director, members of the applicant organization board of directors, financial officers, and system stakeholders. We met with Rick Bucher, Rick McClure, Allen Yee, Tracy Thomas, Catina Downey-Stroble, Max Bornstein, and Heidi Hooker.

Summary and Recommendation

Based on the evaluation of the applicant organization's application for designation, as well as information received during the site visit of the applicant organization, no deficiencies were noted. As such, I recommend that the Old Dominion EMS Alliance be designated by the Virginia Board of Health as a Regional EMS Council for a term of three (3) years.

Respectfully submitted,

Karen D. Wagner

March 22, 2010

Introduction

As pursuant to 12 VAC 5-31-2340 (H-J) of the Virginia Emergency Medical Services Regulations Governing Regional Emergency Medical Services Councils, I, Don Barklage, participated as a member of a site review team, tasked with evaluation of the Old Dominion EMS Alliance on March 12, 2010.

Purpose

The purpose of the review was to provide an objective evaluation of the applicant for designation as a Regional EMS Council, including a review of the submitted application, a visit of the physical location of the applicant, and conducting interviews of applicant organization staff, members of the applicant organization board of directors, and system stakeholders. This evaluation was performed to determine the applicant organization's ability to provide services to the regional EMS system, as outlined in Part VII of Virginia Emergency Medical Services Regulations.

Site Review

On 3/12/10, the review team traveled to the ODEMSEA office, located at 1463 Johnston-Willis Drive, Richmond, VA. During the site visit, the review team evaluated the applicant in the following areas:

- * Regional EMS Council Designation Requirements
- * Site Visit/Inspection
- * Composition of Regional EMS Council
- * Governing Body of Regional EMS Council
- * Regional Planning
- * Financial Assistance for EMS Services
- * Base Funding of Regional EMS Councils
- * Experience in Development and/or Coordination
- * Accountability for public funds

In addition, interviews were conducted with the applicant organization Executive Director, members of the applicant organization board of directors, financial officers, and system stakeholders. These included: Heidi Hooker: Executive Director; Tracy Thomas: Compliance Manager/Administrative Officer; Rick Bucher: ODEMSEA Past President; Rick McClure: ODEMSEA President; Dr. Allen Yee: Regional Medical Director; Catina Downey-Stroble: Accountant; Max Bornstein: Treasurer.

Summary and Recommendation

Based on the evaluation of the applicant organization's application for designation, as well as information received during the site visit of the applicant organization, the following deficiencies were noted (see addendum reports). However, none of these listed deficiencies were of such a nature as to cause me to not recommend this Council for designation. As such, I recommend that the ODEMSEA be designated by the Virginia Board of Health as a Regional EMS Council for a term of three (3) years.

Respectfully submitted,

Don Barklage

Introduction

April 1, 2010

As pursuant to 12 VAC 5-31-2340 (H-J) of the Virginia Emergency Medical Services Regulations Governing Regional Emergency Medical Services Councils, I, David P. Edwards, participated as a member of a site review team tasked with evaluation of the Peninsulas EMS Council on March 16, 2010.

Purpose

The purpose of the review was to provide an objective evaluation of the applicant for designation as a Regional EMS Council, including a review of the submitted application, a visit of the physical location of the applicant, and conducting interviews of applicant organization staff, members of the applicant organization board of directors, and system stakeholders. This evaluation was performed to determine the applicant organization's ability to provide services to the regional EMS system, as outlined in Part VII of Virginia Emergency Medical Services Regulations.

Site Review

On March 16, 2010, the review team traveled to the Peninsulas EMS Council offices, located at 5222 George Washington Memorial Hwy, Suite C, Gloucester, VA 23061. During the site visit, the review team evaluated the applicant in the following areas:

- Regional EMS Council Designation Requirements
- Site Visit/Inspection
- Composition of Regional EMS Council
- Governing Body of Regional EMS Council
- Regional Planning
- Financial Assistance for EMS Services
- Base Funding of Regional EMS Councils
- Experience in Development and/or Coordination
- Accountability for Public Funds

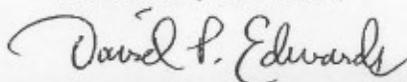
In addition, interviews were conducted with the applicant organization Executive Director, members of the applicant organization board of directors, financial officers, and system stakeholders. A partial list of those interviewed includes:

- Jeff Meyer (Executive Director)
- Louann Miller (Riverside Health System)
- Kim Harper (PEMS Board Member from the Riverside Health System)
- Michael Player (PEMS Board Member representing York County Fire and Safety)
- Dr. Cheryl Lawson (Regional Medical Director/PEMS representative to the Governor's EMS Advisory Board)
- Marsha Weatherwax (PEMS Treasurer)
- Julie Glover (PEMS Board President)
- Jerry Andrews (PEMS Assistant Director)

Summary and Recommendation

Based on the evaluation of the applicant organization's application for designation, as well as information received during the site visit of the applicant organization, no deficiencies were noted. As such, I recommend that the Peninsulas EMS Council be designated by the Virginia Board of Health as a Regional EMS Council for a term of three (3) years.

Respectfully submitted,



David P. Edwards, MBA

March 22, 2010

Introduction

As pursuant to 12 VAC 5-31-2340 (H-J) of the Virginia Emergency Medical Services Regulations Governing Regional Emergency Medical Services Councils, I, Don Barklage, participated as a member of a site review team, tasked with evaluation of the Peninsulas EMS Council on March 16, 2010.

Purpose

The purpose of the review was to provide an objective evaluation of the applicant for designation as a Regional EMS Council, including a review of the submitted application, a visit of the physical location of the applicant, and conducting interviews of applicant organization staff, members of the applicant organization board of directors, and system stakeholders. This evaluation was performed to determine the applicant organization's ability to provide services to the regional EMS system, as outlined in Part VII of Virginia Emergency Medical Services Regulations.

Site Review

On 3/16/10, the review team traveled to the PEMS Council office, located at 5222 George Washington Memorial Hwy, Suite C, Gloucester, VA, 23061. During the site visit, the review team evaluated the applicant in the following areas:

- * Regional EMS Council Designation Requirements
- * Site Visit/Inspection
- * Composition of Regional EMS Council
- * Governing Body of Regional EMS Council
- * Regional Planning
- * Financial Assistance for EMS Services
- * Base Funding of Regional EMS Councils
- * Experience in Development and/or Coordination
- * Accountability for public funds

In addition, interviews were conducted with the applicant organization Executive Director, members of the applicant organization board of directors, financial officers, and system stakeholders, to include:

Jeff Myer, PEMS Executive Director
Louann Miller, PEMS Board member
Kim Harper, PEMS Board member
Michael Player, PEMS Board member
Dr. Cheryl Lawson, Regional OMD
Marsha Weatherwax, Treasurer
Julie Glover, PEMS President
Jerry Andrews, PEMS Assistant Director

Summary and Recommendation

Based on the evaluation of the applicant organization's application for designation, as well as information received during the site visit of the applicant organization, no deficiencies were noted. As such, I recommend that the Peninsulas EMS Council be designated by the Virginia Board of Health as a Regional EMS Council for a term of three (3) years.

Respectfully submitted,
Don Barklage

March 17, 2010

Introduction

As pursuant to 12 VAC 5-31-2340 (H-J) of the Virginia Emergency Medical Services Regulations Governing Regional Emergency Medical Services Councils, I Raphael M. Barishansky, participated as a member of a site review team, tasked with evaluation of the Rappahannock EMS Council on March 9th, 2010.

Purpose

The purpose of the review was to provide an objective evaluation of the applicant for designation as a Regional EMS Council, including a review of the submitted application, a visit of the physical location of the applicant, and conducting interviews of applicant organization staff, members of the applicant organization board of directors, and system stakeholders. This evaluation was performed to determine the applicant organization's ability to provide services to the regional EMS system, as outlined in Part VII of Virginia Emergency Medical Services Regulations.

Site Review

On February 24th, the review team traveled to the Rappahannock EMS Council office, located at 435 Hunter Street, Fredericksburg, VA 22401. During the site visit, the review team evaluated the applicant in the following areas:

- * Regional EMS Council Designation Requirements
- * Site Visit/Inspection
- * Composition of Regional EMS Council
- * Governing Body of Regional EMS Council
- * Regional Planning
- * Financial Assistance for EMS Services
- * Base Funding of Regional EMS Councils
- * Experience in Development and/or Coordination
- * Accountability for public funds

In addition, interviews were conducted with the applicant organization Executive Director, members of the applicant organization board of directors, financial officers, and system stakeholders. These include various staffers of the Rappahannock EMS Council and:

- Tina Skinner – Executive Director
- Kevin Dillard – REMS Board President, and REMS representative on the Governor's Advisory Board
- Dr. David Garth – Regional Medical Director
- Heather Calhoun – REMS Education Program Director
- Wayne Perry – REMS ALS Instructor
- Marianna Bedway – Vice President of Clinical Support – Mary Washington Hospital
- Ray Harvey – Quantico Fire & Emergency Services
- Dr. Joe Saitta – REMS Citizen Board Member
- John Brandup – REMS Board Treasurer
- Debby Loveless – REMS Office Manager

Summary and Recommendation

Based on the evaluation of the applicant organization's application for designation, as well as information received during the site visit of the applicant organization, no deficiencies were noted/the following deficiencies were noted. As such, I recommend that the Rappahannock EMS Council be designated by the Virginia Board of Health as a Regional EMS Council for a term of three (3) years.

Respectfully submitted,
Raphael M. Barishansky

March 18, 2010

Introduction

As pursuant to 12 VAC 5-31-2340 (H-J) of the Virginia Emergency Medical Services Regulations Governing Regional Emergency Medical Services Councils, I, Randy P. Abernathy, participated as a member of a site review team, tasked with evaluation of the Rappahannock Emergency Medical Services Council, Inc. on March 9, 2010.

Purpose

The purpose of the review was to provide an objective evaluation of the applicant for designation as a Regional EMS Council, including a review of the submitted application, a visit of the physical location of the applicant, and conducting interviews of applicant organization staff, members of the applicant organization board of directors, and system stakeholders. This evaluation was performed to determine the applicant organization's ability to provide services to the regional EMS system, as outlined in Part VII of Virginia Emergency Medical Services Regulations.

Site Review

On March 9, 2010, the review team traveled to the Rappahannock Emergency Medical Services Council, Inc. office, located at 435 Hunter St., Fredericksburg, VA 22401. During the site visit, the review team evaluated the applicant in the following areas:

- * Regional EMS Council Designation Requirements
- * Site Visit/Inspection
- * Composition of Regional EMS Council
- * Governing Body of Regional EMS Council
- * Regional Planning
- * Financial Assistance for EMS Services
- * Base Funding of Regional EMS Councils
- * Experience in Development and/or Coordination
- * Accountability for public funds

In addition, interviews were conducted with the applicant organization Executive Director, members of the applicant organization board of directors, financial officers, and system stakeholders, Tina Skinner – Executive Director, Kevin Dillard – REMS Board President, and REMS representative on the Governor's Advisory Board, Dr. David Garth – Regional Medical Director, Heather Calhoun – REMS Education Program Director, Wayne Perry – REMS ALS Instructor, Marianna Bedway – Vice President of Clinical Support – Mary Washington Hospital, Ray Harvey – Quantico Fire & Emergency Services, Dr. Joe Saitta – REMS Citizen Board Member, John Brandup – REMS Board Treasurer, and Debby Loveless – REMS Office Manager.

Summary and Recommendation

Based on the evaluation of the applicant organization's application for designation, as well as information received during the site visit of the applicant organization, no deficiencies were noted/the following deficiencies were noted. As such, **I recommend** that the Rappahannock Emergency Medical Services Council, Inc., be designated by the Virginia Board of Health as a Regional EMS Council for a term of three (3) years.

Respectfully submitted,

Randy P. Abernathy

April 1, 2010

Introduction

As pursuant to 12 VAC 5-31-2340 (H-J) of the Virginia Emergency Medical Services Regulations Governing Regional Emergency Medical Services Councils, I Kenneth G. Cook, Jr., participated as a member of a site review team, tasked with evaluation of the Southwest Virginia Emergency Medical Services Council, Inc. on March 4, 2010.

Purpose

The purpose of the review was to provide an objective evaluation of the applicant for designation as a Regional EMS Council, including a review of the submitted application, a visit of the physical location of the applicant, and conducting interviews of applicant organization staff, members of the applicant organization board of directors, and system stakeholders. This evaluation was performed to determine the applicant organization's ability to provide services to the regional EMS system, as outlined in Part VII of Virginia Emergency Medical Services Regulations.

Site Review

On March 4, 2010, the review team traveled to the Blue Ridge EMS Council office, located at 1000 West Main Street, Abingdon. During the site visit, the review team evaluated the applicant in the following areas:

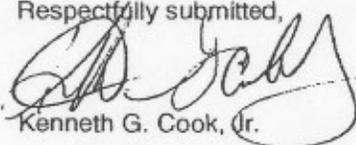
- * Regional EMS Council Designation Requirements
- * Site Visit/Inspection
- * Composition of Regional EMS Council
- * Governing Body of Regional EMS Council
- * Regional Planning
- * Financial Assistance for EMS Services
- * Base Funding of Regional EMS Councils
- * Experience in Development and/or Coordination
- * Accountability for public funds

In addition, interviews were conducted with the applicant organization Executive Director, members of the applicant organization board of directors, financial officers, and system stakeholders. These included Greg Woods, SWVEMS Executive Director; Lonny Gay, SWVEMS Council Board President and representative from Bland County; Pokey Harris, Emergency Management Coordinator for Washington County, past Executive Director of SWVEMS Council, and Governor's Advisory Board representative for the SWVEMS Board of Director; Delilah Long, Lenowisco Planning District Representative to the SWVEMS Board and Board Treasurer; and Kathy White, SWVEMS Administrative Assistant.

Summary and Recommendation

Based on the evaluation of the applicant organization's application for designation, as well as information received during the site visit of the applicant organization, no deficiencies were noted. As such, I recommend that the Southwest Virginia Emergency Medical Services Council, Inc. be designated by the Virginia Board of Health as a Regional EMS Council for a term of three (3) years.

Respectfully submitted,



Kenneth G. Cook, Jr.

March 18, 2010

Introduction

As pursuant to 12 VAC 5-31-2340 (H-J) of the Virginia Emergency Medical Services Regulations Governing Regional Emergency Medical Services Councils, I, Randy P. Abernathy, participated as a member of a site review team, tasked with evaluation of the Southwest Virginia EMS Council, Inc., on March 4, 2010.

Purpose

The purpose of the review was to provide an objective evaluation of the applicant for designation as a Regional EMS Council, including a review of the submitted application, a visit of the physical location of the applicant, and conducting interviews of applicant organization staff, members of the applicant organization board of directors, and system stakeholders. This evaluation was performed to determine the applicant organization's ability to provide services to the regional EMS system, as outlined in Part VII of Virginia Emergency Medical Services Regulations.

Site Review

On March 4, 2010, the review team traveled to the Southwest Virginia Council office, located at 1000 West Main St., Abingdon, VA 24210. During the site visit, the review team evaluated the applicant in the following areas:

- * Regional EMS Council Designation Requirements
- * Site Visit/Inspection
- * Composition of Regional EMS Council
- * Governing Body of Regional EMS Council
- * Regional Planning
- * Financial Assistance for EMS Services
- * Base Funding of Regional EMS Councils
- * Experience in Development and/or Coordination
- * Accountability for public funds

In addition, interviews were conducted with the applicant organization Executive Director, members of the applicant organization board of directors, financial officers, and system stakeholders, Greg Woods – Executive Director, Lonny Gay – SWEMS Board President, and representative from Bland County, Pokey Harris – Emergency Management Coordinator, Washington County – Past Executive Director – SWEMS, and Governor's Advisory Board representative for SWEMS Board of Directors, Delilah Long – Lenowisco Planning District Representative to the SWEMS Board, and SWEMS Board Treasurer, and Kathy White – SWEMS Administrative Assistant

Summary and Recommendation

Based on the evaluation of the applicant organization's application for designation, as well as information received during the site visit of the applicant organization, no deficiencies were noted/the following deficiencies were noted. As such, I **recommend** that the Southwest Virginia EMS Council, Inc., be designated by the Virginia Board of Health as a Regional EMS Council for a term of three (3) years.

Respectfully submitted,

Randy P. Abernathy

March 24, 2010

Introduction

As pursuant to 12 VAC 5-31-2340 (H-J) of the Virginia Emergency Medical Services Regulations Governing Regional Emergency Medical Services Councils, I, Glenn H. Luedtke, participated as a member of a site review team, tasked with evaluation of the Thomas Jefferson EMS Council on March 23, 2010.

Purpose

The purpose of the review was to provide an objective evaluation of the applicant for designation as a Regional EMS Council, including a review of the submitted application, a visit of the physical location of the applicant, and conducting interviews of applicant organization staff, members of the applicant organization board of directors, and system stakeholders. This evaluation was performed to determine the applicant organization's ability to provide services to the regional EMS system, as outlined in Part VII of Virginia Emergency Medical Services Regulations.

Site Review

On March 23, 2010, the review team traveled to the Thomas Jefferson EMS Council office, located at 2205 Fontaine Avenue, Suite 303, Charlottesville, VA 22963. During the site visit, the review team evaluated the applicant in the following areas:

- * Regional EMS Council Designation Requirements
- * Site Visit/Inspection
- * Composition of Regional EMS Council
- * Governing Body of Regional EMS Council
- * Regional Planning
- * Financial Assistance for EMS Services
- * Base Funding of Regional EMS Councils
- * Experience in Development and/or Coordination
- * Accountability for public funds

In addition, interviews were conducted with the applicant organization Executive Director, members of the applicant organization board of directors, financial officers, and system stakeholders. Those interviewed included:

Stephen Rea, Executive Director
Tim Hodge, Member, Board of Directors
Linda Johnson, EMS Specialist/Advisory Board Representative
Bill Wood, Treasurer
Donna Burns, President
Donna Evatt, Program Coordinator, Bookkeeper

Summary and Recommendation

Based on the evaluation of the applicant organization's application for designation, as well as information received during the site visit of the applicant organization, no deficiencies were noted/the following deficiencies were noted. As such, I **recommend** that the Thomas Jefferson EMS Council be designated by the Virginia Board of Health as a Regional EMS Council for a term of three (3) years.

Respectfully submitted,



Glenn H. Luedtke, NREMT/P

March 26, 2010

Introduction

As pursuant to 12 VAC 5-31-2340 (H-J) of the Virginia Emergency Medical Services Regulations Governing Regional Emergency Medical Services Councils, I (Bill Bullock), participated as a member of a site review team, tasked with evaluation of the Thomas Jefferson Regional Council on March 23, 2010.

Purpose

The purpose of the review was to provide an objective evaluation of the applicant for designation as a Regional EMS Council, including a review of the submitted application, a visit of the physical location of the applicant, and conducting interviews of applicant organization staff, members of the applicant organization board of directors, and system stakeholders. This evaluation was performed to determine the applicant organization's ability to provide services to the regional EMS system, as outlined in Part VII of Virginia Emergency Medical Services Regulations.

Site Review

On March 23, the review team traveled to the Thomas Jefferson Regional Council office, located in Charlottesville, VA. During the site visit, the review team evaluated the applicant in the following areas:

- * Regional EMS Council Designation Requirements
- * Site Visit/Inspection
- * Composition of Regional EMS Council
- * Governing Body of Regional EMS Council
- * Regional Planning
- * Financial Assistance for EMS Services
- * Base Funding of Regional EMS Councils
- * Experience in Development and/or Coordination
- * Accountability for public funds

In addition, interviews were conducted with the applicant organization Executive Director, members of the applicant organization board of directors, financial officers, and system stakeholders. Stephen Rea, Executive Director, Tim Hodge, board member, Bill Wood, treasurer, Donna Evatt, office manager, Linda Johnson, EMS specialist and EMS Advisory Board representative, and Donna Burns, president, participated in the interviews and review.

Summary and Recommendation

Based on the evaluation of the applicant organization's application for designation, as well as information received during the site visit of the applicant organization, no deficiencies were noted/the following deficiencies were noted. As such, **I recommend** that the Thomas Jefferson EMS Council be designated by the Virginia Board of Health as a Regional EMS Council for a term of three (3) years.

