

**State Board of Health – Nominating Committee
Agenda
June 6, 2013 – 8:30 a.m.
Perimeter Center – Training Room 2
9960 Mayland Drive
Richmond, Virginia 23233**

Welcome and Introductions	Steven R. Escobar, DVM, Chair
Discussion	Nominating Committee Members
Adjourn	

**State of Board of Health
Agenda
June 6, 2013 – 9:00 a.m.
Perimeter Center – Boardroom 2
9960 Mayland Drive
Richmond, Virginia 23233**

Call to Order and Welcome	Bruce Edwards, Chair
Pledge of Allegiance	Mr. Edwards
Introductions	Mr. Edwards
Review of Agenda	Joseph Hilbert Director of Governmental and Regulatory Affairs
Approval of April 12, 2013 Minutes	Mr. Edwards
Commissioner’s Report	Cynthia C. Romero, MD, FAAFP State Health Commissioner
Obesity Prevention – Overview	Lauri Kalanges, MD, MPH Acting Director, Office of Family Health Services Mr. Hilbert
Break	
Abortion Facility Licensure Status Report	Erik Bodin, Director Office of Licensure and Certification
Regulatory Action Update	Mr. Hilbert
Public Comment Period	

Nominating Committee Report

Dr. Escobar

Election of Officers and Executive
Committee Members

Mr. Edwards

Lunch

Action Items

Designation of Regional Emergency Medical
Services Councils
(§ 32.1-111.11 of the Code of Virginia)

Gary Brown, Director
Office of Emergency

Regulatory Action Items

Regulations Governing Virginia Newborn
Screening Services
12VAC5-71
(Proposed Amendments)

Dr. Kalanges

Regulations for the Conduct of Human Research
12VAC5-20
(Proposed Amendments)

Dr. Kalanges

Member Reports

Other Business

Adjourn



COMMONWEALTH of VIRGINIA
Department of Health

Cynthia C. Romero, MD, FAAFP
State Health Commissioner

Gary R. Brown
Director

P. Scott Winston
Assistant Director

Office of Emergency Medical Services
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Glen Allen, VA 23059-4500

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April 15, 2013

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

Dear Chairman Edwards:

Section 32.1-111.11 of the Code of Virginia states that “The Board shall designate regional emergency medical services councils which shall be authorized to receive and disburse public funds. Each council shall be charged with the development and implementation of an efficient and effective regional emergency medical services delivery system. The Board shall review those agencies that were the designated regional emergency medical services councils. The Board shall, in accordance with the standards established in its regulations, review and may renew or deny applications for such designations every three years. In its discretion, the Board may establish conditions for renewal of such designations or may solicit applications for designation as a regional emergency medical services council.”

In accordance with the Code section above, as well as 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 re-designation as a Regional EMS Council in Virginia.

Applications for designation as Regional EMS Councils were received by OEMS in October of 2012. 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 (Retired), 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

Robert A. Brown
Assistant Chief (Retired), Albemarle County Fire & Rescue
Past Chair – Financial Assistance Review Committee
Past Training Coordinator, Peninsulas EMS Council

Jennie L. Collins
Battalion Chief, Prince William County Department of Fire and Rescue
Past Chair, State EMS Advisory Board
Past Chair, Northern Virginia EMS Council

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

Larry A. Oliver
Deputy Chief, Frederick County Fire and Rescue Department
Member, State EMS Advisory Board
Past Chair, Lord Fairfax EMS Council

Site reviews of all applicant entities were conducted between February 20 and March 28, 2013. A copy of each reviewer report accompanies this cover.

Based on the applications received, as well as the site reviewer reports, the OEMS recommends continued 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.

Northern Virginia EMS Council – Service area including the counties of Arlington, Fairfax, Loudoun, and Prince William; and the cities of Alexandria, Fairfax, Falls Church, Manassas, and Manassas Park.

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.

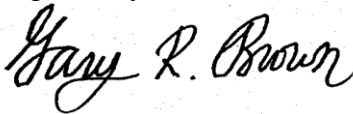
Tidewater EMS Council – Service area including the counties of Accomack, Isle of Wight, Northampton, and Southampton, and the cities of Chesapeake, Franklin, Norfolk, Portsmouth, Suffolk, and Virginia Beach.

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, Danville, 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, 2013.

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.

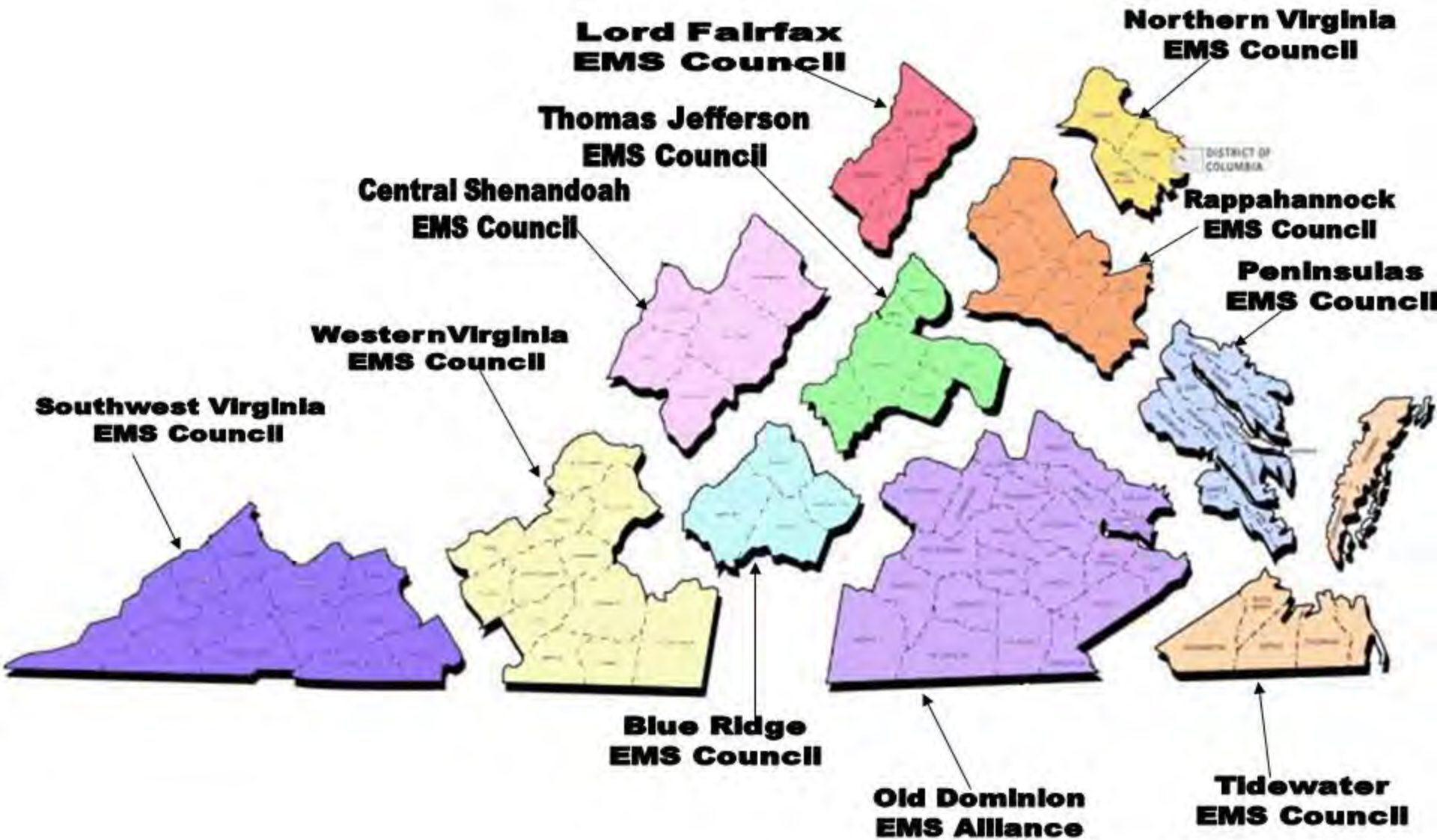
Respectfully submitted,



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

Designated Regional EMS Council Map

July 1, 2013



April 7, 2013

Introduction

As pursuant to 12 VAC 5-31-2300 through 12 VAC 5-31-2300 of the Virginia Emergency Medical Services Regulations Governing Regional Emergency Medical Services Councils, I Jennie L. Collins, participated as a member of a site review team, tasked with evaluation of the Blue Ridge EMS Council on February 26, 2013.