Respectfully submitted,

Bill Bullock

March 31, 2010

Introduction

As pursuant to 12 VAC 5-31-2340 (H-J) of the Virginia Emergency Medical Services Regulations Governing Regional Emergency Medical Services Councils, I **Robert A. Brown**, participated as a member of a site review team, tasked with evaluation of the **Tidewater EMS Council** on **February 24, 2010**.

Purpose

The purpose of the review was to provide an objective evaluation of the applicant for designation as a Regional EMS Council, including a review of the submitted application, a visit of the physical location of the applicant, and conducting interviews of applicant organization staff, members of the applicant organization board of directors, and system stakeholders. This evaluation was performed to determine the applicant organization's ability to provide services to the regional EMS system, as outlined in Part VII of Virginia Emergency Medical Services Regulations.

Site Review

On 2/24/2010 the review team traveled to the Tidewater EMS Council office, located at 6353 Center Drive, Norfolk, Virginia. During the site visit, the review team evaluated the applicant in the following areas:

- * Regional EMS Council Designation Requirements
- * Site Visit/Inspection
- * Composition of Regional EMS Council
- * Governing Body of Regional EMS Council
- * Regional Planning
- * Financial Assistance for EMS Services
- * Base Funding of Regional EMS Councils
- * Experience in Development and/or Coordination
- * Accountability for public funds

In addition, interviews were conducted with the applicant organization members of the applicant organization board of directors, financial officers, and system stakeholders – including:

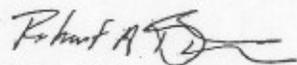
Jim Chandler, TEMS Executive Director
Kent Weber, TEMS Treasurer, and past Executive Director
Bruce Edwards, Chief of EMS, City of Virginia Beach, and TEMS BOD Member
Vince Holt, Fire Chief, City of Franklin, Stakeholder
Robert Hundley, EMS Chief, Nansemond-Suffolk Rescue Squad, and Vice President of TEMS BOD
Several office program staff members

Summary and Recommendation

Based on the evaluation of the applicant organization's application for designation, as well as information received during the site visit of the applicant organization, no deficiencies were noted. As such, I recommend that the Tidewater EMS Council be designated by the Virginia Board of Health as a Regional EMS Council for a term of

three (3) years.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Robert A. Brown", with a stylized flourish extending to the right.

Robert A. Brown

Introduction

As pursuant to 12 VAC 5-31-2340 (H-J) of the Virginia Emergency Medical Services Regulations Governing Regional Emergency Medical Services Councils, I Raphael M. Barishansky, participated as a member of a site review team, tasked with evaluation of the Tidewater EMS Council on February 24th, 2010.

Purpose

The purpose of the review was to provide an objective evaluation of the applicant for designation as a Regional EMS Council, including a review of the submitted application, a visit of the physical location of the applicant, and conducting interviews of applicant organization staff, members of the applicant organization board of directors, and system stakeholders. This evaluation was performed to determine the applicant organization's ability to provide services to the regional EMS system, as outlined in Part VII of Virginia Emergency Medical Services Regulations.

Site Review

On February 24th, the review team traveled to the Tidewater EMS Council office, located at 6353 Center Drive Suite 101, Norfolk, VA 23502. During the site visit, the review team evaluated the applicant in the following areas:

- * Regional EMS Council Designation Requirements
- * Site Visit/Inspection
- * Composition of Regional EMS Council
- * Governing Body of Regional EMS Council
- * Regional Planning
- * Financial Assistance for EMS Services
- * Base Funding of Regional EMS Councils
- * Experience in Development and/or Coordination
- * Accountability for public funds

In addition, interviews were conducted with the applicant organization Executive Director, members of the applicant organization board of directors, financial officers, and system stakeholders. These include various staffers of the Tidewater EMS Council and:

- Jim Chandler – TEMS Executive Director
- Kent Weber – TEMS Treasurer, and past Executive Director
- Bruce Edwards, Chief of Virginia Beach EMS, and TEMS Board Member.
- Vince Holt – Chief of Franklin, VA Fire and Rescue – System Stakeholder
- Robert Hundley – Chief of Nansemond-Suffolk Rescue Squad and Vice-President of TEMS Board of Directors

Summary and Recommendation

Based on the evaluation of the applicant organization's application for designation, as well as information received during the site visit of the applicant organization, no deficiencies were noted/the following deficiencies were noted. As such, I recommend that the Tidewater be designated by the Virginia Board of Health as a Regional EMS Council for a term of three (3) years.

Respectfully submitted,
Raphael M. Barishansky

February 18, 2010

Introduction

As pursuant to 12 VAC 5-31-2340 (H-J) of the Virginia Emergency Medical Services Regulations Governing Regional Emergency Medical Services Councils, I, Glenn H. Luedtke, participated as a member of a site review team, tasked with evaluation of the Western Virginia EMS Council on February 17, 2010.

Purpose

The purpose of the review was to provide an objective evaluation of the applicant for designation as a Regional EMS Council, including a review of the submitted application, a visit of the physical location of the applicant, and conducting interviews of applicant organization staff, members of the applicant organization board of directors, and system stakeholders. This evaluation was performed to determine the applicant organization's ability to provide services to the regional EMS system, as outlined in Part VII of Virginia Emergency Medical Services Regulations.

Site Review

On February 17, 2010, the review team traveled to the Western Virginia EMS Council office, located at 1944 Peters Creek Road, Roanoke, VA 24017. During the site visit, the review team evaluated the applicant in the following areas:

- * Regional EMS Council Designation Requirements
- * Site Visit/Inspection
- * Composition of Regional EMS Council
- * Governing Body of Regional EMS Council
- * Regional Planning
- * Financial Assistance for EMS Services
- * Base Funding of Regional EMS Councils
- * Experience in Development and/or Coordination
- * Accountability for public funds

In addition, interviews were conducted with the applicant organization Executive Director, members of the applicant organization board of directors, financial officers, and system stakeholders. Those interviewed included:

Robert Logan, Executive Director, WVEMS
Dr. Charles Lane, WVEMS Regional Medical Director
Ford S. Wirt, Floyd County EMS & President, WVEMS Board of Directors
Steve Simon, Roanoke County Fire & Rescue, member WVEMS Board of Directors
Steve Davis, Virginia Department of Health, member WVEMS Board of Directors
Steve Allen, Patrick County EMS, member WVEMS Board of Directors
Mary Christian, Business Manager, WVEMS

Summary and Recommendation

Based on the evaluation of the applicant organization's application for designation, as well as information received during the site visit of the applicant organization, no deficiencies were noted/the following deficiencies were noted. As such, I **recommend** that the Western Virginia EMS Council be designated by the Virginia Board of Health as a Regional EMS Council for a term of three (3) years.

Respectfully submitted,



Glenn H. Luedtke, NREMT/P

member of a site review team tasked with evaluation of the Western Virginia EMS Council on February 17, 2010.

Purpose

The purpose of the review was to provide an objective evaluation of the applicant for designation as a Regional EMS Council, including a review of the submitted application, a visit of the physical location of the applicant, and conducting interviews of applicant organization staff, members of the applicant organization board of directors, and system stakeholders. This evaluation was performed to determine the applicant organization's ability to provide services to the regional EMS system, as outlined in Part VII of Virginia Emergency Medical Services Regulations.

Site Review

On February 17, 2010, the review team traveled to the Western Virginia EMS Council office, located at 1944 Peters Creek Road, Roanoke, VA 24017. During the site visit, the review team evaluated the applicant in the following areas:

- Regional EMS Council Designation Requirements
- Site Visit/Inspection
- Composition of Regional EMS Council
- Governing Body of Regional EMS Council
- Regional Planning
- Financial Assistance for EMS Services
- Base Funding of Regional EMS Councils
- Experience in Development and/or Coordination
- Accountability for Public Funds

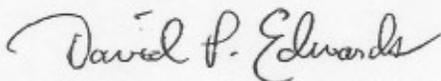
In addition, interviews were conducted with the applicant organization Executive Director, members of the applicant organization board of directors, financial officers, and system stakeholders. A partial list of those interviewed includes:

- Rob Logan, WVEMS Executive Director
- Dr. Charles Lane, WVEMS Regional Medical Director
- Ford S. Wirt – Floyd County EMS and President, WVEMS Board of Directors
- Steve Simon – Roanoke County Fire and Rescue, and member of WVEMS Board of Directors
- Steve Davis - Virginia Department of Health, and member of WVEMS Board of Directors
- Steve Allen - Patrick County EMS, and member of WVEMS Board of Directors
- Mary Christian - WVEMS Business Manager

Summary and Recommendation

Based on the evaluation of the applicant organization's application for designation, as well as information received during the site visit of the applicant organization, no deficiencies were noted. As such, I recommend that the Western Virginia EMS Council be designated by the Virginia Board of Health as a Regional EMS Council for a term of three (3) years.

Respectfully submitted,



David P. Edwards, MBA

Code of Virginia 32.1-111.3 Statewide emergency medical care system

States: *“The Board of Health shall also develop and maintain as a component of the Emergency Medical Services Plan a statewide prehospital and interhospital Stroke Triage Plan designed to promote rapid access for stroke patients to appropriate, organized stroke care through the publication and regular updating of information on resources for stroke care and generally accepted criteria for stroke triage and appropriate transfer.”*

Senate Bill 344 and House Bill 479 of the 2008 General Assembly amended § 32.1-111.3 to require the Virginia Department of Health (VDH), Office of Emergency Medical Services (OEMS) to include a Statewide Prehospital and Interhospital Stroke Triage Plan (Stroke Triage Plan) as a component of the Emergency Medical Services Plan. The Virginia Stroke Systems Task Force (VSSTF) developed and approved the enclosed Stroke Triage Plan. The Stroke Triage Plan was then submitted to the Emergency Medical Services Advisory Board through its Medical Direction sub-committee and received unanimous approval with many positive comments of support.

VDH/OEMS requests the State Board of Health approve the Stroke Triage Plan as presented as a component of the EMS Plan.

Complete Code language:

C. The Board of Health shall also develop and maintain as a component of the Emergency Medical Services Plan a statewide prehospital and interhospital Stroke Triage Plan designed to promote rapid access for stroke patients to appropriate, organized stroke care through the publication and regular updating of information on resources for stroke care and generally accepted criteria for stroke triage and appropriate transfer. The Stroke Triage Plan shall include:

1. A strategy for maintaining the statewide Stroke Triage Plan through formal regional stroke triage plans that incorporate each region's geographic variations and stroke care capabilities and resources, including hospitals designated as “primary stroke centers” through certification by the Joint Commission ~~on Health Care~~ or a comparable process consistent with the recommendations of the Brain Attack Coalition. The regional stroke triage plans shall be reviewed triennially.

2. A uniform set of proposed criteria for prehospital and interhospital triage and transport of stroke patients developed by the Emergency Medical Services Advisory Board, in consultation with the American Stroke Association, the Virginia College of Emergency Physicians, the Virginia Hospital and Healthcare Association, and prehospital care providers. The Board of Health may revise such criteria from time to time to incorporate accepted changes in medical practice or to respond to needs indicated by analyses of data on patient outcomes. Such criteria shall be used as a guide and resource for health care providers and are not intended to establish, in and of themselves, standards of care or to abrogate the requirements of § [8.01-581.20](#). A decision by a health care provider to deviate from the criteria shall not constitute negligence per se.



Virginia Office of Emergency Medical Services
Division of Trauma/Critical Care
Prehospital and Interhospital
State Stroke Triage Plan



DRAFT

Virginia Department of Health
Office of Emergency Medical Services
1041 Technology Park Drive
Glen Allen, Virginia 23059
(804) 612-3950
www.vdh.virginia.gov/oems

Index

Executive Summary	2
Field Stroke Triage Decision Scheme	3
Guidance Documents	4
Acute Stroke Patients	6
Designated Stroke Centers	7
Interhospital Triage Considerations	8
Stroke Triage Quality Monitoring	9
Stroke Related Resources	10

Executive Summary

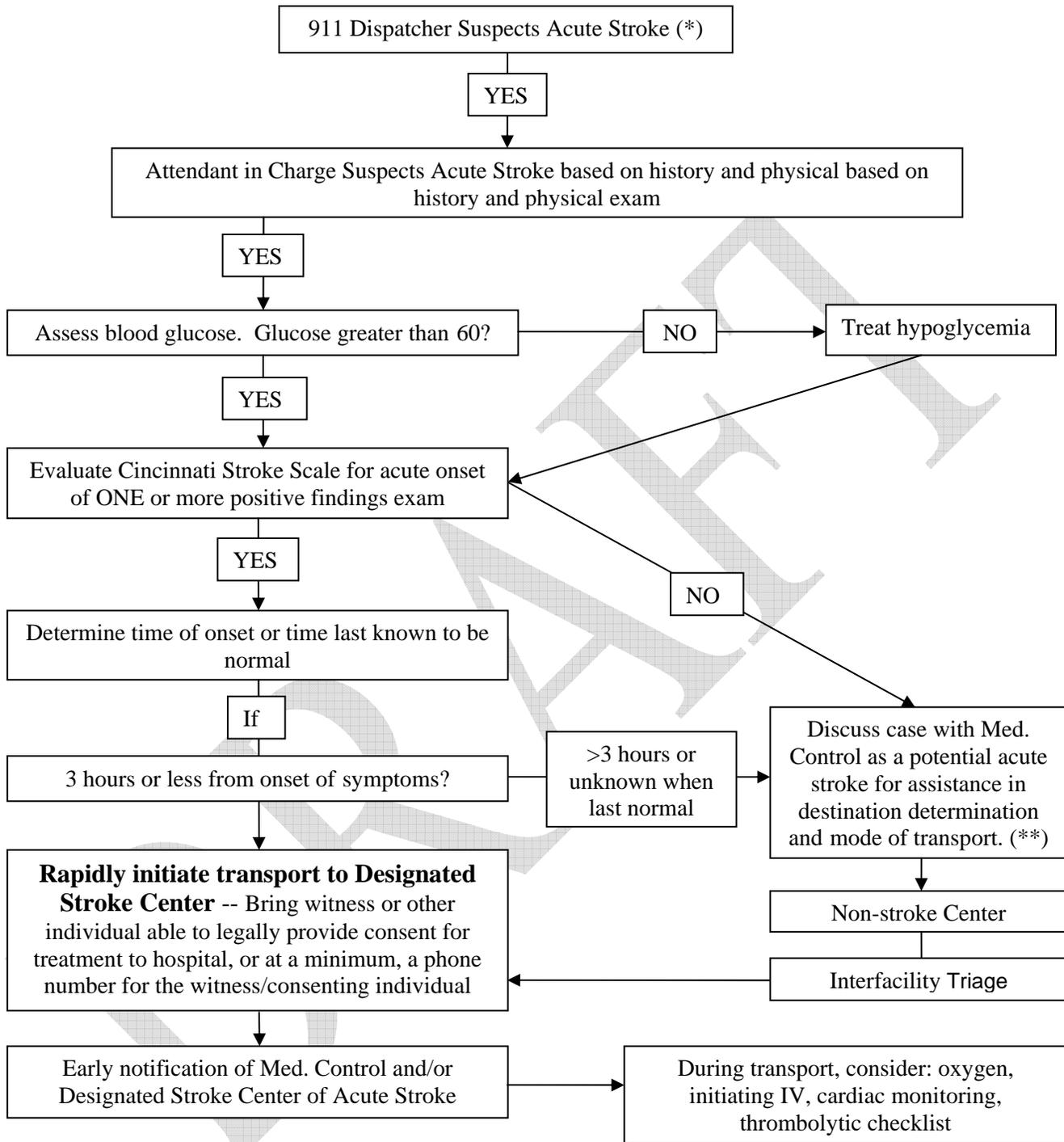
Under the *Code of Virginia* § 32.1-111.3, The Office of Emergency Medical Services acting on behalf of the Virginia Department of Health has been charged with the responsibility of maintaining a Statewide Stroke Triage Plan. The Statewide Stroke Triage Plan establishes a strategy through formal regional stroke triage plans that incorporate each region's geographic variations and acute stroke care capabilities and resources, including hospitals designated as "Primary Stroke Centers" through certification by the Joint Commission or a comparable process consistent with the recommendations of the Brain Attack Coalition. The Statewide Stroke Triage Plan is to include guidelines for prehospital patient care as well as inter-hospital patient transfers.

The purpose of the Statewide Stroke Triage Plan is to establish a uniform set of criteria for the prehospital and inter-hospital triage and transport of acute stroke patients. Formal regional or local stroke triage plans may augment the State Stroke Triage Plan to acknowledge and address variations in each region's EMS and hospital resources. This State Stroke Triage Plan, and the related regional plans, addresses patients experiencing an "acute stroke." For the purposes of this document, "acute stroke" is defined as any patient suspected of having an acute cerebral ischemic event or stroke with the onset of any one symptom within a three hour period. The primary focus of the plan is to provide guidelines to facilitate the early recognition of patients suffering from acute stroke and to expedite their transport to a center capable of providing definitive care within an appropriate time window.

It is very important to note that because of the continuing evolution of scientific evidence indicating successful management of acute stroke greater than the three-hour time window, *real-time contact with regional or local medical direction should be freely used to discuss individual cases outside the three-hour window.* In selected cases it may be determined that expeditious transfer or transport directly to a Designated Stroke Center may be beneficial for a specific patient.

Some selected acute stroke types may benefit from intervention *up to 24 hours* following symptom onset. Regardless of time of onset the sooner an acute stroke is treated, the better the potential outcome ("Time is Brain"). Based on an individual patient's time of onset and following discussion with Medical Command, consider what mode of transport would be most appropriate to transport the patient expeditiously to a Designated Stroke Center.

Field Stroke Triage Decision Scheme



(*) See Appendix A for guidance regarding dispatch protocols

(**) If time from symptom onset is more than 3 hours, discuss case with Medical Command as a potential acute stroke for destination determination. Recall that patients with specific acute stroke types may benefit from intervention up to 24 hours, although the sooner an acute stroke is treated, the better the potential outcome. Based on patient time of onset and discussion with Medical Command, consider whether use of helicopter EMS will offer potential benefit to the patient, either in time to Designated Stroke Center, or for critical care management expertise. EMS does not determine whether a patient is excluded from any or all therapeutic options. Final decisions regarding patient eligibility for any given intervention will be determined by the receiving physician(s).

Guidance Documents

Cincinnati Prehospital Stroke Scale (CPSS)

All patients suspected of having an acute stroke should undergo a formal screening algorithm such as the CPSS. Use of stroke algorithms has been shown to improve identification of acute strokes by EMS providers up to as much as 30 percent. The results of the CPSS should be noted on the prehospital medical record. ANY abnormal (positive) finding which is suspected or known to be acute in onset is considered an indicator of potential acute stroke.

F-(face)	FACIAL DROOP: Have patient smile or show teeth. (Look for asymmetry) Normal: Both sides of the face move equally or not at all. Abnormal: One side of the patient's face droops.
A-(arm)	MOTOR WEAKNESS: Arm drift (close eyes, extend arms, palms up) Normal: Remain extended equally, drifts equally, or does not move at all. Abnormal: One arm drifts down when compared with the other.
S-(speech)	"You can't teach an old dog new tricks" (repeat phrase) Normal: Phrase is repeated clearly and correctly. Abnormal: Words are slurred (dysarthria) or abnormal (aphasia) or none.
T-Time	Time of SYMPTOM ONSET: _____

* Results of the F.A.S.T. should be included on the patient's prehospital medical record

Local/Regional Protocols

Local and regional prehospital patient care protocols for acute stroke should include:

- An initial/primary assessment
- Focused assessment including:
 - Blood glucose level (if authorized to perform skill)
 - Documented time of onset or time last known to be normal
 - Cincinnati Prehospital Stroke Scale
 - SAMPLE history to include mention of acute stroke mimics (i.e. seizures, migraines, hypo/hyper glycemia and others as deemed appropriate)
 - SAMPLE history to include potential thrombolytic exclusions (i.e. pregnancy, seizure at onset, terminal illness and others as deemed appropriate as on check sheet)
- Appropriate treatment for hypoglycemia. IV access and cardiac monitoring if available, reassessment of neurologic exam and stroke scale. Contact with medical command and/or receiving hospital to advise of potential acute stroke patient.
- Transport criteria that direct acute stroke patients with stable airway and without hypotension to Designated Stroke Centers if time of onset is within 3 hours of EMS assessment. If symptoms are acute, but over the 3 hour window, real-time contact with regional or local medical direction should be freely used to discuss the individual patient case to determine whether transport directly to a Designated Stroke Center would be of benefit to that specific patient.
- EMS Regions incorporate specific strategies appropriate to their area to assure that acute stroke patients evaluated more than 3 hours from symptom onset can still potentially access specialty resources for acute stroke intervention and management. Examples may include partnerships with acute stroke specialists at the Designated Stroke Center who can provide input on specific patient cases in a timely manner to either the medical command physician or EMS directly.

-
- For regions wishing to include a thrombolytic checklist, see Appendix A for Sample Acute Stroke Thrombolytic Checklist. EMS does not determine whether a patient is excluded from any or all therapeutic options. Final decisions regarding patient eligibility for any given intervention will be determined by the receiving physician(s).

DRAFT

Acute Stroke Patient Transport Considerations

MODE OF TRANSPORTATION: EMS Patient Care Protocols should address mode of transport considerations. Each jurisdiction is unique in its availability of EMS and acute stroke care resources. Consideration should be given to the hospital(s) that is/are available in the region and the resources that they have available to acute stroke patients when developing plans and protocols, as well as EMS system capacity.

RAPID TRANSPORTATION: Because stroke is a time-critical illness, time is of the essence, and EMS should rapidly initiate transport once acute stroke is suspected. Consideration should also be given to prehospital resources including use of helicopter EMS (HEMS) available at the time of the incident, and other conditions such as transport time and weather conditions. Use of HEMS can facilitate acute stroke patients reaching Designated Stroke Centers in a timeframe that allows for acute treatment interventions. **The likelihood of benefit of acute stroke therapy decreases with time, but there are several therapy options which offer definite benefit outside the standard 3 hour window.** Interventions may include any or all of the following: specialty physician or ICU capability, medical therapy (such as tPA or new experimental therapies), radiologic evaluation and procedures (MRI, intraarterial thrombolytics, mechanical thrombectomy), or life-saving emergent surgery (hemicraniectomy, large artery thrombus extraction).

Field transports of acute stroke patients by helicopter as defined in this plan:

1. should significantly lessen the time from scene to a Designated Stroke Center compared to ground transport
2. should be utilized to achieve the goal of having acute stroke patients expeditiously transported to a Designated Stroke Center, ideally within three hours of symptom onset.
3. should only be to non-stroke centers in very unusual circumstances, following consultation with local or regional medical command. If a HEMS resource is used, the patient should be transported directly to a Designated Stroke Center.

Interhospital Triage Criteria

When acute stroke patients cannot be transported directly to a Designated Stroke Center in a timely manner, ideally within the three-hour window, consideration may be given to transport to a closer hospital. Various hospitals meet many of the components of a Designated Stroke Center based on national survey results and would be the next logical choice. The closest hospital may not be the most appropriate hospital. Resource information via self-reported data on the level of acute stroke care provided by hospitals which are not Designated Stroke Centers is available at <http://virginiastrokesystems.org/>.

These considerations should be addressed specifically within the regional plan in a manner consistent with this state stroke plan, and should be updated as hospital resource availability changes. Individual EMS regions are best qualified to assess the capabilities of their EMS and hospital stroke management resources and provide direction to EMS agencies within their regional guidelines. The default destination for acute stroke patients should be a Designated Stroke Center. Regional plans should provide guidance for situations where patients would be transported to non-stroke centers, as well as specific guidance for use of HEMS for transport to Designated Stroke Centers.

Non-stroke center hospitals should have transfer guidelines and agreements in place for the expeditious and appropriate management of acute strokes when the care required exceeds their capabilities. This is especially critical for transfer of patients following thrombolysis since specific protocols must be followed to diminish the risk of cerebral or systemic hemorrhagic complications.

Stroke Triage Quality Monitoring

The Virginia Office of EMS, acting on behalf of the Commissioner of Health, will report aggregate acute stroke triage findings on an intermittent basis, but no less than annually, to assist EMS systems and the Virginia Stroke Systems Task Force improve the local, regional and Statewide Stroke Triage Plans. A de-identified version of the report will be available to the public and will include, minimally, as defined in the statewide plan, the frequency of (i) over- and undertriage to Designated Stroke Centers in comparison to the total number of acute stroke patients delivered to hospitals and (ii) interfacility transfers that do not meet criteria for transfer to Designated Stroke Centers (iii) HEMS utilization. The program reports shall be used as a guide and resource for health care providers, EMS agencies, EMS regions, the Virginia Office of EMS, and the Virginia Stroke Systems Task Force. Additional specific data points to be collected within the EMS prehospital patient care report (written or electronic) will be established collaboratively between OEMS and VSSTF. Information to be contained in routine reports on both system and patient-level indicators and outcomes will be developed by OEMS in partnership with VSSTF to guide further system development in a patient focused way.

Hospitals, EMS Regions, and EMS agencies are encouraged to utilize their performance improvement programs to perform quality monitoring and improve the delivery of acute stroke care within their regions.

Annual reporting on the State Stroke Triage Plan will typically be provided through the OEMS, Division of Trauma/Critical Care's "Trends" report and on an ad-hoc basis in response to appropriate inquiries.

Stroke Related Resources

Virginia Stroke System Web page: <http://virginiastrokesystems.org/>

Virginia Office of EMS Stroke Web page: <http://www.vdh.virginia.gov/OEMS/Trauma/Stroke.htm>

Joint Commission: <http://www.jointcommission.org/CertificationPrograms/PrimaryStrokeCenters/>



COMMONWEALTH of VIRGINIA

Karen Remley, MD, MBA, FAAP
State Health Commissioner

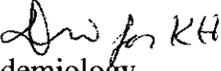
Department of Health
P O BOX 2448
RICHMOND, VA 23218

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

April 5, 2010

Memorandum

To: State Board of Health

From: Keri Hall, M.D., M.S. 
Director, Office of Epidemiology

Subject: Proposed Amendment to the *Regulations for Disease Reporting and Control*

Enclosed is a proposed amendment to the *Regulations for Disease Reporting and Control* for your review and discussion at the April 23, 2010 meeting of the Board of Health. The amendment would expand the reporting requirements for healthcare-associated infections (HAI). It has been developed through many meetings with representatives of the affected community, including hospital infection preventionists, the HAI Steering Committee (composed of partner organizations working closely with the Virginia Department of Health (VDH) on this topic), and a larger VDH/Virginia Hospital and Healthcare Association HAI Advisory Committee. The proposal is to require hospitals to report central line-associated bloodstream infections in two wards outside intensive care, *Clostridium difficile* infections, and Surgical Care Improvement Project measures pertaining to hip and knee replacement and coronary artery bypass graft surgeries.

The comment period for the Notice of Intended Regulatory Action ended on November 25, 2009. No comments were received. The regulation has been reviewed and approved by both Robin Kurz, of the Office of the Attorney General, and Dr. Jim Burns, Deputy Commissioner for Public Health. I look forward to discussing this regulatory action with you at the upcoming meeting.

If the Board approves these regulations, the proposed regulation will be posted to the Virginia Town Hall for Executive Branch review prior to publication in the *Virginia Register*. The proposed amendment will be open for a sixty day comment period after publication.



Proposed Regulation Agency Background Document

Agency name	Department of Health (State Board of)
Virginia Administrative Code (VAC) citation	12 VAC 5 -90
Regulation title	Disease Reporting and Control
Action title	Expanded Requirements for Reporting Healthcare-Associated Infections
Date this document prepared	April 1, 2010

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

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

The Agency is proposing to require hospitals to report three additional measures associated with healthcare-associated infections. The measures would include central line-associated bloodstream infections outside of intensive care units, *Clostridium difficile* infections that meet the CDC definition of a laboratory-identified event, and Surgical Care Improvement Process measures pertaining to hip arthroplasty, knee arthroplasty, and coronary artery bypass graft surgeries.

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.

CDC – Centers for Disease Control and Prevention
CLABSI – central line-associated bloodstream infection
HAI – healthcare-associated infection
NHSN – National Healthcare Safety Network

SCIP – Surgical Care Improvement Process

Legal basis

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

The *Code of Virginia*, § 32.1-35.1, requires acute care hospitals to report infection information to the CDC's National Healthcare Safety Network (NHSN) and for the State Board of Health to define infections to be reported and the patient populations to be included.

Purpose

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

The proposed regulatory action identifies additional measures related to healthcare-associated infections that acute care hospitals shall report to the Centers for Disease Control and Prevention (CDC) and the Virginia Department of Health (VDH). The amendment to the *Regulations for Disease Reporting and Control* is proposed in response to increased interest in measuring and improving patient safety in hospitals and reducing the occurrence of healthcare-associated infections.

Substance

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

The Agency proposes to amend 12 VAC 5-90-370, pertaining to the Reporting of Healthcare-associated Infections. The amendment would involve moving the definitions to 12 VAC 5-90-10 and adding reporting requirements for hospitals. The specific additional reporting requirements proposed are as follows:

- Central line-associated bloodstream infections in one adult inpatient medical ward and one adult inpatient surgical ward. Wards selected should be those with the longest length of stay during the previous calendar year, excluding cardiology, obstetrics, psychiatry, hospice, and step-down units. Data shall include the number of central-line days in each population at risk.
- *Clostridium difficile* infection, laboratory-identified events on inpatient units facility-wide, with the exceptions recommended by CDC protocol. Data shall include patient days.
- Acute care hospitals shall report to the department quarterly, within one month of the close of the calendar year quarter, aggregate counts of the Surgical Care Improvement

Project (SCIP) Core Measures pertaining to the following surgical procedures: hip arthroplasty, knee arthroplasty, and coronary artery bypass graft. Data shall be collected in accordance with the Specification Manual for National Hospital Inpatient Quality Measures and shall include counts of the patient population and the applicable SCIP measures for each of the three surgical procedures. SCIP measures track compliance with procedures that have been shown to reduce the risk of infection following surgeries.

Issues

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

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

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

As evidenced by a national movement, the public is very interested in increased reporting of HAIs and other measures of the quality of medical care. The advantage to the citizens is that more information would be available about hospital quality. The disadvantage to the regulated community (hospitals) is increased workload that would be created.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal, which are 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.

No federal reporting requirement for HAI reporting currently exists.

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 would be particularly affected.

Public participation

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

In addition to any other comments, the board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code 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 written comments may do so via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail, email or fax to Diane Woolard, PhD, MPH, Director, Division of Surveillance and Investigation, Virginia Department of Health, P.O. Box 2448, Suite 516E, Richmond, VA 23218; telephone (804) 864-8141; fax (804) 864-8139; email diane.woolard@vdh.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last date of the public comment period.

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, and (b) a delineation of one-time versus on-going expenditures.</p>	<p>The Agency has federal funds to support this effort through December 2011. After that, the requirement could place a financial hardship on the Agency. Any available opportunities for funding to support the necessary staff resources will be pursued. If none are available, existing staff will be forced to absorb the responsibilities.</p>
<p>Projected cost of the new regulations or changes to existing regulations on localities.</p>	<p>No cost to localities is anticipated.</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>Hospitals will be impacted by the change to the existing regulation.</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 (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>Approximately 90 acute care hospitals will be impacted. Half of those have fewer than 200 beds.</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 do include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of</p>	<p>Hospital staff resources, particularly infection preventionists and performance improvement professionals, will be needed to complete the required tasks.</p>

<p>real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.</p>	
<p>Beneficial impact the regulation is designed to produce.</p>	<p>Increased information for healthcare consumers on hospital infections and quality performance.</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.

The Agency is not aware of any viable alternatives to the proposed amendment. The regulations are mandated per the *Code of Virginia*. The health department believes the regulations provide the best solution in response to the law. Regulated constituents were involved in the development of the proposed amendment.

Regulatory flexibility analysis

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

Multiple meetings and discussions have been held involving the Agency, hospitals of differing bedsizes, and other health-oriented organizations during the past year to develop the contents of this regulatory amendment. Quarterly reporting is being required when monthly reporting is recommended by CDC for some HAI measures. An existing reporting system that most hospitals already use will be used to report the additional infections. The measures being proposed have been discussed with the regulated community and have been determined to be important measures for the Agency to track.

Public comment

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

Commenter	Comment	Agency response
-----------	---------	-----------------

	No comments were received.	
--	----------------------------	--

Family impact

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

The amendment is not expected to have any impact on the family.

Detail of changes

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

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

For changes to existing regulations, use this chart:

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, rationale, and consequences
12VAC5-90-370.A.	12VAC5-90-10	Definitions pertaining to healthcare-associated infections are included in the HAI section of the Regulations	Definitions pertaining to healthcare-associated infections are being moved to the definitions section of the Regulations. New definitions have been added for C. difficile infections and SCIP measures.
12VAC5-90-370.B.	12VAC5-90-370.A.	Hospitals must report central line-associated bloodstream infections (CLABSI) in adult intensive care units	In addition, hospitals would be required to report CLABSI outside intensive care (in one adult medical ward and one adult surgical ward), <i>Clostridium difficile</i> infections identified by the laboratory, and Surgical Care Improvement Project measures pertaining to three surgeries: hip arthroplasty, knee arthroplasty, and coronary artery bypass graft.

Project 2109 - PROPOSED

DEPARTMENT OF HEALTH

CH 90 - Expanded Requirements for Reporting Healthcare-Associated Infections

Part I

Definitions

12VAC5-90-10. Definitions.

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

"Acute care hospital" means a hospital as defined in § 32.1-123 of the Code of Virginia that provides medical treatment for patients having an acute illness or injury or recovering from surgery.

"Adult" means a person 18 years of age or more.

"Affected area" means any part or the whole of the Commonwealth that has been identified as where individuals who are known to have been exposed to or infected with, or who are reasonably suspected to have been exposed to or infected with, a communicable disease of public health threat reside or may be located.

"Board" means the State Board of Health.

"Cancer" means all carcinomas, sarcomas, melanomas, leukemias, and lymphomas excluding localized basal and squamous cell carcinomas of the skin, except for lesions of the mucous membranes.

"Central line-associated bloodstream infection" means a primary bloodstream infection identified by laboratory tests, with or without clinical signs or symptoms, in a patient with a central line device, and meeting the current Centers for Disease Control

and Prevention (CDC) surveillance definition for laboratory-confirmed primary bloodstream infection.

"Central line device" means a vascular infusion device that terminates at or close to the heart or in one of the greater vessels. The following are considered great vessels for the purpose of reporting central line infections and counting central line days: aorta, pulmonary artery, superior vena cava, inferior vena cava, brachiocephalic veins, internal jugular veins, subclavian veins, external iliac veins, and common femoral veins.

"Child care center" means a child day center, child day center system, child day program, family day home, family day system, or registered family day home as defined by § 63.2-100 of the Code of Virginia, or a similar place providing day care of children by such other name as may be applied.

"Clinic" means any facility, freestanding or associated with a hospital, that provides preventive, diagnostic, therapeutic, rehabilitative, or palliative care or services to outpatients.

"Clostridium difficile infection, laboratory-identified event" means laboratory testing on unformed stool that yields a positive result for Clostridium difficile toxin A or B or a toxin-producing Clostridium difficile organism detected in the stool sample by culture or other laboratory means, with duplicate reports on a patient ruled out according to CDC definitions.

"Commissioner" means the State Health Commissioner or his duly designated officer or agent, unless stated in a provision of these regulations that it applies to the State Health Commissioner in his sole discretion.

"Communicable disease" means an illness due to an infectious agent or its toxic products which is transmitted, directly or indirectly, to a susceptible host from an infected

person, animal, or arthropod or through the agency of an intermediate host or a vector or through the inanimate environment.

"Communicable disease of public health significance" means an illness caused by a specific or suspected infectious agent that may be transmitted directly or indirectly from one individual to another. This includes but is not limited to infections caused by human immunodeficiency viruses, bloodborne pathogens, and tubercle bacillus. The State Health Commissioner may determine that diseases caused by other pathogens constitute communicable diseases of public health significance.

"Communicable disease of public health threat" means an illness of public health significance, as determined by the State Health Commissioner in accordance with these regulations, caused by a specific or suspected infectious agent that may be reasonably expected or is known to be readily transmitted directly or indirectly from one individual to another and has been found to create a risk of death or significant injury or impairment; this definition shall not, however, be construed to include human immunodeficiency viruses or the tubercle bacilli, unless used as a bioterrorism weapon.

"Companion animal" means any domestic or feral dog, domestic or feral cat, nonhuman primate, guinea pig, hamster, rabbit not raised for human food or fiber, exotic or native animal, reptile, exotic or native bird, or any feral animal or any animal under the care, custody, or ownership of a person or any animal that is bought, sold, traded, or bartered by any person. Agricultural animals, game species, or any animals regulated under federal law as research animals shall not be considered companion animals for the purpose of this regulation.

"Condition" means any adverse health event, such as a disease, an infection, a syndrome, or as indicated by a procedure (including but not limited to the results of a

physical exam, laboratory test, or imaging interpretation) suggesting that an exposure of public health importance has occurred.

"Contact" means a person or animal known to have been in such association with an infected person or animal as to have had an opportunity of acquiring the infection.

"Contact tracing" means the process by which an infected person or health department employee notifies others that they may have been exposed to the infected person in a manner known to transmit the infectious agent in question.

"Decontamination" means the use of physical or chemical means to remove, inactivate, or destroy hazardous substances or organisms from a person, surface, or item to the point that such substances or organisms are no longer capable of causing adverse health effects and the surface or item is rendered safe for handling, use, or disposal.

"Department" means the State Department of Health.

"Designee" or "designated officer or agent" means any person, or group of persons, designated by the State Health Commissioner, to act on behalf of the commissioner or the board.

"Epidemic" means the occurrence in a community or region of cases of an illness clearly in excess of normal expectancy.

"Essential needs" means basic human needs for sustenance including but not limited to food, water, and health care, e.g., medications, therapies, testing, and durable medical equipment.

"Exceptional circumstances" means the presence, as determined by the commissioner in his sole discretion, of one or more factors that may affect the ability of the department to effectively control a communicable disease of public health threat. Factors to be considered include but are not limited to: (i) characteristics or suspected

characteristics of the disease-causing organism or suspected disease-causing organism such as virulence, routes of transmission, minimum infectious dose, rapidity of disease spread, the potential for extensive disease spread, and the existence and availability of demonstrated effective treatment; (ii) known or suspected risk factors for infection; (iii) the potential magnitude of the effect of the disease on the health and welfare of the public; and (iv) the extent of voluntary compliance with public health recommendations. The determination of exceptional circumstances by the commissioner may take into account the experience or results of investigation in Virginia, another state, or another country.

"Foodborne outbreak" means two or more cases of a similar illness acquired through the consumption of food contaminated with chemicals or an infectious agent or its toxic products. Such illnesses include but are not limited to heavy metal intoxication, staphylococcal food poisoning, botulism, salmonellosis, shigellosis, Clostridium perfringens food poisoning, hepatitis A, and Escherichia coli O157:H7 infection.

"Healthcare-associated infection" means a localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent(s) or its toxin(s) that (i) occurs in a patient in a healthcare setting (e.g., a hospital or outpatient clinic), (ii) was not found to be present or incubating at the time of admission unless the infection was related to a previous admission to a healthcare setting, and (iii) if applicable, meets the criteria for a specific infection site as defined by CDC.

"Healthcare-associated outbreak" means any group of illnesses of common etiology occurring in patients of a healthcare setting acquired by exposure of those patients to the disease agent while in such a facility.

"Hepatitis C, acute" means the following clinical characteristics are met: (i) discrete onset of symptoms indicative of viral hepatitis and (ii) jaundice or elevated serum

aminotransferase levels and the following laboratory criteria are met: (a) serum alanine aminotransferase levels (ALT) greater than 400 IU/L; (b) IgM anti-HAV negative (if done); (c) IgM anti-HBc negative (if done); and (d) hepatitis C virus antibody (anti-HCV) screening test positive with a signal-to-cutoff ratio predictive of a true positive as determined for the particular assay as defined by CDC, HCV antibody positive by immunoblot (RIBA), or HCV RNA positive by nucleic acid test.