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 the Virginia Emergency Medical Services Regulations.

Site Review

On February 26, 2013, the review team traveled to the Blue Ridge EMS Council office, located at 1900 Tate Springs Road, Suite 14, Lynchburg, Virginia 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. Members interviewed were:

Brad Ferguson, President
Connie Purvis, Executive Director
Marilyn McLeod, OMD
Mary Kathryn Allen, 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 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,



Jennie L. Collins

March 4, 2013

Introduction

As pursuant to 12 VAC 5-31-2300 through 12 VAC 5-31-2300 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 Blue Ridge EMS Council on February 26, 2013.

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 the Virginia Emergency Medical Services Regulations.

Site Review

On February 26, 2013, the review team traveled to the Blue Ridge EMS Council office, located at 1900 Tate Springs Road, Suite 14, Lynchburg, 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 Executive Director Connie Purvis, Operational Medical Director Marilyn McLeod, President Brad Ferguson and Assistant Director/Field Coordinator Mary Catherine Allen.

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 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,



Glenn H. Luedtke

April 5, 2013

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 Central Shenandoah EMS Council on March 13, 2013 .

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 , the review team traveled to the CSEMESC 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: Chad Blosser, Executive Director; Gary Critzer, President; Matt Lawler, Assistant Director, Asher Brand, Regional OMD, Mac McCauley, Past President, and Kim Craig, 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 deficiencies were noted. As such, I recommend that the CSEMESC be designated by the Virginia Board of Health as a Regional EMS Council for a term of three (3)years.

Respectfully, Randy P. Abernathy

March 30, 2013

Introduction

As pursuant to 12 VAC 5-31-2300 through 12 VAC 5-31-2300 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 Central Shenandoah EMS Council.

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 the Virginia Emergency Medical Services Regulations.

Site Review

On Wednesday, March 13, 2013, the review team traveled to the Central Shenandoah EMS Council office, located at 2312 West Beverley Street, Staunton, 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 Executive Director, Chad Blosser and members of the applicant organization board of directors, financial officers, and system stakeholders, including:

Gary Critzer – Council President Matt Lawler – Assistant Director/Instructor
Asher Brand, MD – Regional Medical Director Kim Craig – Board Secretary/SARS
Mac McCulley – Past Council President

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,



Robert A. Brown

April 5, 2013

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 Lord Fairfax Emergency Medical Services Council on March 14, 2013

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 , the review team traveled to the LFEMS office, located at 180-1 Prosperity Dr. 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, to include: Tracy McLaurin, Executive Director, Jon Henschel, President, Dr. Chris Turnbull, Regional Medical Director, Janet Spilewski, Administrative Assistant, Gary Dalton, Past President, and Jeff Long, Consumer Representative to the Board.

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 LFEMS Council be designated by the Virginia Board of Health as a Regional EMS Council for a term of three (3) years.

Respectfully, Randy P. Abernathy

March 30, 2013

Introduction

As pursuant to 12 VAC 5-31-2300 through 12 VAC 5-31-2300 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.

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 the Virginia Emergency Medical Services Regulations.

Site Review

On Thursday, March 14, 2013, the review team traveled to the Lord Fairfax EMS Council office, located at 180 Prosperity Drive, Suite 1, 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 Executive Director, Tracy McLaurin, members of the applicant organization board of directors, financial officers, and system stakeholders, including:

Chris Turnbull, MD – Regional Medical Director
Jeff Long – Stakeholder

Jon Henschel – President
Gary Dalton – Valley Medical Transport

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,



Robert A. Brown

April 5, 2013

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 Northern Virginia EMS Council, on March 28, 2013.

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 , the review team traveled to the NOVA office, located at 7250 Heritage Village Plaza, Suite 102 , Gainesville, 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: Greg Rauch, President, Melinda Duncan, Executive Director, Brian Hricik, Past President and Regional 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 deficiencies were noted. As such, I recommend that the NOVA be designated by the Virginia Board of Health as a Regional EMS Council for a term of three (3) years.

Respectfully, Randy P. Abernathy

March 29, 2013

Introduction

As pursuant to 12 VAC 5-31-2300 through 12 VAC 5-31-2300 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 Northern Virginia EMS Council on March 28, 2013.

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 the Virginia Emergency Medical Services Regulations.

Site Review

On March 28, 2013, the review team traveled to the Northern Virginia EMS Council office, located at 7250 Heritage Village Plaza, Suite 102, 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 Executive Director Melinda Duncan, Board President Greg Rauch from the City of Fairfax Fire & EMS Department, and Immediate Past President Brian Hricik from the City of Alexandria Fire/EMS Department.

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 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,



Glenn H. Luedtke

March 24, 2013

Introduction

As pursuant to 12 VAC 5-31-2300 through 12 VAC 5-31-2300 of the Virginia Emergency Medical Services Regulations Governing Regional Emergency Medical Services Councils, I Jennie L. Collins, participated as a member of a site review team, tasked with evaluation of the Old Dominion EMS Council (ODEMSA) on March 19, 2013.

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 the Virginia Emergency Medical Services Regulations.

Site Review

On March 19, 2013, the review team traveled to the Old Dominion EMS Council office, located at 1463 Johnston-Willis Drive, Richmond, Virginia, 23235. 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 and members of the applicant organization board of directors, financial officers, and system stakeholders. Members interviewed were:

Executive Director Heidi Hooker
President Rick McClure
Field Coordinator Max Bornstein
Field Coordinator Delbert Garrett
Program Coordinator Lynn Barbour
Accountant/Bookkeeper Catina Downey

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 Old Dominion EMS Council be designated by the Virginia Board of Health as a Regional EMS Council for a term of three (3) years.

Respectfully submitted,



Jennie L. Collins

April 4, 2013

Introduction

As pursuant to 12 VAC 5-31-2300 through 12 VAC 5-31-2300 of the Virginia Emergency Medical Services Regulations Governing Regional Emergency Medical Services Councils, I **Donald R. Barklage**, participated as a member of a site review team, tasked with evaluation of the **Old Dominion EMS Alliance** on March 19, 2013.

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 the Virginia Emergency Medical Services Regulations.

Site Review

On March 19, 2013, the review team traveled to the Old Dominion EMS Alliance office, located at 1463 Johnston-Willis Drive, Richmond, VA. 23235. 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 (Heidi Hooker), members of the applicant organization board of directors, financial officers, and system stakeholders. These included: Tracy Thomas (Administrative Officer); Max Bornstein (Filed Coordinator); Rick McClure (President); Delbert Garrett (Field Coordinator); Catina Downey (Accountant); Holly Sturdevant (Special Projects Coordinator); Jane Behrend (Office Manager); and Lynn Barbour (Program 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 **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,

Donald R. Barklage Jr.

March 8, 2013

Introduction

As pursuant to 12 VAC 5-31-2300 through 12 VAC 5-31-2300 of the Virginia Emergency Medical Services Regulations Governing Regional Emergency Medical Services Councils, I **Donald R. Barklage Jr.** participated as a member of a site review team, tasked with evaluation of the **Peninsulas EMS Council, Inc.** on February 21, 2013.

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 the Virginia Emergency Medical Services Regulations.

Site Review

On February 21, 2013, the review team traveled to the **Peninsulas EMS Council, Inc.** office, located at 6898 Main Street, 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. These included: Art Jacobs (Treasurer), J. David Barrick, Julie Glover, Cheryl Lawson (OMD), Paul Hoyle, Wes Bowen, Jennifer Smith, and Genie Denstan.

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,

Donald R. Barklage Jr.

March 14, 2013

Introduction

As pursuant to 12 VAC 5-31-2300 through 12 VAC 5-31-2300 of the Virginia Emergency Medical Services Regulations Governing Regional Emergency Medical Services Councils, I **Larry A. Oliver**, participated as a member of a site review team, tasked with evaluation of the **Peninsulas Emergency Medical Services Council, Inc.** on **Thursday, February 21, 2013**.