"Hepatitis C, chronic" means that the laboratory criteria specified in clauses (b), (c) and (d) listed above for an acute case are met but clinical signs or symptoms of acute viral hepatitis are not present and serum alanine aminotransferase (ALT) levels do not exceed 400 IU/L. This category will include cases that may be acutely infected but not symptomatic.

"Immunization" means a procedure that increases the protective response of an individual's immune system to specified pathogens.

"Independent pathology laboratory" means a nonhospital or a hospital laboratory performing surgical pathology, including fine needle aspiration biopsy and bone marrow specimen examination services, which reports the results of such tests directly to physician offices, without reporting to a hospital or accessioning the information into a hospital tumor registry.

"Individual" means a person or companion animal. When the context requires it, "person or persons" shall be deemed to include any individual.

"Infection" means the entry and multiplication or persistence of a disease-causing organism (prion, virus, bacteria, fungus, parasite, or ectoparasite) in the body of an individual. An infection may be inapparent (i.e., without recognizable signs or symptoms but identifiable by laboratory means) or manifest (clinically apparent).

"Invasive" means the organism is affecting a normally sterile site, including but not limited to blood or cerebrospinal fluid.

"Investigation" means an inquiry into the incidence, prevalence, extent, source, mode of transmission, causation of, and other information pertinent to a disease occurrence.

"Isolation" means the physical separation, including confinement or restriction of movement, of an individual or individuals who are infected with, or are reasonably suspected to be infected with, a communicable disease of public health threat in order to prevent or limit the transmission of the communicable disease of public health threat to uninfected and unexposed individuals.

"Isolation, complete" means the full-time confinement or restriction of movement of an individual or individuals infected with, or reasonably suspected to be infected with, a communicable disease in order to prevent or limit the transmission of the communicable disease to uninfected and unexposed individuals.

"Isolation, modified" means a selective, partial limitation of freedom of movement or actions of an individual or individuals infected with, or reasonably suspected to be infected with, a communicable disease. Modified isolation is designed to meet particular situations and includes but is not limited to the exclusion of children from school, the prohibition or restriction from engaging in a particular occupation or using public or mass transportation, or requirements for the use of devices or procedures intended to limit disease transmission.

"Isolation, protective" means the physical separation of a susceptible individual or individuals not infected with, or not reasonably suspected to be infected with, a communicable disease from an environment where transmission is occurring, or is reasonably suspected to be occurring, in order to prevent the individual or individuals from acquiring the communicable disease.

"Laboratory" as used herein means a clinical laboratory that examines materials derived from the human body for the purpose of providing information on the diagnosis, prevention, or treatment of disease.

"Laboratory director" means any person in charge of supervising a laboratory conducting business in the Commonwealth of Virginia.

"Law-enforcement agency" means any sheriff's office, police department, adult or youth correctional officer, or other agency or department that employs persons who have law-enforcement authority that is under the direction and control of the Commonwealth or any local governing body. "Law-enforcement agency" shall include, by order of the Governor, the Virginia National Guard.

"Lead-elevated blood levels" means a confirmed blood level greater than or equal to 10 micrograms of lead per deciliter ($\mu\text{g}/\text{dL}$) of whole blood in a child or children 15 years of age and younger, a venous blood lead level greater than or equal to 25 $\mu\text{g}/\text{dL}$ in a person older than 15 years of age, or such lower blood lead level as may be recommended for individual intervention by the department or the Centers for Disease Control and Prevention.

"Least restrictive" means the minimal limitation of the freedom of movement and communication of an individual while under an order of isolation or an order of quarantine that also effectively protects unexposed and susceptible individuals from disease transmission.

"Medical care facility" means any hospital or nursing home licensed in the Commonwealth, or any hospital operated by or contracted to operate by an entity of the United States government or the Commonwealth of Virginia.

"Midwife" means any person who is licensed as a nurse midwife by the Virginia Boards of Nursing and Medicine or who possesses a midwife permit issued by the State Health Commissioner.

"National Healthcare Safety Network" (NHSN) means a surveillance system created by the CDC for accumulating, exchanging and integrating relevant information on infectious adverse events associated with healthcare delivery.

~~"Nosocomial outbreak" means any group of illnesses of common etiology occurring in patients of a medical care facility acquired by exposure of those patients to the disease agent while confined in such a facility.~~

"Nucleic acid detection" means laboratory testing of a clinical specimen to determine the presence of deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) specific for an infectious agent using any method, including hybridization, sequencing, or amplification such as polymerase chain reaction.

"Nurse" means any person licensed as a professional nurse or as a licensed practical nurse by the Virginia Board of Nursing.

"Occupational outbreak" means a cluster of illness or disease that is indicative of a work-related exposure. Such conditions include but are not limited to silicosis, asbestosis, byssinosis, pneumoconiosis, and tuberculosis.

"Outbreak" means the occurrence of more cases of a disease than expected.

"Period of communicability" means the time or times during which the etiologic agent may be transferred directly or indirectly from an infected person to another person, or from an infected animal to a person.

"Physician" means any person licensed to practice medicine or osteopathy by the Virginia Board of Medicine.

"Quarantine" means the physical separation, including confinement or restriction of movement, of an individual or individuals who are present within an affected area or who are known to have been exposed, or may reasonably be suspected to have been exposed, to a communicable disease of public health threat and who do not yet show signs or symptoms of infection with the communicable disease of public health threat in order to prevent or limit the transmission of the communicable disease of public health threat to unexposed and uninfected individuals.

"Quarantine, complete" means the full-time confinement or restriction of movement of an individual or individuals who do not have signs or symptoms of infection but may have been exposed, or may reasonably be suspected to have been exposed, to a communicable disease of public health threat in order to prevent the transmission of the communicable disease of public health threat to uninfected individuals.

"Quarantine, modified" means a selective, partial limitation of freedom of movement or actions of an individual or individuals who do not have signs or symptoms of the infection but have been exposed to, or are reasonably suspected to have been exposed to, a communicable disease of public health threat. Modified quarantine may be designed to meet particular situations and includes but is not limited to limiting movement to the home, work, and/or one or more other locations, the prohibition or restriction from using public or mass transportation, or requirements for the use of devices or procedures intended to limit disease transmission.

"Reportable disease" means an illness due to a specific toxic substance, occupational exposure, or infectious agent, which affects a susceptible individual, either directly, as from an infected animal or person, or indirectly through an intermediate host, vector, or the environment, as determined by the board.

"SARS" means severe acute respiratory syndrome (SARS)-associated coronavirus (SARS-CoV) disease.

"School" means (i) any public school from kindergarten through grade 12 operated under the authority of any locality within the Commonwealth; (ii) any private or parochial school that offers instruction at any level or grade from kindergarten through grade 12; (iii) any private or parochial nursery school or preschool, or any private or parochial child care center licensed by the Commonwealth; and (iv) any preschool handicap classes or Head Start classes.

"Serology" means the testing of blood, serum, or other body fluids for the presence of antibodies or other markers of an infection or disease process.

"Surgical Care Improvement Project (SCIP)" means a national quality initiative supported by the Joint Commission, the Centers for Medicare and Medicaid Services, and other partners in healthcare that is designed to improve surgical care in hospitals.

"Surveillance" means the ongoing systematic collection, analysis, and interpretation of outcome-specific data for use in the planning, implementation, and evaluation of public health practice. A surveillance system includes the functional capacity for data analysis as well as the timely dissemination of these data to persons who can undertake effective prevention and control activities.

"Susceptible individual" means a person or animal who is vulnerable to or potentially able to contract a disease or condition. Factors that affect an individual's susceptibility include but are not limited to physical characteristics, genetics, previous or chronic exposures, chronic conditions or infections, immunization history, or use of medications.

"Toxic substance" means any substance, including any raw materials, intermediate products, catalysts, final products, or by-products of any manufacturing operation conducted in a commercial establishment, that has the capacity, through its physical,

chemical or biological properties, to pose a substantial risk of death or impairment either immediately or over time, to the normal functions of humans, aquatic organisms, or any other animal but not including any pharmaceutical preparation which deliberately or inadvertently is consumed in such a way as to result in a drug overdose.

"Tubercle bacilli" means disease-causing organisms belonging to the *Mycobacterium tuberculosis* complex and includes *Mycobacterium tuberculosis*, *Mycobacterium bovis*, and *Mycobacterium africanum* or other members as may be established by the commissioner.

"Tuberculin skin test (TST)" means a test for demonstrating infection with tubercle bacilli, performed according to the Mantoux method, in which 0.1 ml of 5 TU strength tuberculin purified protein derivative (PPD) is injected intradermally on the volar surface of the arm. Any reaction is observed 48-72 hours after placement and palpable induration is measured across the diameter transverse to the long axis of the arm. The measurement of the indurated area is recorded in millimeters and the significance of the measured induration is based on existing national and department guidelines.

"Tuberculosis" means a disease caused by tubercle bacilli.

"Tuberculosis, active disease" (also "active tuberculosis disease" and "active TB disease"), as defined by § 32.1-49.1 of the Code of Virginia, means a disease caused by an airborne microorganism and characterized by the presence of either (i) a specimen of sputum or other bodily fluid or tissue that has been found to contain tubercle bacilli as evidenced by culture or nucleic acid amplification, including preliminary identification by rapid methodologies; (ii) a specimen of sputum or other bodily fluid or tissue that is suspected to contain tubercle bacilli as evidenced by smear, and where sufficient clinical and radiographic evidence of active tuberculosis disease is present as determined by a physician licensed to practice medicine in Virginia; or (iii) sufficient clinical and

radiographic evidence of active tuberculosis disease as determined by the commissioner is present, but a specimen of sputum or other bodily fluid or tissue containing, or suspected of containing, tubercle bacilli is unobtainable.

"Tuberculosis infection in children age less than 4 years" means a significant reaction resulting from a tuberculin skin test (TST) or other approved test for latent infection without clinical or radiographic evidence of active tuberculosis disease, in children from birth up to their fourth birthday.

"Vaccinia, disease or adverse event" means vaccinia infection or serious or unexpected events in persons who received the smallpox vaccine or their contacts, including but not limited to bacterial infections, eczema vaccinatum, erythema multiforme, generalized vaccinia, progressive vaccinia, inadvertent inoculation, post-vaccinial encephalopathy or encephalomyelitis, ocular vaccinia, and fetal vaccinia.

"Waterborne outbreak" means two or more cases of a similar illness acquired through the ingestion of or other exposure to water contaminated with chemicals or an infectious agent or its toxic products. Such illnesses include but are not limited to giardiasis, viral gastroenteritis, cryptosporidiosis, hepatitis A, cholera, and shigellosis. A single case of laboratory-confirmed primary amebic meningoencephalitis or of waterborne chemical poisoning is considered an outbreak.

Part XIII

~~Report~~ Reporting of Healthcare-Associated Infections

12VAC5-90-370. Reporting of healthcare-associated infections.

~~A. Definitions. The following words and terms when used in this part shall have the following meanings unless the context clearly indicates otherwise:~~

~~"Acute care hospital" means a hospital as defined in § 32.1-123 of the Code of Virginia that provides medical treatment for patients having an acute illness or injury or recovering from surgery.~~

~~"Adult" means a person 18 years of age or more.~~

~~"Central line-associated bloodstream infection" means a primary bloodstream infection identified by laboratory tests, with or without clinical signs or symptoms, in a patient with a central line device, and meeting the current Centers for Disease Control and Prevention (CDC) surveillance definition for laboratory-confirmed primary bloodstream infection.~~

~~"Central line device" means a vascular infusion device that terminates at or close to the heart or in one of the greater vessels. The following are considered great vessels for the purpose of reporting central line infections and counting central line days: aorta, pulmonary artery, superior vena cava, inferior vena cava, brachiocephalic veins, internal jugular veins, subclavian veins, external iliac veins, and common femoral veins.~~

~~"Healthcare-associated infection" (or nosocomial infection) means a localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent(s) or its toxin(s) that (i) occurs in a patient in a healthcare setting (e.g., a hospital or outpatient clinic), (ii) was not found to be present or incubating at the time of admission unless the infection was related to a previous admission to the same setting, and (iii) if the setting is a hospital, meets the criteria for a specific infection site as defined by CDC.~~

~~"National Healthcare Safety Network" (NHSN) means a surveillance system created by the CDC for accumulating, exchanging and integrating relevant information on infectious adverse events associated with healthcare delivery.~~

~~B. A. Reportable infections and method and timing of reporting.~~

1. Acute care hospitals shall ~~collect~~ enter data on the following healthcare-associated ~~infection~~ infections in the specified patient population into CDC's National Healthcare Safety Network according to CDC protocols. Such hospitals shall ensure that accurate and complete data are entered at least quarterly within one month of the close of the calendar year quarter and shall authorize the department to have access to hospital-specific data contained in the NHSN database.

(i) central line-associated bloodstream infections in adult intensive care units, including the number of central-line days in each population at risk, expressed per 1,000 catheter-days.

(ii) central line-associated bloodstream infections outside intensive care, including in one adult inpatient medical ward and one adult inpatient surgical ward. Wards selected should be those with the longest length of stay during the previous calendar year, excluding cardiology, obstetrics, psychiatry, hospice, and step-down units. Data shall include the number of central-line days in each population at risk.

(iii) *Clostridium difficile* infection, laboratory-identified events on inpatient units, with the exceptions recommended by CDC protocol. Data shall be collected year-round at the overall facility-wide level. Data shall include patient days.

2. ~~All acute care hospitals with adult intensive care units shall (i) participate in CDC's National Healthcare Safety Network by July 1, 2008, (ii) submit data on the above named infection to the NHSN according to CDC protocols and ensure that all data from July 1, 2008, to December 31, 2008, are entered into the NHSN by January 31, 2009, and (iii) enter data quarterly thereafter according to a schedule established by the department.~~

~~3. All acute care hospitals reporting the information noted above shall authorize the department to have access to hospital-specific data contained in the NHSN database.~~

B. Reportable process measures

Acute care hospitals shall report to the department quarterly, within one month of the close of the calendar year quarter, aggregate counts of the Surgical Care Improvement Project (SCIP) Core Measures pertaining to the following surgical procedures: hip arthroplasty, knee arthroplasty, and coronary artery bypass graft. Data shall be collected in accordance with the Specification Manual for National Hospital Inpatient Quality Measures and shall include counts of the patient population and the applicable SCIP measures for each of the above designated surgical procedures. Reports shall be submitted to the department's Division of Surveillance and Investigation.

C. Liability protection and data release. Any person making such report as authorized herein shall be immune from liability as provided by § 32.1-38 of the Code of Virginia. Infection rate data may be released to the public by the department upon request. Data shall be aggregated to ensure that no individual patient may be identified.



COMMONWEALTH of VIRGINIA

Karen Remley, MD, MBA, FAAP
State Health Commissioner

Department of Health
P O BOX 2448
RICHMOND, VA 23218

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

April 5, 2010

Memorandum

To: State Board of Health

From: Keri Hall, M.D., M.S. *KH for KH*
Director, Office of Epidemiology

Subject: Final Amendment to the *Regulations for Disease Reporting and Control*

Enclosed you will find a final amendment to the *Regulations for Disease Reporting and Control* for your review and discussion at the April 23, 2010 meeting of the Board of Health. The overall amendment brings the regulations into compliance with recent changes to the *Code of Virginia*, updates language to reflect current scientific terminology, and enhances provisions to allow the agency to better detect and respond to conditions of public health concern and thereby protect the health of the public.

The comment period for the proposed regulatory packet ended on February 5, 2010. Few comments were received, as shown on the table on the Town Hall form. The final amendment contains only a few minor revisions compared to the proposed language. The name of the disease Rocky Mountain spotted fever has been changed to spotted fever rickettsiosis, paratyphoid fever has been treated the same as typhoid fever throughout, and a clarifying clause was added to one paragraph that a reviewer found to be confusing. The regulation has been reviewed and approved by both Robin Kurz, of the Office of the Attorney General, and Dr. Jim Burns, Deputy Commissioner for Public Health. I look forward to discussing this regulatory action with you at the upcoming meeting.

If the Board approves these regulations, following Executive Branch review, the final regulation will be forwarded to the Registrar of Regulations for final printing in the *Virginia Register* and will go into effect 30 days after the date of publication.



Final Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12 VAC 5-90
Regulation title	Disease Reporting and Control
Action title	2008 Update to comply with changes in Virginia Code and public health practice
Date this document prepared	April 1, 2010

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

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

The *Regulations for Disease Reporting and Control* provide information about the process and procedures for reporting diseases to the Virginia Department of Health, including what diseases must be reported, who must report them and how reporting is conducted. The Virginia Department of Health is proposing an amendment to the regulations in order to bring them into compliance with recent changes in the *Code of Virginia* and with recent changes in the field of communicable disease control and emergency preparedness that are needed to protect the health of the citizens of Virginia.

The specific proposed changes are necessary to ensure the regulations comply with recent changes in the *Code of Virginia* pertaining to the reporting of outbreaks, isolation and quarantine provisions, prenatal testing for HIV infection, immunization requirements, and tuberculosis control. Further amendments are necessary to clarify definitions and edit reportable disease lists.

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.

The Board of Health approved the final amendment to the Regulations for Disease Reporting and Control on _____.

Legal basis

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

Chapter 2 of Title 32.1 of the Code of Virginia, §§ 32.1-12 and 32.1-35 through 32.1-73, contains mandatory language authorizing the State Board of Health to promulgate the proposed regulations. Specifically, § 32.1-35 directs the Board of Health to promulgate regulations specifying which diseases occurring in the Commonwealth are to be reportable and the method by which they are to be reported. Further, § 32.1-42 of the Code of Virginia authorizes the Board of Health to promulgate regulations and orders to prevent a potential emergency caused by a disease dangerous to public health. The Board of Health is empowered to adopt such regulations as are necessary to carry out provisions of laws of the Commonwealth administered by the state health commissioner by § 32.1-12 of the Code of Virginia. The Office of the Attorney General has certified that the agency has statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

Purpose

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

The amendment is necessary in order to ensure that the regulations comply with changes in the Code of Virginia. The proposed changes improve the ability of the Virginia Department of Health to conduct surveillance and implement disease control for conditions of public health concern, including some that may indicate bioterrorism events. The changes will position the agency to better detect and respond to these illnesses to protect the health of the public.

Substance

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

Amendments to current regulations will:

- Update language to ensure that it complies with Code and reflects current public health, medical and scientific terminology;
- Update disease reporting requirements, including reportable diseases and those required to report;
- Update language regarding laboratory reporting requirements;
- Update tuberculosis reporting and control requirements and definitions;
- Update provisions regarding the reporting of toxic substance-related illness;
- Update requirements related to HIV prenatal testing; and
- Update other disease reporting and control provisions necessary to protect the health of the people of the Commonwealth.

Issues

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

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
 - 2) the primary advantages and disadvantages to the agency or the Commonwealth; and*
 - 3) other pertinent matters of interest to the regulated community, government officials, and the public.*
- If there are no disadvantages to the public or the Commonwealth, please indicate.*

The proposed changes improve the ability of the Virginia Department of Health to conduct surveillance and implement disease control for conditions of public health concern, including some that may indicate bioterrorism events. The changes will position the agency to better detect and respond to these illnesses to protect the health of the public.

Except as noted in the paragraphs below, changes are alterations in language and terminology to reflect current scientific use and to provide clarification. For example, the phrase "interrupt the transmission of disease" is replaced by "reduce the occurrence of disease", names of conditions on the Reportable Disease List are modified to comply with scientific usage, and definitions that were in a subsection are moved to the Definitions section. These changes improve the clarity of the regulations but are not substantive.

Updates to disease reporting requirements:

- Conditions requiring rapid communication will be reported "by the most rapid means available", rather than "within 24 hours" to clarify that immediate action is expected for these high priority conditions.
- The change in terminology from "poliomyelitis" to "poliovirus infection" clarifies that all poliovirus infections are reportable, not only those resulting in paralysis.
- Toxic Shock Syndrome is removed from the list of reportable conditions, but is included as a reportable Group A Streptococcal infection. Toxic shock may result from streptococcal or staphylococcal organisms. The number of staphylococcal toxic shock syndrome cases has been minimal over the past 10 years (averaging 1.2 cases per year) and clinical management is effective to limit spread. Streptococcal infections are still of public health concern and will remain reportable.
- Kawasaki syndrome is removed from the list of reportable conditions. The condition was initially added as a reportable condition due to a national research effort to identify the causal agents. However, no cause has been identified and there is no public health intervention to reduce the occurrence of disease. Over the past 5 years, an average of 17 Kawasaki cases was reported each year in Virginia.

- Changes in reporting requirements for laboratory directors pertain to Lyme disease and heavy metals. Lyme disease is added to the list of conditions reportable by laboratories because laboratory findings are essential for identification and confirmation of cases. Because the major reference laboratories currently submit Lyme disease findings, the impact is expected to be minimal. When reporting elevated levels of heavy metal exposure, the amendment proposes requiring laboratories to provide speciation, indicating whether the metal is organic or inorganic, when this information is available. This assists in determining whether public health action is needed to follow up on reports, which applies only to inorganic metals.
- To comply with changes in Virginia Code § 32.1-37, new wording is added to specify that persons in charge of a residential or day program, service, or facility licensed or operated by any agency of the Commonwealth must report outbreaks. The change in Virginia Code, which was made during the 2008 legislative session, addressed a gap in the requirement for persons in charge of schools, child care centers, and summer camps to report outbreaks. Earlier involvement by public health minimizes the number of individuals who become ill and assists the facility in implementing changes to reduce future outbreaks.

Submission of tuberculosis specimens: To comply with changes in Virginia Code § 32.1-50, the updated regulations remove the exception that previously allowed a laboratory to submit drug susceptibility findings for tuberculosis specimens in place of a viable sample. Submission of positive cultures for a member of the *M. tuberculosis* complex to the Division of Consolidated Laboratory Services (DCLS) or other approved laboratory guarantees the availability of drug susceptibility results for public health and treating clinicians. These results are important to ensure the appropriate treatment of individuals impacted by tuberculosis disease. In addition, genetic fingerprinting of the organism by public health laboratories provides insights into disease transmission patterns and identifies points where public health intervention can prevent further transmission.

Submission of specimens for additional confirmation: Laboratories identifying evidence of 14 conditions in addition to tuberculosis have been required to submit specimens to DCLS. In this action the requirement is expanded to include four additional conditions. Two are potential bioterrorism conditions not currently included on the list (brucellosis and Q fever). The third is novel influenza A viruses, which could herald the arrival of a new strain of influenza that could potentially lead to a large-scale epidemic or pandemic. The fourth is vancomycin-intermediate or vancomycin-resistant *Staphylococcus aureus*. VDH generally receives less than 24 reports per year of these four conditions combined (not counting the novel 2009 H1N1 influenza). Resistance to vancomycin in *Staphylococcus aureus* is an emerging health concern; however, most preliminary findings of resistance are ruled out with confirmatory testing. The other changes in this section offer clarifications. Typhoid fever is caused by *Salmonella typhi*, and was intended to be covered in the requirement for evidence identifying salmonellosis, but specific mention of the organism will ensure specimen submission. For *E. coli* O157, the new requirement specifies that when EIA testing is done without culture, the positive broth may be submitted; previously the regulations referred only to the submission of specimens for further testing. Additional testing performed at the state laboratory for these 17 conditions is essential for identifying and delineating outbreaks. On a national level, the ability to obtain and act on this type of analysis is expected of state health departments.

Isolation and quarantine: Changes to the regulations specify that if the risk of infection or transmission continues at the end of the confinement, new orders may be issued to extend the confinement. The procedures for extending orders protect the individual while minimizing health risks to the public. These changes make isolation and quarantine orders more practical to implement and enforce.

Immunization requirements: The regulations are updated to be in conformance with changes in Virginia Code § 32.1-46, which updated the immunization requirements for children. Additionally, the immunization requirements for school entry in 12 VAC5-110-70 are referenced, rather than repeated. This section makes reference to the changes in immunization requirements in § 32.1-46 and those in 12VAC5-110-70, which is under separate review, but does not modify the requirements themselves nor incur any additional costs. The changes reduce duplication in regulations and eliminate the need to modify both sets of regulations when immunization requirements are updated.

Prenatal testing for HIV infection: The regulations are updated to be in conformance with changes in Virginia Code § 54.1-2403.01, which was amended in the 2008 Session of the General Assembly, and with current guidelines of the Centers for Disease Control and Prevention (CDC). HIV testing during pregnancy is a standard of medical care, and universal screening with an opt-out provision is supported by the American College of Obstetricians and Gynecologists. The change in regulation language would change HIV testing during pregnancy from opt-in to opt-out, and increase from one to two the number of HIV tests to be performed on pregnant women. This change would potentially benefit women by identifying HIV infection, and benefit their newborns through identifying those who would require HIV preventive treatment. The change would ultimately benefit society by decreasing the number of children with HIV infection. This regulation would bring Virginia in line with CDC guidance as well as Virginia Code, which makes prenatal HIV testing a routine opt-out procedure. In guidance released in 2006, the CDC identified states where two HIV tests should be performed during pregnancy, because those states have an elevated incidence of HIV or AIDS among women 15 – 45 years of age. Virginia was one of the identified states, and the Association of Maternal and Child Health Programs, to which the Title V Maternal and Child Health Block Grant recipients belong, recommends that state and national policymakers take steps to implement universal opt-out screening which includes the second HIV test during the third trimester in the jurisdictions identified by CDC. The only disadvantage to the public or the Commonwealth is the cost of the HIV testing.

Changes made since the proposed stage

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

Section number	Requirement at proposed stage	What has changed	Rationale for change
12VAC5-90-80 (A) & (B)	1) Reporting of Rocky Mountain spotted fever is required. 2) Reporting of Vancomycin-intermediate or vancomycin-resistant <i>Staphylococcus aureus</i> infection is required in (A) but reporting of <i>Staphylococcus aureus</i> infection, vancomycin-intermediate or vancomycin-resistant is required in (B)	1) Name of condition was changed to Spotted fever rickettsiosis. 2) Name of conditions was changed to <i>Staphylococcus aureus</i> infection, vancomycin-intermediate or vancomycin-resistant in (A)	1) This updates language to current scientific and medical usage. 2) This provides consistency in terminology between 12VAC5-90-80 (A) & (B)
12VAC5-90-80 (A), (B), (C)	Condition is listed as Typhoid/paratyphoid fever	Capitalization is changed to list condition as Typhoid/Paratyphoid fever	Names of all conditions are capitalized
12VAC5-90-90 (B)	Submission of isolates is required for Typhoid fever	Requirements are changed to include submission of isolates for Typhoid/Paratyphoid fever.	Typhoid fever and Paratyphoid fever are closely related and they require similar public health intervention.

12VAC5-90-90 (D)	Reporting of outbreaks is required of 'Any person in charge of a residential or day program, service, or facility licensed or operated by any agency of the Commonwealth, school, child care center, or summer camp...'	Phrase was added to separate residential or daycare programs, services, or facilities from other facilities that need to report.	Language clarifies that 'program, service, or facility licensed or operated by any agency of the Commonwealth' refers to residential or daycare programs, services, or facilities.
------------------	---	--	--

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.

Commenter	Comment	Agency response
Environmental Health Food Consultant, Thomas Jefferson Health District	Modify wording in 12VAC5-90-90 (D) to clarify whether this includes all VDH permitted foodservice facilities.	The proposed regulations are only intended to apply to residential or day programs, services, or facilities that are licensed or operated by an agency of the Commonwealth, not to foodservice facilities. In order to clarify the requirement, the phrase 'or a' has been inserted following this description and before listing other institutions required to report.
Entomologist, VDH	Supports requirement for all laboratories to report positive results for Lyme disease.	This is supportive of proposed change. No modification is needed.
Health Director, Richmond Health District; Health Director, Cumberland Plateau Health District; Epidemiologist, Thomas Jefferson Health District	Require that laboratories report results to the health district where the patient resides, rather than the health district where the laboratory is located. This would help ensure that the health department where the patient resides is able to respond in a more timely manner.	Requiring the reporting laboratory to submit findings to the health department where the patient lives, rather than to the health department where the facility is located, would streamline public health response and the public health workload. However, with the technology currently available, it would significantly increase the work load of the reporting laboratory. VDH has invested efforts in automating reporting from laboratories to a centralized database which presents the findings to the appropriate health department. While only two national reference laboratories are currently reporting in this manner, it represents over 90% of the lab reports submitted. Over the next few years, efforts will focus on automating electronic reporting from major hospital laboratories within the Commonwealth to improve the timeliness and efficiency with which laboratory findings reach the appropriate health department. We believe that this is a more effective strategy to address the identified gap.

Deputy State Epidemiologist, VDH	Clarify whether requirement for reporting of novel influenza A applies only to the 2009 strain of novel H1N1 influenza or to any new novel influenza identified.	Use of the terminology requiring reporting of any finding of 'influenza A, novel virus' was proposed by the U.S. Centers for Disease Control and Prevention before the 2009 novel H1N1 virus appeared and was intended to address just such an event. We believe this terminology is important to support our ability to identify novel influenza strains as they may emerge and that no change is needed.
Communicable Disease Epidemiologist, VDH	Change regulations to replace the outdated term 'Rocky Mountain Spotted Fever' with 'Spotted Fever Rickettsiosis', the term in current scientific and medical usage.	This terminology change has been incorporated in 12VAC5-90-80 (A) and 12VAC5-90-80 (B).
Communicable Disease Epidemiologist, VDH	Modify wording of 12 VAC 5-90-360 to specify that all reports submitted to the registry are protected, regardless of the submitter.	This section is not currently under revision. The change will be considered at a later date.

Enter any other statement here

All changes made in this regulatory action

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail new provisions and/or all changes to existing sections.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12VAC5-90-10		Definitions	<ul style="list-style-type: none"> • Move definitions related to reporting of healthcare-associated infections to this section from 12VAC5-90-370. • "Affected area" – Modify definition to indicate what may constitute an "area". • "Arboviral infection" – Add definition to clarify disease reporting requirements. • Ehrlichiosis/anaplasmosis – Add definition to clarify disease reporting requirements. • "Influenza A, novel virus" – Add definition. • "Midwife" – Amend definition to reflect current licensing requirements. • Nosocomial outbreak – Remove definition. Term is outdated. • Isolation and Quarantine – Modify both to change "communicable disease of public health threat" to "communicable disease".
12VAC5-90-30		Purpose	Replace "interrupt the transmission of disease" with "reduce the occurrence of disease" to more accurately portray the

<p>12VAC5-90-80 (A)</p>		<p>Reportable disease list</p>	<p>objective of these regulations</p> <ul style="list-style-type: none"> • Change disease names to comply with scientific usage and ensure internal consistency. • Change reporting requirement for conditions requiring rapid communication. They must be submitted “by the most rapid means available”, rather than “within 24 hours”, to allow rapid mobilization of the public health response. • Remove Kawasaki syndrome from the list of reportable conditions. There is no public health action for this condition. • Change “Poliomyelitis” to “Poliovirus infection, including poliomyelitis” to clarify that non-paralytic poliovirus infections are to be reported. • Replace ‘Rocky Mountain Spotted Fever’ with ‘Spotted Fever Rickettsiosis’ to reflect terminology in current scientific and medical usage. • Change Vancomycin-intermediate or vancomycin-resistant Staphylococcus aureus infection to Staphylococcus aureus infection, vancomycin-intermediate or vancomycin-resistant • Capitalize Paratyphoid • Remove Toxic shock syndrome from the list of reportable conditions. Reporting of streptococcal toxic shock continues with the reporting of Group A streptococcal infections. Staphylococcal toxic shock will no longer be reported.
<p>12VAC5-90-80 (B)</p>		<p>Conditions reportable by directors of laboratories</p>	<ul style="list-style-type: none"> • Change disease names and reporting specifications to comply with scientific usage and ensure internal consistency. • Change reporting requirement for conditions requiring rapid communication. They must be submitted “by the most rapid means available”, rather than “within 24 hours”, to allow rapid mobilization of the public health response • Add Lyme disease to facilitate case identification and confirmation. • Change “Poliomyelitis” to “Poliovirus infection” to clarify that non-paralytic poliovirus infections are to be reported. • Replace ‘Rocky Mountain Spotted Fever’ with ‘Spotted Fever Rickettsiosis’ to reflect terminology in current scientific and medical usage. • Capitalize Paratyphoid • Require results of speciation for heavy metals, when performed, to improve

12VAC5-90-80 (C)		Reportable diseases requiring rapid communication	<p>classification</p> <ul style="list-style-type: none"> • Change disease names and reporting specifications to comply with scientific usage and ensure internal consistency. • Change reporting requirement for conditions requiring rapid communication. They must be submitted “by the most rapid means available”, rather than “within 24 hours”, to allow rapid mobilization of the public health response • Add “Influenza A, novel virus” to assist in detection and identification of potential pandemic influenza strains. • Add congenital rubella syndrome by including it with the listing for rubella, as it is presented on the reportable disease list in 12VAC5-90-80(A), to allow rapid response • Capitalize Paratyphoid
12VAC5-90-90 (B)		Those required to report – directors of laboratories	<ul style="list-style-type: none"> • Re-format for clarity • Expand requirement for submission of specimens for confirmation and further characterization by laboratories to include evidence of brucellosis and Q fever, two bioterrorism conditions; novel influenza A viruses, an indicator of a possible pandemic situation; and vancomycin-intermediate or vancomycin-resistant <i>Staphylococcus aureus</i>, an emerging condition. • Clarify that specimens are to be submitted for typhoid fever and paratyphoid fever, two conditions caused by <i>Salmonella</i> organisms, to allow confirmation and further characterization. • For shiga toxin producing <i>E. coli</i>, allow laboratories using EIA methodologies without performing culture to submit positive broths or stool specimens (the current regulation states only stool) to DCLS for confirmation and further characterization. Additional characterization performed by DCLS is important for the identification and delineation of potential outbreaks. • To improve compliance, reflect the requirements for tuberculosis specimen submission from 12VAC5-90-225 in this section.
12VAC5-90-90 (D)		Those required to report – persons in charge of a facility	<ul style="list-style-type: none"> • Make explicit the expectation that persons required to report outbreaks include those managing state operated or state licensed residential or day programs, services or facilities. Addresses a gap in the identification and response to disease

			<p>outbreaks.</p> <ul style="list-style-type: none"> • Add citation for the Section of Virginia Code defining camps. • Clarify that information on the affected individuals may be provided. This is needed for investigation of outbreaks.
12VAC5-90-90 (E)		Those required to report – local health directors	<ul style="list-style-type: none"> • Change reporting requirement for conditions requiring rapid communication. Specify that they must be submitted “by the most rapid means available” to be consistent with 12VAC5-90-80(C)
12VAC5-90-103		Isolation for communicable disease of public health threat	<ul style="list-style-type: none"> • Modify wording for clarity and compliance with Code. • Provide clarification regarding appropriate parties for delivery of isolation orders • Specify that new orders may be issued to extend the confinement if risk persists
12VAC5-90-107		Quarantine	<ul style="list-style-type: none"> • Modify wording for clarity • Provide clarification regarding appropriate parties for delivery of quarantine orders • Specify that new orders may be issued to extend the confinement if risk persists
12VAC5-90-110		Dosage and age requirements for immunizations; obtaining immunizations	<ul style="list-style-type: none"> • Change “child” to “person...less than 18 years of age” to be consistent with the Advisory Committee on Immunization Practices nomenclature. • Change immunization requirements to be consistent with <i>Code of Virginia</i> § 32.1-46. • Remove listing of immunization requirements for school entry, and reference section 12 VAC 5-110-70, where these requirements are specified. This eliminates duplication and reduces the need to update both sets of regulations with changes to the immunization requirements for school entry.
12VAC5-90-130		Prenatal testing	<ul style="list-style-type: none"> • Modify wording for clarity • Expand explanation of persons at high risk for syphilis to include persons in high prevalence communities and populations. • Make HIV testing an “opt-out” component of the prenatal panel rather than an “opt-in” component. This will encourage testing and is consistent with national guidelines and medical standards of care and with the <i>Code of Virginia</i>. • Recommend a second HIV test in the third trimester to be consistent with CDC recommendations for areas with elevated incidence of infection.
12VAC5-90-140		Procedure for preventing ophthalmia neonatorum	<ul style="list-style-type: none"> • To ensure consistency with language used in other Virginia Department of

			Health regulations (12VAC5-71-50) regarding procedures for newborns and with the recommendations of the American Academy of Pediatrics.
12VAC5-90-225		Additional data to be reported related to persons with active tuberculosis disease (confirmed or suspected)	<ul style="list-style-type: none"> To be consistent with Code of Virginia §32.1-50, require laboratories to submit a viable sample of a positive culture for a member of the <i>M. tuberculosis</i> complex.
12VAC5-90-370		Reporting of healthcare-associated infections	<ul style="list-style-type: none"> Move definitions to 12VAC5-90-10 to be consistent with other parts of these regulations. Clarify that data are not necessarily entered quarterly, but that data must be available quarterly. It is preferred that data are entered monthly, in accordance with the protocols of the National Healthcare Safety Network.

Regulatory flexibility analysis

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

These changes in regulation are expected to have little impact on small businesses. The regulations have been designed to minimize costs to all businesses. Most of the changes that would have an impact are already required by the *Code of Virginia*. No additional mechanisms to reduce the burden to small businesses are available.

Family impact

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

The proposed changes will indirectly protect and improve the health of the people of the Commonwealth. No adverse impacts on the institution of the family or on family stability are anticipated.

**Project 1409 – FINAL – Regulations for Disease Reporting and Control
SECTIONS CHANGED SINCE PROPOSED STAGE ONLY**

DEPARTMENT OF HEALTH

2008 Update

Part III

Reporting of Disease

12VAC5-90-80. Reportable disease list.

A. The board declares suspected or confirmed cases of the following named diseases, toxic effects, and conditions to be reportable by the persons enumerated in 12VAC5-90-90. Conditions identified by an asterisk (*) require ~~rapid~~ immediate communication to the local health department ~~within 24 hours of~~ by the most rapid means available upon suspicion or confirmation, as defined in subsection C of this section. Other conditions should be reported within three days of suspected or confirmed diagnosis.

Acquired immunodeficiency syndrome (AIDS)

Amebiasis

*Anthrax

Arboviral infections (e.g., dengue, EEE, LAC, SLE, WNV)

*Botulism

*Brucellosis

Campylobacteriosis

Chancroid

Chickenpox (Varicella)

Chlamydia trachomatis infection

*Cholera

Creutzfeldt-Jakob disease if <55 years of age

Cryptosporidiosis

Cyclosporiasis

*Diphtheria

*Disease caused by an agent that may have been used as a weapon

~~Ehrlichiosis~~ Ehrlichiosis/Anaplasmosis

Escherichia coli infection, Shiga toxin-producing

Giardiasis

Gonorrhea

Granuloma inguinale

*Haemophilus influenzae infection, invasive

Hantavirus pulmonary syndrome

Hemolytic uremic syndrome (HUS)

*Hepatitis A

Hepatitis B: (acute and chronic)

Hepatitis C (acute and chronic)

Hepatitis, other acute viral

Human immunodeficiency virus (HIV) infection

Influenza

*Influenza-associated deaths in children <18 years of age

~~Kawasaki syndrome~~

~~Lead-elevated blood levels~~ Lead, elevated blood levels

Legionellosis

Leprosy (Hansen's Hansen disease)

Listeriosis

Lyme disease

Lymphogranuloma venereum

Malaria

*Measles (Rubeola)

*Meningococcal disease

*Monkeypox

Mumps

Ophthalmia neonatorum

*Outbreaks, all (including but not limited to foodborne, nosocomial, healthcare-associated, occupational, toxic substance-related, and waterborne)

*Pertussis

*Plague

~~*Poliomyelitis~~ *Poliovirus infection, including poliomyelitis

*Psittacosis

*Q fever

*Rabies, human and animal

Rabies treatment, post-exposure

~~[Rocky Mountain spotted fever]~~

*Rubella, including congenital rubella syndrome

Salmonellosis

*Severe acute respiratory syndrome (SARS)

Shigellosis

*Smallpox (Variola)

[Spotted fever rickettsiosis]

[Staphylococcus aureus infection, vancomycin-intermediate or vancomycin-resistant]

Streptococcal disease, Group A, invasive or toxic shock

Streptococcus pneumoniae infection, invasive, in children <5 years of age

Syphilis (report *primary and *secondary syphilis by rapid means)

Tetanus

~~Toxic shock syndrome~~

Toxic substance-related illness

Trichinosis (Trichinellosis)

*Tuberculosis, active disease

Tuberculosis infection in children <4 years of age

*Tularemia

~~*Typhoid~~ [~~*Typhoid/paratyphoid~~ *Typhoid/Paratyphoid] fever

*Unusual occurrence of disease of public health concern

*Vaccinia, disease or adverse event

[~~Vancomycin-intermediate or vancomycin-resistant Staphylococcus aureus infection~~]

*Vibrio infection

*Viral hemorrhagic fever

*Yellow fever

Yersiniosis

B. Conditions reportable by directors of laboratories.

Conditions identified by an asterisk (*) require ~~rapid~~ immediate communication to the local health department ~~within 24 hours of~~ by the most rapid means available upon suspicion or confirmation, as defined in subsection C of this section. Other conditions should be reported within three days of suspected or confirmed diagnosis.