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 the Virginia Emergency Medical Services Regulations.

Site Review

On **February 21, 2013**, the review team traveled to the **Peninsulas Emergency Medical Services Council, Inc.** office, located at **6898 Main Street, Gloucester, 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 Executive Director, members of the applicant organization board of directors, financial officers, and system stakeholders. Interviews were conducted with the following individuals: **Michael B. Payer, Executive Director; James D. Barrick, Vice President; Wesley Bowen, Emergency Field Coordinator – Operations; Jeannie Dunston, Office Manager; Julia B. Glover, President; Arthur M. Jacobs, Treasurer; Cheryl L. Lawson, Regional Medical Director; and Jennifer Smith, EMS Education and Communications 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 deficiencies were noted/the following deficiencies were noted. As such, I **recommend** that the **Peninsulas 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,

Larry A. Oliver, Site Reviewer

March 29, 2013

Introduction

As pursuant to 12 VAC 5-31-2300 through 12 VAC 5-31-2300 of the Virginia Emergency Medical Services Regulations Governing Regional Emergency Medical Services Councils, I **Larry A. Oliver**, participated as a member of a site review team, tasked with evaluation of the **Rappahannock Emergency Medical Services Council, Inc.** on **Monday, March 4, 2013.**

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 the Virginia Emergency Medical Services Regulations.

Site Review

On **March 4, 2013**, the review team traveled to the **Rappahannock Emergency Medical Services Council, Inc.** office, located at **435 Hunter Street, Fredericksburg, 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 Executive Director, members of the applicant organization board of directors, financial officers, and system stakeholders. Interviews were conducted with the following individuals: **Wayne Perry, Executive Director; John C. Brandrup, Treasurer; Kevin L. Dillard, President; Linda C. Harris, Regional Education Coordinator; and Nael Hasan, 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 **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,

Larry A. Oliver, Site Reviewer

April 5, 2013

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, on March 4, 2013..

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 , the review team traveled to the REMS office, located 435 Hunter Street, Fredericksburg, 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: Wayne Perry, Executive Director, Kevin Dillard, President, Debby Loveless, Office Manager, John Brandrup, Treasurer, and Dr Nael Hasan, 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. As such, I recommend that the REMS Council be designated by the Virginia Board of Health as a Regional EMS Council for a term of three (3)years.

Respectfully, Randy P. Abernathy

March 31, 2013

Introduction

As pursuant to 12 VAC 5-31-2300 through 12 VAC 5-31-2300 of the Virginia Emergency Medical Services Regulations Governing Regional Emergency Medical Services Councils, I Jennie L. Collins, participated as a member of a site review team, tasked with evaluation of the Southwest EMS Council on March 12, 2013.

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 the Virginia Emergency Medical Services Regulations.

Site Review

On March 12, 2013, the review team traveled to the Southwest EMS Council office, located at 306 Piedmont Avenue, Bristol, VA 24201. 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. Members interviewed were:

Anita Ashby, Board of Director Member	B.J. Scyphers, Stakeholder
Morgan O'Quinn, Stakeholder	Roger Burke, Treasurer
Chief J.C. Bolling, President	Bryan Kimberlin, Senior Field Coordinator
Jay Gource, Stakeholder	Greg Woods, Executive 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 Southwest EMS Council be designated by the Virginia Board of Health as a Regional EMS Council for a term of three (3) years.

Respectfully submitted,



Jennie L. Collins

April 1, 2013

Introduction

As pursuant to 12 VAC 5-31-2300 through 12 VAC 5-31-2300 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 **Southwestern Virginia EMS Council** on March 12, 2013.

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 the Virginia Emergency Medical Services Regulations.

Site Review

On 3/12/13, the review team traveled to the **Southwestern Virginia EMS Council** office, located at 306 Piedmont Avenue, Bristol, VA 24201. 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 (Greg Woods), members of the applicant organization board of directors, financial officers, and system stakeholders. These included: Anita Ashley (BOD), Morgan O'Quinn (Stakeholder), J.C. Bolling (President), B.J. Scyphers (stakeholder), J. Googe (stakeholder), Roger Burke (Treasurer), and Bryan Kimberlin (Filed 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 deficiencies were noted. As such, **I recommend** that the Southwestern 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,

Donald R. Barklage Jr.

March 7, 2013

Introduction

As pursuant to 12 VAC 5-31-2300 through 12 VAC 5-31-2300 of the Virginia Emergency Medical Services Regulations Governing Regional Emergency Medical Services Councils, I **Donald R. Barklage Jr.**, participated as a member of a site review team, tasked with evaluation of the **Tidewater EMS Council, Inc.** on February 20, 2013.

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 the Virginia Emergency Medical Services Regulations.

Site Review

On 2/20/13, the review team traveled to the **Tidewater EMS Council, Inc.** office, located at 1104 Madison Plaza, Chesapeake, VA., 23320. 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. The site review team met specifically with Kent Weber (Treasurer), Jeff Myers (Board member), Bruce Edwards (Board member), Genemarie McGee (Board member), Dave Coulling (Council Staff), Wendy Ambrose (Council staff) Jeff Porter (Council staff) and Judy Shvek (Council 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 Tidewater 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,

Donald R. Barklage Jr.

March 13, 2013

Introduction

As pursuant to 12 VAC 5-31-2300 through 12 VAC 5-31-2300 of the Virginia Emergency Medical Services Regulations Governing Regional Emergency Medical Services Councils, I **Larry A. Oliver**, participated as a member of a site review team, tasked with evaluation of the **Tidewater Emergency Medical Services Council, Inc.** on **Wednesday, February 20, 2013**.

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 the Virginia Emergency Medical Services Regulations.

Site Review

On **February 20, 2013**, the review team traveled to the **Tidewater Emergency Medical Services Council, Inc.** office, located at **1104 Madison Plaza, Suite 101, Chesapeake, 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 Executive Director, members of the applicant organization board of directors, financial officers, and system stakeholders. Interviews were conducted with the following individuals: **James M. Chandler, Executive Director; Wendi Ambrose, Regional Field Coordinator II; David Coulling, Regional Field Coordinator; Bruce W. Edwards, Board Member; Genemarie W. McGee, Board Member; Jeffrey J. Meyer, Board Member; Harvey J. Porter, III, Regional Education Coordinator; Judith A. Shuck, Mass Casualty Preparedness Coordinator; and Kent J. Weber, 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, no deficiencies were noted/the following deficiencies were noted. As such, **I recommend** that the **Tidewater 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,

Larry A. Oliver, Site Reviewer

April 7, 2013

Introduction

As pursuant to 12 VAC 5-31-2300 through 12 VAC 5-31-2300 of the Virginia Emergency Medical Services Regulations Governing Regional Emergency Medical Services Councils, I Jennie L. Collins, participated as a member of a site review team, tasked with evaluation of the Thomas Jefferson EMS Council on February 25, 2013.

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 the Virginia Emergency Medical Services Regulations.

Site Review

On February 25, 2013, the review team traveled to the Thomas Jefferson EMS Council office, located at 2205 Fontaine Avenue, Suite 303, Charlottesville, Virginia, 22903. 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. Members interviewed were:

Timothy Hodge, Treasurer	Lilly Bramble, Board member
Tammy Johnson, QA/QI Planner	Curtis Sheets, President
Sheri Markel, Administrative Assistant	Donna Burns, Board member
Linda Johnson, Training Specialist	Stephen Rea, Executive Director
Jane Carroll, Board member	

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,



Jennie L. Collins

March 4, 2013

Introduction

As pursuant to 12 VAC 5-31-2300 through 12 VAC 5-31-2300 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 February 25, 2013.

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 the Virginia Emergency Medical Services Regulations.

Site Review

On February 25, 2013, the review team traveled to the Thomas Jefferson EMS Council office, located at 2205 Fontaine Avenue, Suite 303, Charlottesville, 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 Executive Director Stephen Rea, Treasurer Timothy Hodge, President Curtis Sheets, Bookkeeper/Admin Assistant Sherry Markel, Secretary Jaime Stafford, Board of Directors member Donna Burns, Training Coordinator Linda Johnson, Tammy Johnson, Jan Carroll, and Lily Bramble

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

March 31, 2013

Introduction

As pursuant to 12 VAC 5-31-2300 through 12 VAC 5-31-2300 of the Virginia Emergency Medical Services Regulations Governing Regional Emergency Medical Services Councils, I Jennie L. Collins, participated as a member of a site review team, tasked with evaluation of the Western Virginia EMS Council on March 11, 2013.