Amebiasis—by microscopic examination, culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

*Anthrax—by culture, antigen detection or nucleic acid detection

Arboviral infection—by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

*Botulism—by culture or identification of toxin in a clinical specimen

*Brucellosis—by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

Campylobacteriosis—by culture

Chancroid—by culture, antigen detection, or nucleic acid detection

Chickenpox (varicella)—by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

Chlamydia trachomatis infection—by culture, antigen detection, nucleic acid detection or, for lymphogranuloma venereum, serologic results consistent with recent infection

*Cholera—by culture or serologic results consistent with recent infection

Creutzfeldt-Jakob disease if <55 years of age ~~—presumptive diagnosis—~~ by histopathology in patients under the age of 55 years

Cryptosporidiosis—by microscopic examination, antigen detection, or nucleic acid detection

Cyclosporiasis—by microscopic examination or nucleic acid detection

*Diphtheria—by culture

~~Ehrlichiosis—by~~ Ehrlichiosis/Anaplasmosis—by culture, nucleic acid detection, or serologic results consistent with recent infection

Escherichia coli infection, Shiga toxin-producing—by culture of E. coli O157 or other Shiga toxin-producing E. coli, Shiga toxin detection (e.g., by EIA), or nucleic acid detection

Giardiasis—by microscopic examination or antigen detection

Gonorrhea—by microscopic examination of a urethral smear specimen (males only), culture, antigen detection, or nucleic acid detection

*Haemophilus influenzae infection, invasive—by culture, antigen detection, or nucleic acid detection from a normally sterile site

Hantavirus pulmonary syndrome—by antigen detection (immunohistochemistry), nucleic acid detection, or serologic results consistent with recent infection

*Hepatitis A—by detection of IgM antibodies

Hepatitis B (acute and chronic)—by detection of HBsAg or IgM antibodies

Hepatitis C (acute and chronic)—by hepatitis C virus antibody (anti-HCV) screening test positive with a signal-to-cutoff ratio predictive of a true positive as determined for the particular assay as defined by CDC, HCV antibody positive by immunoblot (RIBA), or HCV RNA positive by nucleic acid test. For all hepatitis C

patients, also report available results of serum alanine aminotransferase (ALT), anti-HAV IgM, anti-HBc IgM, and HBsAg

Human immunodeficiency virus infection—by culture, antigen detection, nucleic acid detection, or detection of antibody confirmed with a supplemental test. For HIV-infected patients, report all results of CD4 and HIV viral load tests

Influenza—by culture, antigen detection by direct fluorescent antibody (DFA)₁ or nucleic acid detection

~~Lead-elevated~~ Lead, elevated blood levels—by blood lead level greater than or equal to 10 µg/dL in children ages 0-15 years, or greater than or equal to 25 µg/dL in persons older than 15 years of age

Legionellosis—by culture, antigen detection (including urinary antigen), nucleic acid detection, or serologic results consistent with recent infection

Listeriosis—by culture

Lyme disease—by culture, antigen detection, or detection of antibody confirmed with a supplemental test

Malaria—by microscopic examination, antigen detection, or nucleic acid detection

*Measles (rubeola)—by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

*Meningococcal disease—by culture or antigen detection from a normally sterile site

*Monkeypox—by culture or nucleic acid detection

Mumps—by culture, nucleic acid detection, or serologic results consistent with recent infection

*Mycobacterial diseases—(See 12VAC5-90-225 B) Report any of the following:

1. Acid fast bacilli by microscopic examination;
2. Mycobacterial identification—preliminary and final identification by culture or nucleic acid detection;
3. Drug susceptibility test results for *M. tuberculosis*.

*Pertussis—by culture, antigen detection, or nucleic acid detection

*Plague—by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

~~*Poliomyelitis—by~~ *Poliovirus infection—by culture

*Psittacosis—by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

*Q fever—by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

*Rabies, human and animal—by culture, antigen detection by direct fluorescent antibody test, nucleic acid detection, or, for humans only, serologic results consistent with recent infection

~~[Rocky Mountain spotted fever—by culture, antigen detection (including immunohistochemical staining), nucleic acid detection, or serologic results consistent with recent infection]~~

*Rubella—by culture, nucleic acid detection, or serologic results consistent with recent infection

Salmonellosis—by culture

*Severe acute respiratory syndrome—by culture, nucleic acid detection, or serologic results consistent with recent infection

Shigellosis—by culture

*Smallpox (variola)—by culture or nucleic acid detection

[Spotted fever rickettsiosis—by culture, antigen detection (including immunohistochemical staining), nucleic acid detection, or serologic results consistent with recent infection]

Staphylococcus aureus infection, resistant, as defined below.

1. Methicillin-resistant - by antimicrobial susceptibility testing of a Staphylococcus aureus isolate, with a susceptibility result indicating methicillin resistance, cultured from a normally sterile site
2. Vancomycin-intermediate or vancomycin-resistant Staphylococcus aureus infection - by antimicrobial susceptibility testing of a Staphylococcus aureus isolate, with a vancomycin susceptibility result of intermediate or resistant, cultured from a clinical specimen

Streptococcal disease, Group A, ~~invasive~~—by invasive or toxic shock—by culture from a normally sterile site

Streptococcus pneumoniae infection, invasive, in children <5 years of age—by culture from a normally sterile site in a child under the age of five years

*Syphilis—by microscopic examination (including dark field), antigen detection (including direct fluorescent antibody), or serology by either treponemal or nontreponemal methods

Toxic substance-related illness—by blood or urine laboratory findings above the normal range, including but not limited to heavy metals, pesticides, and industrial-type solvents and gases. When applicable and available, report speciation of metals when blood or urine levels are elevated in order to differentiate the chemical species (elemental, organic, or inorganic).

Trichinosis (trichinellosis)—by microscopic examination of a muscle biopsy or serologic results consistent with recent infection

*Tularemia—by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

~~*Typhoid~~ [~~*Typhoid/paratyphoid~~ *Typhoid/Paratyphoid] fever—by culture

*Vaccinia, disease or adverse event—by culture or nucleic acid detection

*Vibrio infection—by culture

*Viral hemorrhagic fever—by culture, antigen detection (including immunohistochemical staining), nucleic acid detection, or serologic results consistent with recent infection

*Yellow fever—by culture, antigen detection, nucleic acid detection, or serologic results consistent with recent infection

Yersiniosis—by culture, nucleic acid detection, or serologic results consistent with recent infection

C. Reportable diseases requiring rapid communication. Certain of the diseases in the list of reportable diseases, because of their extremely contagious nature or their potential for greater harm, or both, require immediate identification and control. Reporting of persons confirmed or suspected of having these diseases, listed below, shall be made ~~within 24 hours~~ immediately by the most rapid means available, preferably that of telecommunication (e.g., telephone, telephone transmitted facsimile, pagers, etc.) to the local health director or other professional employee of the department. (These same diseases are also identified by an asterisk (*) in subsection A and subsection B, where applicable, of this section.)

Anthrax

Botulism

Brucellosis

Cholera

Diphtheria

Disease caused by an agent that may have been used as a weapon

Haemophilus influenzae infection, invasive

Hepatitis A

~~Influenza~~ Influenza-associated deaths in children <18 years of age

Influenza A, novel virus

Measles (Rubeola)

Meningococcal disease

Monkeypox

Outbreaks, all

Pertussis

Plague

~~Poliomyelitis~~ Poliovirus infection, including poliomyelitis

Psittacosis

Q fever

Rabies, human and animal

Rubella, including congenital rubella syndrome

Severe acute respiratory syndrome (SARS)

Smallpox (Variola)

Syphilis, primary and secondary

Tuberculosis, active disease

Tularemia

Typhoid [~~*Typhoid/paratyphoid~~ *Typhoid/Paratyphoid] fever

Unusual occurrence of disease of public health concern

Vaccinia, disease or adverse event

Vibrio infection

Viral hemorrhagic fever

Yellow ~~Fever~~ fever

D. Toxic substance-related illnesses. All toxic substance-related illnesses, including pesticide and heavy metal poisoning or illness resulting from exposure to an occupational dust or fiber or radioactive substance, shall be reported.

If such illness is verified or suspected and presents an emergency or a serious threat to public health or safety, the report of such illness shall be by rapid communication as in subsection C of this section.

E. Outbreaks. The occurrence of outbreaks or clusters of any illness which may represent a group expression of an illness which may be of public health concern shall be reported to the local health department by the most rapid means available.

F. Unusual or ill-defined diseases or emerging or reemerging pathogens. Unusual or emerging conditions of public health concern shall be reported to the local health department by the most rapid means available. In addition, the commissioner or his designee may establish surveillance systems for diseases or conditions that are not on the list of reportable diseases. Such surveillance may be established to identify cases (delineate the magnitude of the situation), to identify the mode of transmission and risk factors for the disease, and to identify and implement appropriate action to protect public

health. Any person reporting information at the request of the department for special surveillance or other epidemiological studies shall be immune from liability as provided by § 32.1-38 of the Code of Virginia.

12VAC5-90-90. Those required to report.

A. Physicians. Each physician who treats or examines any person who is suffering from or who is suspected of having a reportable disease or condition shall report that person's name, address, age, date of birth, race, sex, and pregnancy status for females; name of disease diagnosed or suspected; the date of onset of illness; and the name, address, and telephone number of the physician and medical facility where the examination was made, except that influenza should be reported by number of cases only (and type of influenza, if available). Reports are to be made to the local health department serving the jurisdiction where the physician practices. A physician may designate someone to report on his behalf, but the physician remains responsible for ensuring that the appropriate report is made. Any physician, designee, or organization making such report as authorized herein shall be immune from liability as provided by § 32.1-38 of the Code of Virginia.

Such reports shall be made on a form to be provided by the department (Form Epi-1), a computer generated printout containing the data items requested on Form Epi-1, or a Centers for Disease Control and Prevention (CDC) surveillance form that provides the same information and shall be made within three days of the suspicion or confirmation of disease unless the disease in question requires rapid reporting under 12VAC5-90-80 C. Reporting may be done by means of secure electronic transmission upon agreement of the physician and the department.

Pursuant to § 32.1-49.1 of the Code of Virginia, additional elements are required to be reported for individuals with confirmed or suspected active tuberculosis disease. Refer to Part X for details on these requirements.

B. Directors of laboratories. Any person who is in charge of a laboratory conducting business in the Commonwealth shall report any laboratory examination of any clinical specimen, whether performed in-house or referred to an out-of-state laboratory, which yields evidence, by the laboratory method(s) indicated or any other confirmatory test, of a disease listed in 12VAC5-90-80 B.

Each report shall give the source of the specimen and the laboratory method and result; the name, address, age, date of birth, race, sex, and pregnancy status for females (if known) of the person from whom the specimen was obtained; and the name, address, and telephone number of the physician and medical facility for whom the examination was made. When the influenza virus is isolated, the type should be reported, if available. Reports shall be made within three days of identification of evidence of disease, except that those identified by an asterisk shall be reported ~~within 24 hours~~ by the most rapid means available, to the local health department serving the jurisdiction in which the laboratory is located. Reports shall be made on Form Epi-1 or on the laboratory's own form if it includes the required information. Computer generated reports containing the required information may be submitted. Reporting may be done by means of secure electronic transmission upon agreement of the laboratory director and the department. Any person making such report as authorized herein shall be immune from liability as provided by § 32.1-38 of the Code of Virginia.

A laboratory identifying evidence of ~~anthrax, cholera, diphtheria, E. coli O157 infection, invasive H. influenzae infection, listeriosis, meningococcal disease, pertussis, plague, poliomyelitis, salmonellosis, shigellosis, invasive Group A streptococcal disease,~~

~~yersiniosis, and other diseases as may be requested by the health department, shall notify the health department of the positive culture and submit the initial isolate to the Virginia Division of Consolidated Laboratory Services (DCLS). Stool specimens that test positive for Shiga toxin shall be submitted to DCLS for organism identification. A laboratory identifying Mycobacterium tuberculosis complex (see 12VAC5-90-225) shall submit a representative and viable sample of the initial culture to DCLS or other laboratory designated by the board to receive such specimen. any of the following conditions shall notify the health department of the positive culture and submit the initial isolate to the Virginia Division of Consolidated Laboratory Services (DCLS). All specimens must be identified with the patient and physician information required in this subsection.~~

Anthrax

Brucellosis

Cholera

Diphtheria

E. coli infection, Shiga toxin-producing. (Laboratories that use a Shiga toxin EIA methodology but do not perform simultaneous culture for Shiga toxin-producing E. coli should forward all positive stool specimens or positive broth cultures to DCLS for confirmation and further characterization.)

Haemophilus influenzae infection, invasive

Influenza A, novel virus

Listeriosis

Meningococcal disease

Pertussis

Plague

Poliovirus infection

Q fever

Salmonellosis

Shigellosis

Streptococcal disease, Group A, invasive

Tuberculosis (A laboratory identifying Mycobacterium tuberculosis complex (see 12VAC5-90-225) shall submit a representative and viable sample of the initial culture to DCLS or other laboratory designated by the board to receive such specimen.)

[Typhoid Typhoid/Paratyphoid] fever

Vancomycin-intermediate or vancomycin-resistant Staphylococcus aureus infection

Yersiniosis

Other diseases as may be requested by the health department

Laboratories operating within a medical care facility shall be considered to be in compliance with the requirement to notify the health department when the director of that medical care facility assumes the reporting responsibility; however, laboratories are still required to submit isolates to DCLS or other designated laboratory as noted above.

C. Persons in charge of a medical care facility. Any person in charge of a medical care facility shall make a report to the local health department serving the jurisdiction where the facility is located of the occurrence in or admission to the facility of a patient with a reportable disease listed in 12VAC5-90-80 A unless he has evidence that the occurrence has been reported by a physician. Any person making such report as

authorized herein shall be immune from liability as provided by § 32.1-38 of the Code of Virginia. The requirement to report shall include all inpatient, outpatient and emergency care departments within the medical care facility. Such report shall contain the patient's name, address, age, date of birth, race, sex, and pregnancy status for females; name of disease being reported; the date of admission; hospital chart number; date expired (when applicable); and attending physician. Influenza should be reported by number of cases only (and type of influenza, if available). Reports shall be made within three days of the suspicion or confirmation of disease unless the disease in question requires rapid reporting under 12VAC5-90-80 C and shall be made on Form Epi-1, a computer generated printout containing the data items requested on Form Epi-1, or a Centers for Disease Control and Prevention (CDC) surveillance form that provides the same information. Reporting may be done by means of secure electronic transmission upon agreement of the medical care facility and the department.

A person in charge of a medical care facility may assume the reporting responsibility on behalf of the director of the laboratory operating within the facility.

D. Persons in charge of a residential or day program, service, or facility licensed or operated by any agency of the Commonwealth, [or a] school, child care center, or summer camp. Any person in charge of a residential or day program, service, or facility licensed or operated by any agency of the Commonwealth, [or a] school, child care center, or summer camp as defined in § 35.1-1 of the Code of Virginia shall report immediately to the local health department the presence or suspected presence in his program, service, facility, school, child care center, or summer camp of children persons who have common symptoms suggesting an ~~epidemic~~ or outbreak situation. Such persons may ~~notify the local health department of~~ report additional information, including

individual cases of communicable diseases that occur in their facilities. Any person so reporting shall be immune from liability as provided by § 32.1-38 of the Code of Virginia.

E. Local health directors. The local health director shall forward any report of a disease or report of evidence of a disease which has been made on a resident of his jurisdiction to the Office of Epidemiology within three days of receipt. This report shall be submitted immediately by ~~telecommunication~~ the most rapid means available if the disease is one requiring rapid communication, as required in 12VAC5-90-80 C. All such rapid reporting shall be confirmed in writing and submitted to the Office of Epidemiology within three days. Furthermore, the local health director shall immediately forward to the appropriate local health director any disease reports on individuals residing in the latter's jurisdiction or to the Office of Epidemiology on individuals residing outside Virginia.

F. Persons in charge of hospitals, nursing facilities or nursing homes, assisted living facilities, and correctional facilities. In accordance with § 32.1-37.1 of the Code of Virginia, any person in charge of a hospital, nursing facility or nursing home, assisted living facility, or correctional facility shall, at the time of transferring custody of any dead body to any person practicing funeral services, notify the person practicing funeral services or his agent if the dead person was known to have had, immediately prior to death, an infectious disease which may be transmitted through exposure to any bodily fluids. These include any of the following infectious diseases:

Creutzfeldt-Jakob disease

Human immunodeficiency virus infection

Hepatitis B

Hepatitis C

Monkeypox

Rabies

Smallpox

Syphilis, infectious

Tuberculosis, active disease

Vaccinia, disease or adverse event

Viral hemorrhagic fever

G. Employees, applicants, and persons in charge of food establishments. 12VAC5-421-80 of the Food Regulations requires a food employee or applicant to notify the person in charge of the food establishment when diagnosed with certain diseases that are transmissible through food. 12VAC5-421-120 requires the person in charge of the food establishment to notify the health department. Refer to the appropriate sections of the Virginia Administrative Code for further guidance and clarification regarding these reporting requirements.



COMMONWEALTH of VIRGINIA

Karen Remley, MD, MBA, FAAP
State Health Commissioner

Department of Health
P O BOX 2448
RICHMOND, VA 23218

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

April 2, 2010

Memorandum

To: State Board of Health

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

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

Enclosed you will find draft *Regulations for the Virginia Immunization Information System (VIIS)* for your review and discussion at the April 23, 2010, meeting of the Board of Health. Their purpose is to establish a system that will contain birth to death immunization histories of participants. The Board is required to promulgate regulations to implement VIIS by the Code of Virginia, §32.1-46.01.

The comment period for the Notice of Intended Regulatory Action ended on September 30, 2009. No comments were received. The regulation has been reviewed and approved by both Robin Kurz, of the Office of the Attorney General, and Dr. James Burns, Deputy Commissioner for Public Health. I look forward to discussing this regulatory action with you at the upcoming meeting.

If the Board approves them, the proposed regulations will be posted to the Virginia Town Hall for Executive Branch review prior to publication in the *Virginia Register*. The public will be able to comment on the proposed regulations for a sixty day period after publication.



Proposed Regulation Agency Background Document

Agency name	Department of Health/Office of Epidemiology/Division of Immunization
Virginia Administrative Code (VAC) citation	12 VAC 5 -115
Regulation title	Virginia Immunization Information System
Action title	Regulations for the Virginia Immunization Information System (VIIS)
Date this document prepared	4-5-2010

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

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

§32.1-46.01 of the Code of Virginia requires the State Board of Health to establish regulations for the Virginia Immunization Information System (VIIS). VIIS is a statewide immunization registry that consolidates patient immunization histories from birth to death into a complete, accurate, and definitive record that can be available to Virginia's participating health care providers. VIIS is intended to (i) protect the public health of all citizens of the Commonwealth, (ii) prevent under- and over-immunization of children (iii) ensure up-to-date recommendations for immunization scheduling to health care providers and the Board, (iv) generate parental reminder and recall notices and manufacturer recalls, (v) develop immunization coverage reports, (vi) identify areas of under-immunized population, and (vii) provide, in the event of a public health emergency, a mechanism for tracking the distribution and administration of immunizations, immune globulins, or other preventive medications or emergency treatments.

The VIIS regulations are designed to: (1) ensure compatibility with current state and federal guidelines in the areas of patient data confidentiality and system security; (2)

support the public and private health sectors, and current medical guidelines; (3) support VDH/Emergency Preparedness and Response during a public health emergency; (4) facilitate data capture of patient immunization transactions into VIIS; (5) support the delivery of complete, accurate, and up-to-date patient immunization records to VIIS participants in the health care community; (6) define who is allowed access to VIIS; (7) specify requirements for access; (8) specify procedures for patient opt-out; and (9) define penalties for misuse of VIIS or its data.

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.

"ACIP" means Advisory Committee on Immunization Practices

"CDC" means Centers for Disease Control and Prevention

"DOE" means Department of Education

"DMAS" means Department of Medical Assistance Services

"DSS" means Department of Social Services

"EHR" means electronic health record

"IIS" means an immunization information system

"UTD" means the client has received all age-appropriate vaccines

"VDH" means the Virginia Department of Health

"VDH/DOI" means the Virginia Department of Health/ Division of Immunization

"VIIS" means the Virginia Immunization Information System

Legal basis

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

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

Purpose

The purpose of this regulatory action is to comply with two bills dealing with the statewide immunization registry, SB 1132 and HB 2519. The identical bills were presented by Senator Janet D. Howell and Delegate John M. O'Bannon, III, during the 2005 session of the General Assembly, and called for the establishment of the Virginia Immunization Information System. VIIS contains the birth to death immunization histories of participants and merges this immunization data from all health care providers for a patient into one complete, accurate and definitive record. This consolidated record will be available to participating health care providers in Virginia. § 32.1-46.01 of the Code of Virginia requires the State Board of Health to establish regulations for VIIS.

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

Substance

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

Regulations for VIIS will include all necessary definitions and cover three main areas: 1) users of the VIIS application; 2) data entry by organizations exchanging immunization data with VIIS; and 3) approved and non-approved uses of VIIS data.

The regulations will define who may be an authorized user of VIIS; describe the voluntary enrollment process and the necessary registration procedures, including any forms or agreements for compliance with regulations of the U.S. Department of Health & Human Services concerning patient privacy; and describe the process for confirming, continuing and terminating participation in VIIS. They will also include opt-out procedures for clients who choose not to be included in VIIS.

Regulations dealing with the exchange of immunization information from other electronic systems will include ensuring secure data exchange and entry and will also address patient confidentiality. The regulations will describe reporting procedures, including timelines and formats; the use of data from Vital Statistics in populating VIIS; and the incorporation of existing immunization data into VIIS. They will also define patient-identifying information and immunization data.

The approved uses of data, both with and without personal identifiers, will be defined and will include handling requests for immunization records as well as requests for aggregate data. The procedures for requesting data, the identity of qualified recipients, the purpose and mechanism for its release will be defined. Disciplinary procedures for

unauthorized use or disclosure of data will be stated. VIIS will also include mechanisms for entering into data-sharing agreements with other state and regional immunization registries or organizations on a non-emergency basis, and methods for access to or release of data in public health emergencies declared by the Commissioner of Health.

Issues

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

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
 - 2) the primary advantages and disadvantages to the agency or the Commonwealth; and*
 - 3) other pertinent matters of interest to the regulated community, government officials, and the public.*
- If the regulatory action poses no disadvantages to the public or the Commonwealth, please so indicate.*

An accurate patient immunization record allows health care providers to diagnose more effectively and to recommend immunizations to ensure patients receive all the age-appropriate vaccines that are recommended by ACIP at the CDC. Accurate information also decreases costs in the areas of duplicated immunizations, reminders of vaccinations that are due, manufacturer recall procedures, and data collection for identifying and targeting immunization coverage improvement activities.

An additional advantage to the Commonwealth is that VIIS will protect and improve the health of Virginians. It will allow for improved patient care because the system allows physicians to provide information regarding all of the age-appropriate immunizations. An incomplete immunization record can lead to under- or over-immunized children. Under-immunized children do not receive the recommended ACIP vaccines and are vulnerable to preventable and serious illness, and over-immunized children have received unneeded duplicate vaccines. Over-immunization is costly because of unnecessary health care visits and time away from work for a parent or guardian; unnecessary discomfort to the child with an increased chance of reaction to unnecessary vaccine; wasted vaccine, and unnecessary administrative costs and staff time.

Additional benefits include:

- removing the parental requirement to take the immunization record to each visit to the child's provider(s);
- preventing additional visits to the child's provider(s) by identifying all age-appropriate immunizations that may be given at the current visit;
- providing emergency room access to check the child's immunization status at the time of an injury;
- providing information needed to create reminder/recall notices for recommended immunizations that are due or overdue;
- simplifying the process for obtaining the child's immunization history for admission to schools, daycares, camps, etc.;

- identifying and recalling the child who may need additional vaccines due to:
 - having received a vaccine that was later recalled, or
 - not having received a recommended vaccine due to short supply;
- guaranteeing lifetime access to the client’s immunization history even if the health care provider’s office is no longer in operation.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal, which are 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.

VIIS is a partnership between the public and private health sectors of Virginia. All localities in the state would be 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 board/agency is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code 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.

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

Economic impact

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

<p>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source, and (b) a delineation of one-time versus on-going expenditures.</p>	<p>There are three types of costs incurred with an IIS: building costs for construction, maintenance costs for continued operation (including costs for improving and upgrading the system), and user costs for participants. As VIIS has been operational since 2006, the building costs have been met with 100% federal financial assistance and only on-going maintenance and user costs will be discussed.</p> <p>Historically, the state maintenance costs for the operation of VIIS are approximately \$2.3 million per year. The federal funding codes are 607 40502 1000. This figure includes the following on-going expenditures: management of the system by an outside vendor; salaries for VDH/DOI staff necessary for program management, including planning and performing of daily operations as well as quality assurance and improvement activities, and recruitment, training and monitoring of participants; supplies; hardware upgrades for the system's successful operation, and travel expenses for continuing education of staff and for necessary visits to participant's offices.</p>
<p>Projected cost of the <i>new regulations or changes to existing regulations</i> on localities.</p>	<p>There are no projected costs to localities for VIIS. Enrollment in VIIS is voluntary, and the web-based system is available free of charge. If qualified persons elect to participate, the costs incurred by the users are limited: a computer with internet access (high speed connection is desirable, but not necessary), staff time to complete registration and security forms for participation, training and customizing the system for their facility, adding users within their facility, and if they elect to do so, staff time for entering their client's previous immunization histories. After VIIS access is granted to the provider, the</p>

	<p>staff must enter inventory into the system and when giving an immunization, register the client (if the client does not already exist in the system) and enter their immunization data.</p>																				
<p>Description of the individuals, businesses or other entities likely to be affected by the <i>new regulations or changes to existing regulations.</i></p>	<p>Various categories of persons and entities that normally give immunizations would be affected by VIIS regulations. Because there would be one consolidated immunization record for the VIIS client from multiple providers, users could provide age-appropriate immunizations to these patients, and thus avoid unnecessary duplicate immunizations because either no record or an incomplete immunization record was available for the child. These immunizers are listed in Chart 1 below.</p> <p>CHART 1- Typical users of VIIS</p> <table border="1" data-bbox="857 961 1432 1877"> <thead> <tr> <th data-bbox="863 961 1175 1033">Category of Typical User</th> <th data-bbox="1182 961 1425 1033">Approximate Number</th> </tr> </thead> <tbody> <tr> <td data-bbox="863 1041 1175 1289">Private doctors, including pediatricians, family medicine practices, internal medicine physicians and OB/GYN practices.</td> <td data-bbox="1182 1041 1425 1289">4,500 with 1700 sites that may be large or small practices</td> </tr> <tr> <td data-bbox="863 1297 1175 1436">Community Health Centers and Federally Qualified Health Centers</td> <td data-bbox="1182 1297 1425 1436">200</td> </tr> <tr> <td data-bbox="863 1444 1175 1478">Care-A-Vans</td> <td data-bbox="1182 1444 1425 1478">2</td> </tr> <tr> <td data-bbox="863 1486 1175 1583">Local health departments and clinics</td> <td data-bbox="1182 1486 1425 1583">135</td> </tr> <tr> <td data-bbox="863 1591 1175 1625">Hospitals</td> <td data-bbox="1182 1591 1425 1625">200</td> </tr> <tr> <td data-bbox="863 1633 1175 1701">Adult and Child Care Programs</td> <td data-bbox="1182 1633 1425 1701">3,000</td> </tr> <tr> <td data-bbox="863 1709 1175 1776">Schools, Colleges and Universities</td> <td data-bbox="1182 1709 1425 1776">4,000</td> </tr> <tr> <td data-bbox="863 1785 1175 1818">Health Care Plans</td> <td data-bbox="1182 1785 1425 1818">100</td> </tr> <tr> <td data-bbox="863 1827 1175 1877">Detention Centers and other</td> <td data-bbox="1182 1827 1425 1877">NA</td> </tr> </tbody> </table>	Category of Typical User	Approximate Number	Private doctors, including pediatricians, family medicine practices, internal medicine physicians and OB/GYN practices.	4,500 with 1700 sites that may be large or small practices	Community Health Centers and Federally Qualified Health Centers	200	Care-A-Vans	2	Local health departments and clinics	135	Hospitals	200	Adult and Child Care Programs	3,000	Schools, Colleges and Universities	4,000	Health Care Plans	100	Detention Centers and other	NA
Category of Typical User	Approximate Number																				
Private doctors, including pediatricians, family medicine practices, internal medicine physicians and OB/GYN practices.	4,500 with 1700 sites that may be large or small practices																				
Community Health Centers and Federally Qualified Health Centers	200																				
Care-A-Vans	2																				
Local health departments and clinics	135																				
Hospitals	200																				
Adult and Child Care Programs	3,000																				
Schools, Colleges and Universities	4,000																				
Health Care Plans	100																				
Detention Centers and other	NA																				

	Government agencies such as DMAS, DSS and DOE	
	Military	NA
<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 (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>Over 12,137 sites will be affected by VIIS (See Chart 1 for details).</p>	
<p>All projected costs of the <i>new regulations or changes to existing regulations</i> for affected individuals, businesses, or other entities. Please be specific and do include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.</p>	<p>As stated earlier, the VIIS system is free to all users who have been approved by VDH. VIIS may be used in two ways: direct entry of immunization data into the system through user interface or by data exchange of immunization data from other information systems (e.g., billing systems or electronic medical records such as Regional Health Information Organizations, and Health Information Exchanges). If data exchange is chosen, the organization has the cost of putting the data from their system in the required format that is accepted by VIIS.</p> <p>For persons electing to use VIIS by user interface, there would be the cost of additional staff time to complete registration and security forms for participation, training and customizing the application for their facility, adding users within their facility, and if they elect to do so, entering the previous immunization history of their clients. After VIIS access is granted to the provider, the staff must enter inventory into the system and when giving an immunization, register the client (if s/he does not already exist in the system) and enter the immunization data. A computer with internet access is necessary (a high speed connection is desirable, but not necessary).</p>	
<p>Beneficial impact the regulation is designed</p>	<p>1. Provide accurate immunization records</p>	

<p>12. to produce.</p>	<ol style="list-style-type: none"> 2. Identify age-appropriate vaccines for specific client 3. Reduce duplicate vaccines 4. Notify recipients of recalled vaccines 5. Recall patients after vaccine shortages have been alleviated 6. Improve inventory management 7. Identify pockets of need 8. Use in a public health emergency 9. Provide official immunization records for parents/guardians 10. Improve health by the use of health information technology 11. Improve immunization rates 12. Save the state money by changing existing programs * <p>* documentation available from VDH/DOI</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.

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

Regulatory flexibility analysis

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

There is no alternative to developing the VIIS regulations because the Code of Virginia requires it. Participation in VIIS is voluntary, so health care practices are not required to participate.

Public comment

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

No comments were received following the publication of the NOIRA.

Family impact

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

No adverse impact on the institution or the family or family stability is anticipated in developing the regulations for VIIS. VIIS should protect and improve the health of Virginians. The most obvious benefit to the family is the provision of complete immunization histories for children, which allows physicians to provide all age-appropriate immunizations recommended by ACIP. An incomplete immunization history can lead to under- or over-immunized children

Detail of changes

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

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
12VAC5-115-10	Definitions of words and terms used in chapter 115.	§32.1-46.01	To ensure consistency in interpretation of VIIS regulations.
12VAC5-115-20	Authority granted to promulgate regulations for the operation of VIIS.	§32.1-46.01	To allow the Board of Health to develop regulations for the operation of VIIS.
12VAC5-115-30	Describes the policies and procedures for implementation of VIIS.	§32.1-46.01	To define the purpose of the regulations.
12VAC5-115-40	Authorized users of VIIS that include, but are not limited to, health care plans, schools, licensed or certified health care services or	§32.1-46.01 § 8.01-	To identify the persons or organizations that are allowed to use VIIS.

	providers, and other immunization registries or systems.	581.1	
12VAC5-115-50	Describe registration procedures and activation by VDH. Non-compliance with security agreements may result in termination of VIIS access.	§32.1-46.01	To identify the forms and procedures necessary for compliance with the VIIS regulations.
12VAC5-115-60	Patient confidentiality shall be assured by all users who will comply with federal and state laws and regulations.	§32.1-46.01	To assure clients, parents/guardians and health care providers of the confidentiality of VIIS data.
12VAC5-115-70	Describes additional security requirements for the use of VIIS.	§32.1-46.01	To assure clients, parents/guardians and health care providers of the security of VIIS data.
12VAC5-115-80	Birth certificate data from VDH/Division of Vital Statistics used to populate VIIS initially. Participant data requirements are described. Every effort shall be made to ensure the accuracy of additional data which shall be reported either by online data entry or by data exchange.	§32.1-46.01 §32.1-46	To explain source of VIIS data and to identify the types of information that are entered into the application.
12VAC5-115-90	Data are shared only with approved entities who must submit a written agreement that specifies the intended use of the requested data and with whom it shall be shared. Unless the entity receiving the data is the provider/health care plan for the clients involved, the data shall be stripped of personal identifying data or redacted to prevent identifiable information. All data are encrypted.	§32.1-46.01	To explain the requirements for sharing data with others.
12VAC5-115-100	The Health Commissioner may access VIIS and shall designate authorized viewers of VIIS information in the event of a public health emergency.	§32.1-46.01	To allow the Health Commissioner to designate persons who may view VIIS in the event of a public health emergency.

DEPARTMENT OF HEALTH

Establishment of the Virginia Immunization Information System

CHAPTER 115

VIRGINIA IMMUNIZATION INFORMATION SYSTEM

-

Part I

Definitions

12VAC5-115-10. Definitions.

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

"Commissioner" means the State Health Commissioner, or duly designated officer agent.

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

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

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

"HIPAA" means, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (42 U.S.C.,P.L.104-191; 42 C.F.R. Part 164).

"Immunization" means a process to produce immunity by vaccination.

"Outbreak" means the occurrence of more cases of a disease than expected.

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

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

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

"Record" means the demographic and immunization information of the patient.

"VDH" or "Department of Health" means the Virginia Department of Health.

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

Part II

General Information

12VAC5-115-20. Authority.

§ 32.1-46 of the Code of Virginia requires the Board of Health to establish VIIS, and to promulgate regulations for the operation of VIIS.

12VAC5-115-30. Purpose.

This purpose of these regulations is to address the policies and procedures for the implementation of VIIS, the Virginia statewide immunization registry.

Part III

VIIS Participants

12VAC5-115-40. Authorized participants.

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

B. Any health care plan, school or organization may participate, as long as it is licensed or certified in Virginia to deliver or support health care services or public health,

requires immunization data to perform the health service function, and uses VIIS only for exchanging information on persons for whom it provides services.

C. Other state or regional immunization information systems may have access to and share data with VIIS.

D. Access to VIIS information is authorized under the condition that having access to immunization information is required to perform the job function of the participant.

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

12VAC5-115-50. Registration procedures.

A. Participation in VIIS is voluntary.

B. Participants shall register to assure compliance with necessary confidentiality and security access provisions. Participants shall update their registration on a regular schedule as designated per VDH.

C. Qualifying participant organizations shall designate an administrator for their organization. The administrator may then allow VIIS access by an employee in the organization, and in doing so shall assume responsibility for registering that person, obtain the necessary security forms, retain all forms, assign the security role, accept legal responsibility for the proper use of VIIS, and terminate access to VIIS if an employee is noncompliant with the VIIS Confidentiality/Security Agreement or no longer requires access.

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

Part IV

Data

12VAC5-115-60. Patient confidentiality.

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

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

C. Any inappropriate use of VIIS, including a violation of HIPAA, shall result in immediate suspension of participant privileges and an investigation conducted by VDH. Additional actions may be taken pursuant to Virginia Code § 32.1-27. Upon satisfaction as to the compensatory actions of the participant, and guarantee of proper use of VIIS in the future, the manager of the VIIS program at VDH may reinstate privileges.

D. All patients shall have the opportunity to decline to participate in VIIS. Records of patients who have declined to participate will be viewable only by the primary care provider.

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

F. Nothing in these regulations alters the provision in HIPAA that permits covered entities to disclose identifiable health information to a public health authority without individual authorization.

12VAC5-115-70. Security.

Participants must agree not to disclose their user identification code or password to anyone; to have physical security and password-enabled screen savers on computers accessing VIIS; to make every effort to protect VIIS screens from unauthorized view; and to log off of the system whenever leaving the VIIS workstation.

12VAC5-115-80. Population of VIIS.

A. VDH and Vital Statistics have an agreement to populate VIIS with birth certificate data of children born in Virginia and remove deceased clients in VIIS based on death certificate data.

B. Each participant shall make every effort to ensure the accuracy of all immunization and demographic information and shall include enough identifying information to allow matching of incoming data with existing client records so data may be merged appropriately.

C. Data shall be reported in VIIS either by online data entry or by data exchange of files from other information systems. The health care provider or the designated health care plan billed for the immunization may report. Reporting shall occur within designated time frames as determined by VDH.

D. Any organizations or individuals participating in data exchange shall provide an acceptable level of data quality as defined by VDH. Any rejected records shall be resolved by the participant in a timely way. VDH may suspend system privileges and refer to Virginia Code § 32.1-27 for additional action for any organization that knowingly submits erroneous data.

E. Both demographic and immunization data shall be reported by the participant in accordance with standards as established by VDH.

F. Participants shall identify a contact person to work with VDH on files with insufficient information.

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

A. Specific patient data shall be released only to those participants providing and delivering health care services to that patient. Requests for patient-level data must identify the nature of the information requested and include evidence of the authority of the requester and identification of the person to whom the information is to be disclosed.

B. Aggregate data from VIIS may be released for the purposes of research, statistical analysis or reporting only after approval by VDH. Individual identifying information shall not be released for research studies unless VIIS data verify that the client information belongs to the health care organization or provider receiving the data.

C. Entities utilizing data exchange shall enter into a written data sharing agreement with VDH for the exchange of patient demographic and immunization information. The agreement shall specify the intended use of the data and any other information as required by VDH.

D. Inappropriate use of VIIS data shall result in immediate suspension of user privileges and result in an investigation conducted by VDH. Additional actions may be taken due to unauthorized or inappropriate use.

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

A. The Commissioner of Health may access VIIS data in the event of an epidemic, outbreak of a vaccine-preventable disease or any disease of public health significance.

B. The Commissioner shall designate who is authorized to view VIIS information during a public health emergency.

Certification Statement:

I certify that this regulation is full, true, and correctly dated.