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 the Virginia Emergency Medical Services Regulations.

Site Review

On March 11, 2013, 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. Members interviewed were:

BC Mike Jefferson, Board member
DC Billy Altman, Board member
BC Bill Duff, Stakeholder
Ford Wirth, President

Carey Harveycutter, Treasurer
Dr. Carol Gilbert, OMD
Dr. Charles Lane, Regional OMD
Rob Logan, Executive 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 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,



Jennie L. Collins

March 26, 2013

Introduction

As pursuant to 12 VAC 5-31-2300 through 12 VAC 5-31-2300 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 **Western Virginia EMS Council** on **March 11, 2013**.

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 the Virginia Emergency Medical Services Regulations.

Site Review

On March 11, 2013, the review team traveled to the **Western Virginia EMS Council** office, located at 1944 Peters Creek Road NW, Roanoke, VA 240176. 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 (Rob Logan), members of the applicant organization board of directors, financial officers, and system stakeholders. These included: Mike Jefferson, Billie Altman, Bill Duff (Stakeholders), Ford Wirt (President), Carey Harvey cutter (Treasurer), Danielle Lissberger, and Dr. Carol Gilbert.

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,

Donald R. Barklage Jr.



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448
RICHMOND, VA 23218

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

Cynthia C. Romero, MD, FAAFP
State Health Commissioner

MEMORANDUM

DATE: May 1, 2013

TO: Virginia Board of Health

FROM: Lauri Kalanges, MD, MPH
Acting Director, Office of Family Health Services

SUBJECT: Proposed Amendments to 12VAC5-71 "Regulations Governing Virginia Newborn Screening Services"

Enclosed for your review are proposed amendments to 12VAC5-71 "Regulations Governing Virginia Newborn Screening Services." The Virginia State Board of Health is requested to approve the proposed amendments. Should the State Board of Health approve these amendments, the regulatory package will then be submitted for executive branch review. Following executive review and approval, the proposed amendments will be published in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall for a 60-day public comment period.

The proposed amendments are designed to update the list of disorders for which newborn screening is performed on infants born in the Commonwealth. This list is maintained in Section 30 of 12VAC5-71 as required by the Code of Virginia Section 32.1-65. The intent of this action is to add Severe Combined Immunodeficiency (SCID) to the Virginia panel of screened disorders.

The Notice of Intended Regulatory Action (NOIRA) was published on February 11, 2013 in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall. Twenty six comments were received during the public comment period which ended on March 13, 2013. All of the comments were made in support of adding SCID to the core panel of heritable disorders and genetic diseases.

Thank you for your consideration. I look forward to discussing these proposed amendments with you at the June meeting.



Proposed Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12VAC5-71
Regulation title	Regulations Governing Virginia Newborn Screening Services
Action title	Amend regulations to add Severe Combined Immunodeficiency (SCID) to the Virginia Newborn Screening System core panel of heritable disorders and genetic diseases.
Date this document prepared	May 2, 2013

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

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

The proposed regulatory action would add Severe Combined Immunodeficiency (SCID) to the newborn screening panel. Blood spot newborn screening services are provided by the Department of General Services' Division of Consolidated Laboratory Services in partnership with the Virginia Department of Health. SCID is a primary immunodeficiency disease that is estimated to occur in approximately 1 out of every 50,000 live births. Effective treatment for SCID is available if it is detected early. Screening is necessary as this disease cannot be detected through physical examinations. The addition of SCID to the newborn screening panel has been recommended by the Virginia Genetics Advisory Committee and on a national level, this disease has been added to the core panel of 31 genetic disorders included in the Recommended Uniform Screening Panel of the US Secretary of Health and Human Services' Advisory Committee on Heritable Disorders in Newborns and Children.

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.

SCID means Severe Combined Immunodeficiency.
DCLS means Division of Consolidated Laboratory Services.

Legal basis

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

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

Section 32.1-65 of the Code of Virginia requires newborn screening to be conducted on every infant born in the Commonwealth of Virginia.

Section 32.1-67 of the Code of Virginia requires the Board of Health to promulgate regulations as necessary to implement Newborn Screening Services. The regulations are required to include a list of newborn screening tests pursuant to § 32.1-65.

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.

All newborns in Virginia would be screened for SCID as a result of this proposed regulatory action. SCID is currently estimated to occur in approximately 1 out of every 50,000 live births and some data suggest that figure could be higher. SCID is a term applied to a group of inherited disorders characterized by defects in both T and B cell responses. The defining characteristic of SCID is the absence of T-cells and, as a result, lack of B-cell function, the specialized white blood cells made in the bone marrow to fight infection. Neonates with SCID appear healthy at birth, but without early treatment, most often by bone marrow transplant from a healthy donor, these infants cannot survive or if they do, have significant morbidities. In addition, the success of the bone marrow transplantation decreases with delayed diagnosis, mostly due to underlying infections. All these factors also add to the cost of care of these patients. Undiagnosed cases are 100% fatal.

Screening for SCID gives affected infants the advances of early diagnosis and treatment. Early identification results in a higher survival rate, better outcomes and lower healthcare costs. Screening for SCID is an imperative diagnostic tool since SCID cannot be detected by a physical examination. Laboratory screening is available for high volume testing at a reasonable cost.

SCID was added to the Recommended Uniform Screening Panel (RUSP) by the US Health and Human Services Secretary Kathleen Sebelius following extensive study and recommendation from the Secretary's Advisory Panel on Heritable Disorders in Newborns and Children. The Virginia Genetics Advisory Committee also unanimously voted to recommend to the State Health Commissioner that SCID be added to the state newborn screening panel. A Virginia SCID Planning Workgroup met September 20-

21, 2012 to formulate a plan and discuss issues surrounding the possible addition of this condition to the Virginia panel. It is anticipated that Virginia would begin screening for SCID in 2014.

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 changes proposed to 12VAC5-71 will revise the Section 30 listing of specific disorders for which screening is conducted by adding SCID to the state's core panel. Currently, the DCLS analyzes biological markers that may be indicative of 28 certain disorders that constitute the core panel. Section 32.1-67 of the Code of Virginia requires that this list of screened disorders be in the regulation. Section 32.1-65 of the Code requires that Virginia's screening tests are consistent with the panel recommended by the U.S. Secretary of Health and Human Services and the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children.

Issues

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

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

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

The primary advantage of this regulatory action to the public and to the Commonwealth is universal access to early diagnosis and treatment of SCID. Screening for SCID allows for early identification of the disease, which then leads to higher survival rates, better health outcomes and lower costs.

A pertinent matter of interest to the regulated community, government officials, and the public is the projected increase in the cost of the blood spot screening panel. Newborn screening is a fee-for-service program, and the fee is paid by hospitals and other screeners who must purchase the filter paper kits used for blood spot collection. Most screening is performed in hospitals, with about 10-15% of screening performed by private physicians and military facilities. Hospitals do not generally pass on these costs to patients because third party payers usually pay a negotiated bundled amount per delivery, and Medicaid-reimbursed delivery payment is set by the state. Self-pay patients may be responsible to pay the screening fee themselves if they have the resources to do so.

Since the SCID screening assay is based on new highly sensitive, specific molecular detection methodology not previously employed by the newborn screening laboratory, the DCLS requires additional capital equipment, staff and some laboratory renovation to conduct SCID screening. Based on current cost estimates and the current number of samples being tested annually, the cost to add SCID screening will be \$7.50 per sample. Adjustments to this estimate are possible if DCLS receives a grant for two-year funding from the Centers for Disease Control and Prevention. This funding source could potentially contribute up to \$300,000 in both FY 2014 and FY 2015 towards lab related costs associated with adding SCID to the panel.

The \$7.50 fee for SCID testing is part of a more comprehensive fee increase for the newborn screening panel that will also cover costs for additional VDH follow-up personnel and other screening-related

expenses such as test kits used for cystic fibrosis mutation analysis. These other screening-related expenses will have an estimated fiscal impact of an additional \$15.50-\$17.50 per panel. As a result, the total cost of the blood spot screening panel is estimated to increase from \$53.00 to between \$76.00 and \$78.00. This estimate reflects a cost that would be at or below the national average fee of \$78.00 among seven fee-based newborn screening programs that have implemented SCID testing. It should also be noted that the Virginia newborn screening program has not had a fee increase since 2006.