_____ (Signature of certifying official)

Name and title of certifying official: _____

Name of agency: _____

Date: _____

MEMORANDUM

DATE: March 17, 2010

TO: Board of Health

FROM: Diane Helentjaris, M.D., Deputy Director
Office of Epidemiology

SUBJECT: **Request For Action By The State Board of Health to Amend Regulations Entitled: Virginia Radiation Protection Regulations, 12 VAC5-481 (Notice of Intended Regulatory Action).**

The Virginia Department of Health (VDH) intends to amend the existing *Virginia Radiation Protection Regulations* (12 VAC 5-481) in order to adopt the latest version of the *Suggested State Regulations Part F Diagnostic X-rays and Imaging Systems in the Healing Arts and Part X Medical Therapy* published in 2009 by the Conference of Radiation Control Program Directors. The request for approval to publish a Notice of Intended Regulatory Action is being presented to the Board of Health for approval at its meeting on April 23, 2010.

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 radiographic practices. The purpose of registering facilities that use x-ray machines is to have an accurate database of who is using these machines and to track the inspection record of the machines. The purpose of machine inspections is to assure compliance with equipment standards. VDH registers approximately 20,000 X-ray machines, and inspects X-ray machines whenever a private inspector is not available, or upon request of a registrant.

Upcoming Steps

Notice of Intended Regulatory Action, TH01, will be published upon approval by the Board of Health . Once the document is submitted for executive review and publication, a public comment period will start.



Virginia
Regulatory
Town Hall

townhall.virginia.gov

Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Department of Health
Virginia Administrative Code (VAC) citation	12 VAC 5-481
Regulation title	Radiation Protection Regulations
Action title	Amend regulation to update sections related to X-ray machines based on latest version of the Suggested State Regulations.
Date this document prepared	March 30, 2010

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

The Virginia Department of Health (VDH) intends to amend the existing Radiation Protection Regulations to update those sections related to X-ray machines using the latest version of the *Suggested State Regulations* published by the Conference of Radiation Control Program Directors, Inc. The amended regulations will provide performance standards for bone densitometers, hand-held X-ray machines, computed radiography and air kerma rate meters on new fluoroscopic and CT machines. The proposed regulatory action is intended to supersede the Radiation Protection Regulations, which became effective September 12, 2006.

Legal basis

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

These regulations are authorized by the Code of Virginia Sections 32.1-227 et seq.

Section 32.1-229.1 The Board shall, in accordance with the Administrative Process Act (§ 2.2-4000 et seq.), promulgate such regulations as the Board deems necessary to protect the health and safety of health care workers, patients, and the general public, including but not limited to regulations to: 2. Schedule for inspections of X-ray machines;... 4. Standards for certification of X-ray machines; and 5. Qualifications for private inspectors.

Refer to the following web site for viewing the statutory authority cited in Section 32.1-229.1 of the Code of Virginia:

<http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-229.1>

The authority to promulgate schedules for inspecting X-ray machines and standards for certification of X-ray machines are mandatory.

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

The Code of Virginia requires VDH to ensure all X-ray machines are registered, periodically inspected and all X-ray machines used in the healing arts must be certified for use. The current regulations do not have performance standards for new technologies such as bone densitometers, hand-held X-ray machines, computed radiography and air kerma rate meters on new fluoroscopic and CT machines. Performance standards must be adopted in order to provide a meaningful certification for these machines and devices. Of particular importance is adopting a performance standard for the air kerma rate meter on new fluoroscopic and CT machines. The meter provides the physician user information regarding the patient's radiation exposure during the medical procedure. Recent scientific literature has reported significant increase in the population's exposure to radiation from medial use of X-ray equipment, specifically fluoroscopic and CT machines.

VDH staff are aware of certain inconsistencies in the regulation. The most significant is the definition of misadministration which is a term that was used for the regulation of both X-ray machines and radioactive materials. However, the U.S. Nuclear Regulatory Commission (NRC), which regulates radioactive material, now uses the term medical event and the definition for misadministration in the regulation was deleted to be compatible with NRC. This deletion inadvertently impacted the sections pertaining to X-ray machines, which still uses this term.

Substance

Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.

Sections of the regulation relating to X-ray machines, including radiation therapy will be updated using the *Suggested State Regulations* published by the Conference of Radiation Control Program Directors, Inc. This publication has been reviewed by the appropriate federal agencies which have concurred with its contents. The specific documents that will be adopted are as follows: Part F Diagnostic X-rays and Imaging Systems in the Healing Arts (2009) and Part X Medical Therapy (2009). These publications and the rationale are available on line at: <http://www.crcpd.org/ssrcr.aspx>

Performance standards for new technologies such as bone densitometers, hand-held X-ray machines, computed radiography and air kerma rate meters on new fluoroscopic and CT machines will be adopted. X-ray machines used in radiation therapy will include performance standards for Intensity Modulated Radiation Therapy, electronic brachytherapy and therapy related computer systems.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

Abolishing the regulation or failure to update the existing regulation would be inconsistent with the agency's mission and the need to provide an adequate regulatory program that protects public health and safety. VDH will consider recommendations from the Radiation Advisory Board and the regulated community for alternative means of meeting the intent of the model regulations or additional requirements to address concerns that may be unique within the Commonwealth.

Public participation

Please indicate the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments on this notice.

The agency is seeking comments on the intended regulatory action, including but not limited to 1) ideas to assist in the development of a proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency is also 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 via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail, email or fax to Les Foldesi, Director, Division of Radiological Health, VDH 109 Governor Street, Room 732, Richmond, VA 23219, Phone:(804) 864-8151, FAX (804) 864-8155, (e-mail: Les.Foldesi@vdh.virginia.gov). Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last day of the public comment period.

A public hearing will not be held.

Participatory approach

Please indicate, to the extent known, if advisers (e.g., ad hoc advisory committees, technical advisory committees) will be involved in the development of the proposed regulation. Indicate that 1) the agency is not using the participatory approach in the development of the proposal because the agency has authorized proceeding without using the participatory approach; 2) the agency is using the participatory

approach in the development of the proposal; or 3) the agency is inviting comment on whether to use the participatory approach to assist the agency in the development of a proposal.

The agency is using the participatory approach in the development of the proposal.

Family impact

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

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

March 26, 2010

MEMORANDUM

TO: The Board of Health

FROM: Chris T. Durrer, FACHE
Director

SUBJ: Exempt regulatory action: Rules and Regulations for the Licensure of Hospitals

After BOH adoption, this regulation will be published in the Virginia Register for 30 days as a final promulgation. This is a nondiscretionary regulatory action and is exempt from the regulatory promulgation process.

Section 2.2-4006 of the Virginia Administrative Process Act (APA) provides that regulatory actions may be exempted from the APA when such actions are “necessary to conform to changes in Virginia statutory law or the appropriation act where no agency discretion is involved.” Chapter 177 of the 2005 Acts of Assembly requires that the physical plant standards for hospitals and outpatient surgery centers be consistent with the current edition of the “Guidelines for Design and Construction of Hospital and Health Care Facilities” (Guidelines) of the Facilities Guideline Institute (FGI), formerly of the American Institute of Architects. This regulatory action adopts the 2010 edition of the Guideline as required by the 2005 legislation.

The Office of Licensure and Certification is taking similar action on the Rules and Regulations for the Licensure of Nursing Facilities.

Thank you.



Exempt Action Final Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12 VAC5-410
Regulation title	Rules and Regulations for the Licensure of Hospitals
Action title	Update of the hospital building/construction regulations
Final agency action date	
Document preparation date	

When a regulatory action is exempt from executive branch review pursuant to § 2.2-4002 or § 2.2-4006 of the Virginia Administrative Process Act (APA), the agency is encouraged to provide information to the public on the Regulatory Town Hall using this form.

Note: While posting this form on the Town Hall is optional, the agency must comply with requirements of the Virginia Register Act, the *Virginia Register Form, Style, and Procedure Manual*, and Executive Orders 36 (06) and 58 (99).

Summary

Please provide a brief summary of all regulatory changes, including the rationale behind such changes. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

Chapter 177 of the 2005 Acts of Assembly requires that the physical plant standards for hospitals and outpatient surgery centers be consistent with the current edition of the “Guidelines for Design and Construction of Hospital and Health Care Facilities” (Guidelines) of the Facilities Guideline Institute (FGI), formerly of the American Institute of Architects. Therefore, the department is amending the *Rules and Regulations for the Licensure of Hospitals in Virginia* (12 VAC 5-410) pursuant to § 2.2-4006 A 4 a of the Code of Virginia (Code). The 2010 edition of the Guideline was released January 2010. This regulatory action adopts the 2010 edition of the Guideline as required by the 2005 legislation. The requirements of the Uniform Statewide Building Code take precedence as authorized by §36-98 of the Code.

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.

The Board of Health approved this non-discretionary action at its April 23, 2010 meeting.

Family impact

Assess the impact of this regulatory action on the institution of the family and family stability.

There is no direct impact on the institution of the family or family stability.

Rules and Regulations for the Licensure of Hospitals in Virginia

Project 2340 - none

DEPARTMENT OF HEALTH
Update of hospital building/construction regulations

12VAC5-410-445. Newborn service design and equipment criteria.

A. Construction and renovation of a hospital's nursery shall be consistent with section ~~2.1-3.6~~ 2.2-2.12.1 through 2.2-2.12.6.6 of Part 2 of the ~~2006~~ 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute (formerly of the American Institute of Architects). Hospitals with higher-level nurseries shall comply with ~~section 2.1-3.4.6~~ sections 2.2-2.10.1 through 2.2-10.9.3 of Part 2 of the ~~2006~~ 2010 guideline as applicable.

B. The hospital shall provide the following equipment in the general level nursery and all higher level nurseries, unless additional equipment requirements are imposed for the higher level nurseries:

1. Resuscitation equipment as specified for the delivery room in 12VAC5-410-442 G 2 shall be available in the nursery at all times;
2. Equipment for the delivery of 100% oxygen concentration, properly heated, blended, and humidified, with the ability to measure oxygen delivery in fractional inspired concentration (FI02). The oxygen analyzer shall be calibrated every eight hours and serviced according to the manufacturer's recommendations by a member of the hospital's respiratory therapy department or other responsible personnel trained to perform the task;
3. Saturation monitor (pulse oximeter or equivalent);
4. Equipment for monitoring blood glucose;
5. Infant scales;
6. Intravenous therapy equipment;
7. Equipment and supplies for the insertion of umbilical arterial and venous catheters;
8. Open bassinets, self-contained incubators, open radiant heat infant care system or any combination thereof appropriate to the service level;
9. Equipment for stabilization of a sick infant prior to transfer that includes a radiant heat source capable of maintaining an infant's body temperature at 99°F;
10. Equipment for insertion of a thoracotomy tube; and
11. Equipment for proper administration and maintenance of phototherapy.

C. The additional equipment required for the intermediate level newborn service and for any higher service level is:

1. Pediatric infusion pumps accurate to plus or minus 1 milliliter (ml) per hour;
2. On-site supply of PgE1;

Virginia Department of Health
Office of Licensure and Certification

Rules and Regulations for the Licensure of Hospitals in Virginia

3. Equipment for 24-hour cardiorespiratory monitoring for neonatal use available for every incubator or radiant warmer;
4. Saturation monitor (pulse oximeter or equivalent) available for every infant given supplemental oxygen;
5. Portable x-ray machine; and
6. If a mechanical ventilator is selected to provide assisted ventilation prior to transport, it shall be approved for the use of neonates.

D. The additional equipment required for the specialty level newborn service and a higher newborn service is as follows:

1. Equipment for 24-hour cardiorespiratory monitoring with central blood pressure capability for each neonate with an arterial line;
2. Equipment necessary for ongoing assisted ventilation approved for neonatal use with on-line capabilities for monitoring airway pressure and ventilation performance;
3. Equipment and supplies necessary for insertion and maintenance of chest tube for drainage;
4. On-site supply of surfactant;
5. Computed axial tomography equipment (CAT) or magnetic resonance imaging equipment (MRI);
6. Equipment necessary for initiation and maintenance of continuous positive airway pressure (CPAP) with ability to constantly measure delineated pressures and including alarm for abnormal pressure (i.e., vent with PAP mode); and
7. Cardioversion unit with appropriate neonatal paddles and ability to deliver appropriate small watt discharges.

E. The hospital shall document that it has the appropriate equipment necessary for any of the neonatal surgical and special procedures it provides that are specified in its medical protocol and that are required for the specialty level newborn service.

F. The additional equipment requirements for the subspecialty level newborn service are:

1. Equipment for emergency gastrointestinal, genitourinary, central nervous system, and sonographic studies available 24 hours a day;
2. Pediatric cardiac catheterization equipment;
3. Portable echocardiography equipment; and
4. Computed axial tomography equipment (CAT) and magnetic resonance imaging equipment (MRI).

G. The hospital shall document that it has the appropriate equipment necessary for any of the neonatal surgical and special procedures it provides that are specified in the medical protocol and are required for the subspecialty level newborn service.

Virginia Department of Health
Office of Licensure and Certification

Rules and Regulations for the Licensure of Hospitals in Virginia

Part III

Standards and Design Criteria for New Buildings and Additions, Alterations and Conversion of Existing Buildings

12VAC5-410-650. General building and physical plant information.

A. All construction of new buildings and additions, renovations, alterations or repairs of existing buildings for occupancy as a hospital shall conform to state and local codes, zoning and building ordinances, and the Uniform Statewide Building Code.

In addition, hospitals shall be designed and constructed according to Part 1 and sections 2.1-1 through ~~2.1-4~~ 2.2-8 of Part 2 of the ~~2006~~ 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute (formerly of the American Institute of Architects). However, the requirements of the Uniform Statewide Building Code and local zoning and building ordinances shall take precedence.

B. All buildings shall be inspected and approved as required by the appropriate building regulatory entity. Approval shall be a Certificate of Use and Occupancy indicating the building is classified for its proposed licensed purpose.

Part V

Design Standards for New Outpatient Surgical Hospitals and Additions and Alterations to Existing Outpatient Surgical Hospitals

Article 1

General Considerations

12VAC5-410-1350. Codes; fire safety; zoning; construction standards.

A. All construction of new buildings and additions alterations or repairs to existing buildings for occupancy as a "free-standing" outpatient hospital shall conform to state and local codes, zoning and building ordinances, and the Statewide Uniform Building Code.

In addition, hospitals shall be designed and constructed according to Part 1 and sections 3.1-1 through ~~3.2-4~~ 3.1-8 and 3.7 of Part 3 of the ~~2006~~ 2010 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute (formerly of the American Institute of Architects). However, the requirements of the Uniform Statewide Building Code and local zoning and building ordinances shall take precedence.

B. All buildings shall be inspected and approved as required by the appropriate building regulatory entity. Approval shall be a Certificate of Use and Occupancy indicating the building is classified for its proposed licensed purpose.

C. The use of an incinerator shall require permitting from the nearest regional office of the Department of Environmental Quality.

Virginia Department of Health
Office of Licensure and Certification

Rules and Regulations for the Licensure of Hospitals in Virginia

D. Water shall be obtained from an approved water supply system. Outpatient surgery centers shall be connected to sewage systems approved by the Department of Health or the Department of Environmental Quality.

E. Each outpatient surgery center shall establish a monitoring program for the internal enforcement of all applicable fire and safety laws and regulations.

F. All radiological machines shall be registered with the Office of Radiological Health of the Virginia Department of Health. Installation, calibration and testing of machines and storage facilities shall comply with 12VAC5-480, Radiation Protection Regulations.

G. Pharmacy services shall comply with Chapter 33 (§ 54.1-3300 et seq.) of Title 54.1 of the Code of Virginia and 18VAC110-20, Regulations Governing the Practice of Pharmacy.

DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-410)

Guidelines for Design and Construction of Health Care Facilities, Facilities Guidelines Institute (formerly of the American Institute of Architects), Washington, D.C., 2006 2010 Edition.

March 26, 2010

MEMORANDUM

TO: The Board of Health

FROM: Chris T. Durrer, FACHE
Director

SUBJ: Exempt regulatory action:
Rules and Regulations for the Licensure of Nursing Facilities

After BOH adoption, this regulation will be published in the Virginia Register for 30 days as a final promulgation. This is a nondiscretionary regulatory action and is exempt from the regulatory promulgation process.

Section 2.2-4006 of the Virginia Administrative Process Act (APA) provides that regulatory actions may be exempted from the APA when such actions are “necessary to conform to changes in Virginia statutory law or the appropriation act where no agency discretion is involved.” Chapter 177 of the 2005 Acts of Assembly requires that the physical plant standards for nursing facilities be consistent with the current edition of the “Guidelines for Design and Construction of Hospital and Health Care Facilities” (Guidelines) of the Facilities Guideline Institute (FGI), formerly of the American Institute of Architects. This regulatory action adopts the 2010 edition of the Guideline as required by the 2005 legislation.

The Office of Licensure and Certification is taking similar action on the Rules and Regulations for the Licensure of Hospitals.

Thank you.



Exempt Action Final Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12 VAC5-371
Regulation title	Rules and Regulations for the Licensure of Nursing Facilities
Action title	Update of the nursing facility building/construction regulations
Final agency action date	
Document preparation date	

When a regulatory action is exempt from executive branch review pursuant to § 2.2-4002 or § 2.2-4006 of the Virginia Administrative Process Act (APA), the agency is encouraged to provide information to the public on the Regulatory Town Hall using this form.

Note: While posting this form on the Town Hall is optional, the agency must comply with requirements of the Virginia Register Act, the *Virginia Register Form, Style, and Procedure Manual*, and Executive Orders 36 (06) and 58 (99).

Summary

Please provide a brief summary of all regulatory changes, including the rationale behind such changes. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

Chapter 177 of the 2005 Acts of Assembly requires that the physical plant standards for nursing facilities be consistent with the current edition of the “Guidelines for Design and Construction of Hospital and Health Care Facilities” (Guideline) of the Facilities Guideline Institute (FGI), formerly of the American Institute of Architects. Therefore, the department is amending the *Rules and Regulations for the Licensure of Nursing Facilities* (12 VAC 5-371) pursuant to § 2.2-4006 A 4a of the Code of Virginia (Code). The 2010 edition of the Guideline was released January 2010. This regulatory action adopts the 2010 edition of the Guideline as required by the 2005 legislation. The requirements of the Uniform Statewide Building Code (USBC) of the Department of Housing and Community Development, as mandated by § 36-98 of the Code of Virginia (Code), and local zoning and building ordinances shall take precedence.

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.

The Board of Health approved this non-discretionary action at its April 23, 2010 meeting.

Family impact

Assess the impact of this regulatory action on the institution of the family and family stability.

There is no direct impact on the institution of the family or family stability.

**Virginia Department of Health
Office of Licensure and Certification**

Rules and Regulations for the Licensure of Nursing Facilities

Project 2341 - none

**DEPARTMENT OF HEALTH
Nursing facility building/construction regulation update**

Part V
Physical Environment

12VAC5-371-410. Architectural drawings and specifications.

A. All construction of new buildings and additions, renovations or alterations of existing buildings for occupancy as a nursing facility shall conform to state and local codes, zoning and building ordinances, and the Uniform Statewide Building Code.

In addition, nursing facilities shall be designed and constructed according to Part 1 (~~4.1 through 1.6-2~~) and sections 4.1-1 through ~~4.1-10~~ 4.2-8 of Part 4 of the 2006 Guidelines for Design and Construction of Health Care Facilities of the Facilities Guidelines Institute (formerly of the American Institute of Architects). However, the requirements of the Uniform Statewide Building Code and local zoning and building ordinances shall take precedence.

B. Architectural drawings and specifications for all new construction or for additions, alterations or renovations to any existing building, shall be dated, stamped with licensure seal and signed by the architect. The architect shall certify that the drawings and specifications were prepared to conform to building code requirements.

C. Additional approval may include a Certificate of Public Need.

D. Upon completion of the construction, the nursing facility shall maintain a complete set of legible "as built" drawings showing all construction, fixed equipment, and mechanical and electrical systems, as installed or built.

DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-371)

Guidelines for Design and Construction of Health Care Facilities, The Facilities Guideline Institute (formerly of the American Institute of Architects Academy of Architecture for Health), 2006 2010 Edition.

Guidelines for Preventing Health Care-Associated Pneumonia, 2003, MMWR 53 (RR03), Advisory Committee on Immunization Practices, Centers for Disease Control and Prevention.

Prevention and Control of Influenza, MMWR 53 (RR06), Advisory Committee on Immunization Practices, Centers for Disease Control and Prevention.