Requirements more restrictive than federal

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

There are no requirements of this proposal that are more restrictive than federal requirements.

Localities particularly affected

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

No localities are particularly affected by the proposed regulation or bear any identified disproportionate material impact.

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 Town Hall website (<http://www.townhall.virginia.gov>), or by mail, email or fax to Dev Nair, Virginia Department of Health, 109 Governor Street, Richmond, Virginia 23219, (804) 864-7662, dev.nair@vdh.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on 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 requirements 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>Projected costs to the state to implement the addition of SCID to the newborn screening panel will be incurred by DCLS. Costs related to capital equipment, staff, and laboratory renovation to conduct SCID screening are estimated to cost \$950,000 in the first year and \$750,000 in the second year, with on-going, annual costs thereafter. Two potential funding sources may help offset these costs, including the Centers for Disease Control and Prevention (CDC) and the Jeffrey Modell Foundation. Possible two-year grant funding available through CDC could contribute up to \$300,000 for DCLS costs in both FY 2014 and FY 2015. Modell Foundation funding could provide \$1 to DCLS for each newborn screened for SCID during the first twelve months of implementation. The remainder of the projected costs will be funded through the fee increase of the blood spot screening panel resulting from the addition of SCID to the core panel.</p>
<p>Projected cost of the new regulations or changes to existing regulations on localities.</p>	<p>There are no projected costs on localities.</p>
<p>Description of the individuals, businesses or other entities likely to be affected by the new regulations or changes to existing regulations.</p>	<p>Hospitals, birth centers, and midwives</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>There are sixty three birth hospitals and birth centers in Virginia; all of these institutions will be affected by the increased fee associated with the blood spot screening panel. Midwives who collect newborn screening samples will also be affected. Currently, there are sixty seven licensed midwives in Virginia.</p>
<p>All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs. 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>The current cost of the newborn screening panel is \$53.00. It is estimated that adding SCID to the newborn screening panel will result in an increase of \$7.50 per sample. The \$7.50 fee for SCID testing is part of a more comprehensive newborn screening panel fee increase that will also cover costs not specifically related to SCID testing. Those costs include additional VDH newborn screening follow-up personnel and other screening-related expenses including test kits used for cystic fibrosis mutation analysis.</p> <p>It is estimated that the total cost of the blood spot screening panel will increase from \$53.00 to</p>

	between \$76.00 and \$78.00. This cost reflects both the \$7.50 for SCID testing and an additional \$15.50-\$17.50 for other screening-related expenses.
Beneficial impact the regulation is designed to produce.	Better health outcomes and higher survival rates for infants through SCID screening.

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 alternative to this proposed regulatory action is to not add Severe Combined Immunodeficiency (SCID) to the core panel of disorders for which newborns are screened. However this option would be in direct conflict with both the nationally Recommended Uniform Screening Panel (RUSP) and the recommendation of the Virginia Genetics Advisory Committee.

Regulatory flexibility analysis

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

The Virginia Department of Health convened a SCID workgroup comprised of internal and external stakeholders including pediatric immunologists and Centers for Disease Control and Prevention SCID experts as well as representatives from the Immune Deficiency Foundation and the Hospital and Healthcare Association to evaluate and consider this proposed regulatory change and cost effectiveness. The addition of SCID to the newborn screening panel cannot be achieved by an alternative regulatory method or less stringent requirements. There are no other applicable regulations to consolidate which impact newborn screening. Small businesses may not be exempted as a category because screening for all infants must be managed equitably by their providers, regardless of business size, to assure optimal outcomes.

Public comment

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

Twenty six comments were received during the public comment period following the publication of the NOIRA. All comments expressed support of adding SCID to the core panel of heritable disorders and genetic diseases. Several comments reflected personal experience with a family member diagnosed with

SCID in the explanation of support. Comments also referenced the importance of early diagnosis and treatment that would result from screening. VDH notes the support; no response is required.

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 amendment to the regulation will not strengthen or erode the rights of parents in the education, nurturing, and supervision of their children. Parents have the right to refuse newborn screening for religious reasons. Parents also have the right to seek additional newborn screening testing outside of the state program if desired.

The proposed amendment will not encourage or discourage economic self-sufficiency, self-pride, or the assumption of responsibility for oneself, one’s spouse, one’s children and/or elderly parents.

The proposed amendment will not strengthen or erode marital commitment.

The proposed amendment will not increase or decrease disposable family income.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action.

*If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all differences between the **pre-emergency** regulation and this proposed regulation, and (2) only changes made since the publication of the emergency regulation.*

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

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12VAC5-71-30		Core panel of heritable disorders and genetic diseases	This section lists the conditions of the core panel of heritable disorders and genetic diseases for which the newborn-dried-blood-spot testing is conducted. The proposed change would add SCID to the core panel.

Project 3657 - none

DEPARTMENT OF HEALTH

Addition of SCID to Newborn Screening Panel

CHAPTER 71

REGULATIONS GOVERNING VIRGINIA NEWBORN SCREENING SERVICES

12VAC5-71-10. Definitions.

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

"Attending physician" means the physician in charge of the infant's care.

"Board" means the State Board of Health.

"Business days" means Monday through Friday from 9 a.m. to 5 p.m., excluding federal and state holidays.

"Care Connection for Children" means a statewide network of centers of excellence for children with special health care needs (CSHCN) that provides leadership in the enhancement of specialty medical services, care coordination, medical insurance benefits evaluation and coordination, management of the CSHCN Pool of Funds, information and referral to CSHCN resources, family-to-family support, and training and consultation with community providers on CSHCN issues.

"Care coordination" means a process that links individuals and their families to services and resources in a coordinated effort to maximize their potential and provide them with optimal health care.

"Certified nurse midwife" means a person licensed to practice as a nurse practitioner in the Commonwealth pursuant to § 54.1-2957 of the Code of Virginia and in accordance with Part II (18VAC90-30-60 et seq.) of 18VAC90-30 and 18VAC90-30-120 and 18VAC90-30-160.

"Chief executive officer" means a job descriptive term used to identify the individual appointed by the governing body to act in its behalf in the overall management of the hospital. Job titles may include administrator, superintendent, director, executive director, president, vice-president, and executive vice-president.

"Child" means a person less than 18 years of age and includes a biological or an adopted child, and a child placed for adoption or foster care unless otherwise treated as a separate unit for the purposes of determining eligibility and charges under these regulations.

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

"Confirmatory testing" means a test or a panel of tests performed following a screened-abnormal result to verify a diagnosis.

"Core panel conditions" means those heritable disorders and genetic diseases considered appropriate for newborn screening. The conditions in the core panel are similar in that they have (i) specific and sensitive screening tests, (ii) a sufficiently well understood natural history, and (iii) available and efficacious treatments.

"Department" means the state Department of Health.

"Dried-blood-spot specimen" means a clinical blood sample collected from an infant by heel stick method and placed directly onto specially manufactured absorbent specimen collection (filter) paper.

"Guardian" means a parent-, court-, or clerk-appointed guardian of the person.

"Healthcare provider" means a person who is licensed to provide health care as part of his job responsibilities and who has the authority to order newborn dried-blood-spot screening tests.

"Heritable disorders and genetic diseases" means pathological conditions (i.e., interruption, cessation or disorder of body functions, systems, or organs) that are caused by an absent or defective gene or gene product, or by a chromosomal aberration.

"Hospital" means a medical care facility licensed as a hospital by the Virginia Department of Health.

"Infant" means a child less than 12 months of age.

"Low protein modified foods" means foods that are (i) specially formulated to have less than one gram of protein per serving, (ii) intended to be used under the direction of a physician for the dietary treatment of an inherited metabolic disease, (iii) not natural foods that are naturally low in protein, and (iv) prescribed as medically necessary for the therapeutic treatment of inherited metabolic diseases.

"Metabolic formula" means nutritional substances that are (i) prescribed by a health professional with appropriate prescriptive authority; (ii) specifically designed and formulated to be consumed or administered internally under the supervision of such health professional; (iii) specifically designed, processed, or formulated to be distinct in one or more nutrients that are present in natural food; and (iv) intended for the medical and nutritional management of patients with limited capacity to metabolize ordinary foodstuffs or limited capacity to metabolize certain nutrients contained in ordinary foodstuffs.

"Metabolic supplements" means certain dietary or nutritional substances intended to be used under the direction of a physician for the nutritional management of inherited metabolic diseases.

"Midwife" means a person licensed as a nurse practitioner in the category of certified nurse midwife by the Boards of Nursing and Medicine or licensed as a midwife by the Board of Medicine.

"Newborn" means an infant who is 28 days old or less.

"Nurse" means a person holding a current license as a registered nurse or licensed practical nurse by the Virginia Board of Nursing or a current multistate licensure privilege to practice in Virginia as a registered nurse or licensed practical nurse.

"Parent" means a biological, adoptive, or stepparent.

"Pediatric Comprehensive Sickle Cell Clinic Network" means a statewide network of clinics that are located in major medical centers and provide comprehensive medical and support services for newborns and children living with sickle cell disease and other genetically related hemoglobinopathies.

"Physician" means a person licensed to practice medicine or osteopathic medicine in the Commonwealth pursuant to Chapter 29 (§ 54.1-2900 et seq.) of Title 54.1 of the Code of Virginia and in accordance with applicable regulations.

"Pool of funds" means funds designated for payment of direct health care services. Access to the pool is not an entitlement and is subject to availability of funds and guidelines that govern its eligibility and coverage of services. Pool of funds is a mix of federal Title V funds and state match.

"Population-based" means preventive interventions and personal health services developed and available for the entire infant and child health population of the Commonwealth rather than for individuals in a one-on-one situation.

"Preterm infant" means a neonate whose birth occurs through the end of the last day of the 36th week following the onset of the last menstrual period.

"Repeat specimen" means an additional newborn dried-blood-spot screening specimen submitted to the testing laboratory voluntarily or by request.

"Resident" means an individual who resides within the geographical boundaries of the Commonwealth.

"Satisfactory specimen" means a newborn dried-blood-spot screening specimen that has been determined to be acceptable for laboratory analyses by the testing laboratory.

"Screened-abnormal" means a newborn dried-blood-spot screening test result that is outside the established normal range or normal value for that test method.

"Testing laboratory" means the laboratory that has been selected by the department to perform newborn dried-blood-spot screening tests services.

"Total parenteral nutrition (TPN)" means giving nutrients through a vein for babies who cannot be fed by mouth.

"Treatment" means appropriate management including genetic counseling, medical consultation, and pharmacological and dietary management for infants diagnosed with a disease listed in 12VAC5-71-30 D.

"Unsatisfactory specimen" means a newborn dried-blood-spot screening specimen that is inadequate for performing an accurate analysis.

"Virginia Genetics Advisory Committee" means a formal group that advises the department on issues pertaining to access to clinical genetics services across the Commonwealth and the provision of genetic awareness, quality services, and education for consumers and providers.

"Virginia Newborn Screening System" means a coordinated and comprehensive group of services, including education, screening, follow up, diagnosis, treatment and management, and program evaluation, managed by the department's Virginia Newborn Screening Services and

Virginia Early Hearing Detection and Intervention Program for safeguarding the health of children born in Virginia.

"Virginia Sickle Cell Awareness Program" means a statewide program for the education and screening of individuals for the disease of sickle cell anemia or sickle cell trait and for such other genetically related hemoglobinopathies.

12VAC5-71-20. Administration of chapter.

This chapter is administered by the commissioner.

The commissioner may issue a guidance document that interprets these regulations and provides guidance for their implementation. Such a document shall be reviewed and revised whenever the regulations of this chapter are reviewed and may also be amended or revised as needed to meet changing circumstances.

Guidance documents shall include procedures for accessing program services including available assistance when not otherwise addressed in these regulations or the Code of Virginia.

12VAC5-71-30. Core panel of heritable disorders and genetic diseases.

A. The Virginia Newborn Screening System, which includes Virginia Newborn Screening Services and the Virginia Early Hearing and Intervention Program, shall ensure that the core panel of heritable disorders and genetic diseases for which newborn screening is conducted is consistent with but not necessarily identical to the recommendations for screening by the American College of Medical Genetics in its 2005 report "Newborn Screening: Toward a Uniform Screening Panel and System."

B. The department shall review, at least biennially, national recommendations and guidelines and may propose changes to the core panel of heritable disorders and genetic diseases for which newborn dried-blood-spot screening tests are conducted.

C. The Virginia Genetics Advisory Committee may be consulted and provide advice to the commissioner on proposed changes to the core panel of heritable disorders and genetic diseases for which newborn dried-blood-spot screening tests are conducted.

D. Infants under six months of age who are born in Virginia shall be screened in accordance with the provisions set forth in this chapter for the following heritable disorders and genetic diseases, which are identified through newborn dried-blood-spot screening tests:

1. Argininosuccinic acidemia (ASA);
2. Beta-ketothiolase deficiency (\pm KT);
3. Biotinidase deficiency (BIOT);
4. Carnitine uptake defect (CUD);
5. Citrullinemia (CIT);
6. Congenital adrenal hyperplasia (CAH);
7. Congenital hypothyroidism (CH);
8. Cystic fibrosis (CF);
9. Galactosemia (GALT);
10. Glutaric acidemia type I (GA I);
11. Hemoglobin Sickle/Beta-thalassemia (Hb S/ \pm Th);
12. Hemoglobin Sickle/C disease (Hb S/C);
13. Homocystinuria (HCY);
14. Isovaleric acidemia (IVA);
15. Long chain hydroxyacyl-CoA dehydrogenase deficiency (LCHAD);
16. Maple syrup urine disease (MSUD);

17. Medium-chain acyl-CoA dehydrogenase deficiency (MCAD);
18. Methylmalonic acidemia (mutase deficiency) (MUT);
19. Methylmalonic acidemia (Cbl A,B);
20. Multiple carboxylase deficiency (MCD);
21. Phenylketonuria (PKU);
22. Propionic acidemia (PROP);
23. Severe combined immunodeficiency (SCID);
- ~~23.~~ 24. Sickle cell anemia (Hb SS disease) (Hb SS);
- ~~24.~~ 25. Tyrosinemia type I (TYR I);
- ~~25.~~ 26. Trifunctional protein deficiency (TFP);
- ~~26.~~ 27. Very long-chain acyl-CoA dehydrogenase deficiency (VLCAD);
- ~~27.~~ 28. 3-hydroxy 3-methyl glutaric aciduria (HMG); and
- ~~28.~~ 29. 3-Methylcrotonyl-CoA carboxylase deficiency (3MCC).

E. Infants born in Virginia shall be screened for hearing loss in accordance with provisions set forth in §§ 32.1-64.1 and 32.1-64.2 of the Code of Virginia and as governed by 12VAC5-80.

12VAC5-71-40. Religious exemption from newborn dried-blood-spot screening requirements.

Refusal by the infant's parent or guardian to consent to the collection and submission of a newborn dried-blood-spot screening specimen because the test conflicts with his religious practices or tenets shall be documented in the medical record and communicated to the department.

12VAC5-71-50. Responsibilities of the physician or midwife.

For every live birth in the Commonwealth, the physician or midwife in charge of the infant's care after delivery shall cause the initial collection and submission of a newborn dried-blood-spot screening specimen for testing of those heritable disorders and genetic diseases listed in 12VAC5-71-30 D and in accordance with 12VAC5-71-70 or 12VAC5-71-80.

12VAC5-71-60. Responsibilities of the first attending healthcare provider.

In the event that a physician or midwife does not attend the birth and newborn dried-blood-spot screening tests have not been performed, the first attending healthcare provider shall cause the initial collection and submission of a newborn dried-blood-spot screening specimen for testing of those heritable disorders and genetic diseases listed in 12VAC5-71-30 D in accordance with 12VAC5-71-110.

12VAC5-71-70. Newborn dried-blood-spot screening specimen collection, specimen submission, and notification for hospital deliveries.

A. Newborn dried-blood-spot specimen collection and submission shall be done in accordance with requirements that are determined by the department's designated testing laboratory.

B. Newborn dried-blood-spot specimen collection shall occur after 24 hours of age or immediately before the newborn's discharge, whichever comes first.

C. If the initial newborn dried-blood-spot specimen is collected before 24 hours of age, a repeat specimen shall be collected at the time of discharge or no later than 14 days of age, regardless of earlier test results.

D. If the newborn is a preterm infant, the newborn dried-blood-spot specimen shall be collected at seven days of age or at the time of discharge from the hospital, whichever occurs first.

E. If the newborn requires a blood transfusion or total parenteral nutrition (TPN) or if the newborn is suspected of having a heritable disorder or genetic disease that is listed in 12VAC5-71-30 D:

1. The newborn dried-blood-spot specimen may be collected before 24 hours of age and subsequently submitted; and
2. A repeat newborn dried-blood-spot specimen shall be collected at the time of discharge or no later than 14 days of age, regardless of earlier test results, and subsequently submitted.

F. On notification by the hospital that the infant was discharged before a newborn dried-blood-spot specimen was collected, the healthcare provider in charge of the infant's care or his designee shall:

1. Notify the infant's parent that the infant was discharged before a newborn dried-blood-spot specimen was collected;
2. Cause the collection of a specimen within 48 hours of that parental notification; and
3. Cause the submission of the specimen.

G. If the newborn is to be transferred to another hospital and is less than 24 hours of age:

1. The physician or certified nurse midwife in charge of the infant's care at the hospital of birth shall:
 - a. Cause the collection a newborn dried-blood-spot specimen before the newborn is transferred to another hospital;
 - b. Cause the submission of the specimen; and
 - c. Notify the receiving physician or healthcare provider that a newborn dried-blood-spot specimen was collected before 24 hours of age.

2. The receiving physician or healthcare provider shall:

- a. Cause the collection of a repeat specimen at the time of discharge or no later than 14 days of age, regardless of earlier test results; and
- b. Cause the submission of the specimen.

H. If the infant is transferred to another hospital and is 24 hours of age or older, the physician in charge of the infant's care at the hospital of birth shall:

1. Cause the initial collection and submission of a newborn dried-blood-spot specimen for the infant who is being transferred;
2. Notify the receiving physician or physician of record on transfer that the infant's specimen has been collected; and
3. Notify the receiving physician or physician of record if a newborn dried-blood-spot specimen needs to be repeated or if confirmatory testing is required.

I. The healthcare provider in charge of the infant's care, on receiving notice from the testing laboratory that the infant's newborn dried-blood-spot specimen is unsatisfactory, shall:

1. Cause the collection of a repeat specimen as soon as possible but no later than two business days after notice; and
2. Cause the submission of the specimen.

J. The healthcare provider in charge of the infant's care, on receiving notice of the results of the infant's newborn dried-blood-spot screening test, shall place or cause to be placed the results in the infant's medical record and cause parental notification of test results.

K. The healthcare provider in charge of the infant's care, on receiving notice of the infant's screened-abnormal result, shall:

1. Cause the collection of a repeat newborn dried-blood-spot specimen for repeat or confirmatory testing as soon as possible but no later than two business days after notice;
2. Cause the submission of the specimen; and
3. Take immediate action, as instructed, when notified of a critically abnormal screening result.

12VAC5-71-80. Newborn dried-blood-spot screening specimen collection, specimen submission, and notification for deliveries outside of the hospital.

A. In the event that the infant is born outside of a hospital, the attending physician or midwife shall ensure that:

1. Newborn dried-blood-spot specimen collection and submission is done in accordance with requirements that are determined by the department's designated testing laboratory.
2. Newborn dried-blood-spot specimen collection occurs after 24 hours of age.
3. If the initial newborn dried-blood-spot specimen is collected before 24 hours of age, a repeat specimen shall be collected no later than 14 days of age, regardless of earlier test results.
4. If the newborn is hospitalized, the infant's healthcare provider shall cause the newborn dried-blood-spot screening specimen collection and submission in accordance with 12VAC5-71-70.

B. The healthcare provider in charge of the infant's care, on receiving notice of the results of the infant's newborn dried-blood-spot screening test, shall place or cause to be placed the results in the infant's medical record and cause parental notification of test results.

C. The healthcare provider in charge of the infant's care, on receiving notice from the testing laboratory that the infant's newborn dried-blood-spot specimen is unsatisfactory, shall:

1. Cause the collection of a repeat specimen as soon as possible but no later than two business days after notice; and
2. Cause the submission of the specimen.

D. The healthcare provider in charge of the infant's care, on receiving notice of the infant's screened-abnormal result, shall:

1. Cause the collection of a repeat newborn dried-blood-spot specimen for repeat or confirmatory testing as soon as possible but no later than two business days after notice;
2. Cause the submission of the specimen; and
3. Take immediate action, as instructed, when notified of a critically abnormal screening result.

If a licensed midwife has ordered the newborn-dried-blood-spot screening test and is notified that the results are unsatisfactory or abnormal, the infant shall be immediately referred to a physician or health care facility for repeat collection and submission and for care and treatment as necessary.

The licensed midwife shall cause the collection and submission of a repeat newborn dried-blood-spot specimen if the specimen is unsatisfactory and referring the infant to a physician or health care facility for repeat collection will result in a delay of more than two business days.

12VAC5-71-90. Responsibilities of the chief executive officer.

The chief executive officer shall assure that the hospital providing birthing services develops and implements policies and procedures to make certain that the following steps take place:

1. Collection of newborn dried-blood-spot screening specimens shall occur after 24 hours of birth, and collection and submission of the specimens shall meet the standards required by the testing laboratory;

2. Notification of the newborn's physician of record or designee shall occur within one business day in the event that the infant is discharged before the newborn dried-blood-spot screening specimen has been collected;
3. Communication of the newborn dried-blood-spot screening test results to the newborn's physician of record or designee shall occur so that test results may become part of the infant's medical record on file with the physician;
4. Information relative to newborn screening dried-blood-spot results and treatment shall be recorded in the patient's medical record, and retention of the information shall comply with applicable medical record retention requirements; and
5. Training of staff on newborn dried-blood-spot screening specimen collection and submission and parental notification shall be implemented in a way that ensures an adequately trained and knowledgeable workforce is maintained for implementing specimen collection and submission and parental notification according to standards required by the testing laboratory and guidance from the department.

12VAC5-71-100. Responsibilities of the testing laboratory providing newborn dried-blood-spot screening tests.

A. Newborn dried-blood-spot screening tests shall be performed by the Division of Consolidated Laboratory Services or other laboratory the department has contracted with to provide this service in accordance § 32.1-65 of the Code of Virginia.

B. The testing laboratory shall maintain accreditation under the Clinical Laboratory Improvement Amendments as defined in 42 CFR Part 493.

C. The testing laboratory shall perform required initial and secondary tests using validated analytical test methods and establish normal ranges and notification protocols as defined in the

contract with the department. The testing laboratory may seek the advice of the Newborn Screening Subcommittee of the Virginia Genetics Advisory Committee.

D. On completion of newborn dried-blood-spot screening tests for the infant, the testing laboratory shall provide the completed test results to the submitting facility and to the infant's healthcare provider, as indicated on the newborn screening sample.

E. The testing laboratory shall provide the department's newborn screening services with the newborn dried-blood-spot screening test data that are necessary to carry out follow-up services.

F. The testing laboratory shall manage the distribution of newborn dried-blood-spot screening specimen collection kits.

G. The testing laboratory is authorized to set the fee charged to birthing hospitals and physicians for purchase of newborn dried-blood-spot screening specimen collection kits in consultation with the department and in accordance with applicable state statutes and regulations.

H. The testing laboratory shall maintain an information management system capable of electronic data exchange between the laboratory and the department's newborn screening services.

12VAC5-71-110. Reporting to the commissioner.

A. Physicians, midwives, public health nurses and other nurses who receive newborn dried-blood-spot screening test results, and administrators of hospitals in the Commonwealth shall make or cause to be made a report to the commissioner of a person under the age of two diagnosed as having a heritable disorder or genetic disease for which newborn dried-blood-spot screening tests are conducted.

B. The diagnosed cases shall be reported in accordance with § 32.1-69.1 of the Code of Virginia.

12VAC5-71-120. Scope and content of Virginia Newborn Screening Services.

A. The mission of Virginia Newborn Screening Services is to prevent mental retardation, permanent disability, or death through early identification and treatment of infants who are affected by those heritable disorders and genetic diseases listed in 12VAC5-71-30 D.

B. The scope of newborn screening services shall include the following:

1. Ensure that infants born in the Commonwealth receive newborn dried-blood-spot screening, confirmatory testing, and follow-up services for selected heritable disorders or genetic diseases;
2. Locate and track infants with screened-abnormal results or unsatisfactory results, a short-term process of ensuring that the identified healthcare provider is informed of results, in a timely matter, by at least six months of age, to determine if the infant has a selected heritable disorder or genetic disease;
3. Ensure that the department receives all diagnostic test results, both normal and screened-abnormal results, from healthcare providers;
4. Ensure that appropriate diagnostic data are collected, stored, and organized in a secure data management information system that allows for efficient extraction of appropriate data from the testing laboratory to newborn screening services in accordance with federal and state laws and regulations;
5. Assess and evaluate newborn screening services follow-up activities by collecting and reporting data required annually for Title V national performance measures that address how well the system functions;
6. Educate healthcare providers, parents, and the general public by electronic or written materials and educational sessions, as deemed necessary by the department;

7. Facilitate the entry of infants with screened-abnormal results into medical and dietary management services as needed upon receiving notification from the contracted lab of such results;

8. Ensure that residents of the Commonwealth who are diagnosed with selected heritable disorders or genetic diseases identified through newborn screening services are referred to the Care Connection for Children network for care coordination services; and

9. Provide information to residents of the Commonwealth who are diagnosed with selected heritable disorders or genetic diseases identified through newborn screening services regarding available assistance for obtaining metabolic formula, low protein modified foods, and metabolic supplements that are medically necessary to manage their diagnosed heritable disorder or genetic disease listed in 12VAC5 71-30-D.

C. To ensure full implementation of newborn screening services, the department may establish contracts with, but not be limited to, the following entities, and the established contracts shall comply with all federal assurances:

1. A designated testing laboratory;
2. Medical facilities to provide metabolic treatment and genetic services; and
3. Other entities as needed.

D. The Title V national performance measures, as required by the federal Government Performance and Results Act (GPRA; Public Law 103-62), shall be used to establish newborn screening services goals. The following goals shall change as needed to be consistent with applicable Title V national performance measures: All infants who are born in the Commonwealth and who are residents of Virginia will receive appropriate newborn dried-blood-spot screening, confirmatory testing, and follow-up services. All infants who are born in the

Commonwealth and who are not residents of Virginia will receive appropriate newborn dried-blood-spot screening and be referred to their state of residence for confirmatory testing and follow-up services.

12VAC5-71-130. Responsibilities of the Pediatric Comprehensive Sickle Cell Clinic Network.

A. Upon notification by Virginia Newborn Screening Services of an infant diagnosed with sickle cell disease, the Virginia Sickle Cell Awareness Program shall track infants identified with sickle cell disease and related hemoglobinopathies to ensure that they receive care and refer the infants to the Pediatric Comprehensive Sickle Cell Clinic Network.

B. The Pediatric Comprehensive Sickle Cell Clinic Network shall provide the following services:

1. Consultation on screened-abnormal results to primary care providers and parents;
2. Family counseling and support;
3. Regularly scheduled clinics, which meet the needs of the population served; and
4. Referral to appropriate inpatient care facilities.

C. The Pediatric Comprehensive Sickle Cell Clinic Network shall provide data as needed by the department's newborn screening services.

12VAC5-71-140. Responsibilities of metabolic treatment and genetic centers facilities.

A. The department's contracted metabolic treatment and genetic centers facilities shall collaborate with a specialized testing laboratory or laboratories for performing diagnostic testing on infants referred by the department's newborn screening services in accordance with § 32.1-65 of the Code of Virginia.

B. The department's contracted metabolic treatment and genetic centers facilities shall provide the following clinical services:

1. Consultation on screened-abnormal results to healthcare providers;
2. Family counseling and support;
3. Regularly scheduled clinics;
4. Appropriate inpatient care facilities;
5. Clinical genetic services; and
6. Nutritional counseling and support.

C. The department's contracted metabolic treatment and genetic centers facilities shall provide written diagnostic and other related case information to the department's newborn screening services.

12VAC5-71-150. Responsibilities of the Care Connection for Children network.

A. The Care Connection for Children network shall provide the following services:

1. Care coordination services for residents of the Commonwealth who are diagnosed with selected heritable disorders or genetic diseases and are referred to the network by Virginia Newborn Screening Services.
2. Other network services for eligible individuals in accordance with the § 32.1-77 of the Code of Virginia and applicable regulations.

B. The Care Connection for Children network shall provide data as needed by the department's newborn screening services.

12VAC5-71-160. Availability of assistance for obtaining metabolic formula, low protein modified foods, and metabolic supplements.

A. The department shall maintain a procedure to assist eligible persons in obtaining metabolic formula, low protein modified foods, and metabolic supplements.

B. Expenditures shall be limited to available funding.

C. Resident children under the age of 21 who have a diagnosis of a heritable disorder or genetic disease listed in 12VAC5-71-30 D and meet financial eligibility criteria for the Children with Special Health Care Needs Program pool of funds in accordance with the State Board of Health Regulations Governing Eligibility Standards and Charges for Medical Care Services to Individuals (12VAC5-200) may qualify to receive metabolic formula at no cost. Applicants who qualify must demonstrate that they are not eligible for available state and federal medical assistance programs and must demonstrate that they do not have insurance coverage for metabolic formula.

D. Resident children under the age of 21 who have a diagnosis of a heritable disorder or genetic disease listed in 12VAC5 71-30 D and do not meet financial eligibility criteria for the Children with Special Health Care Needs Program pool of funds in accordance with the State Board of Health Regulations Governing Eligibility Standards and Charges for Medical Care Services to Individuals (12VAC5-200) may be eligible to purchase metabolic formula through the Virginia Department of Health.

E. Resident adults ages 21 or older who have a diagnosis of a heritable disorder or genetic disease listed in 12VAC5-71-30 D and who have a gross family income at or below 300% of the federal poverty level in accordance with the State Board of Health Regulations Governing Eligibility Standards and Charges for Medical Care Services to Individuals (12VAC5-200) may qualify to receive metabolic formula at no cost. Applicants who qualify must demonstrate that

they are not eligible for available state and federal medical assistance programs and must demonstrate that they do not have current insurance coverage for metabolic formula.

F. Resident adults ages 21 or older who have a diagnosis of a heritable disorder or genetic disease listed in 12VAC5-71-30 D and who do not meet financial criteria or other eligibility criteria in accordance with the State Board of Health Regulations Governing Eligibility Standards and Charges for Medical Care Services to Individuals (12VAC5-200) may qualify to purchase metabolic formula through the Virginia Department of Health.

G. Residents who have a diagnosis of a heritable disorder or genetic disease listed in 12VAC5-71-30 D and who have a gross family income at or below of 300% of the federal poverty level in accordance with the State Board of Health Regulations Governing Eligibility Standards and Charges for Medical Care Services to Individuals (12VAC5-200) may be eligible to receive reimbursement from the department up to \$1,500 per year for purchase of low protein modified foods and metabolic supplements. Applicants who qualify must demonstrate that they are not eligible for available state and federal medical assistance programs and must demonstrate that they do not have current insurance coverage for low protein modified foods or metabolic supplements for which they are seeking reimbursement.

12VAC5-71-170. Emergency suspension of assistance.

The commissioner may suspend any portion of the assistance plan to ensure the financial integrity of Virginia Newborn Screening Services. The commissioner shall report any action taken under the provisions of this section to the Board of Health at its next scheduled meeting.

12VAC5-71-180. Use of federal, state, or other resources.

A. The commissioner or his designee may seek, receive, and expend federal, state general, or other nongeneral funds for the department necessary to administer newborn screening services.

B. Federal Title V funds received for the Children with Special Health Care Needs Program, authorized by § 32.1-77 of the Code of Virginia, may be used to support the department's newborn screening services, in accordance with applicable federal and state laws and regulations.

12VAC5-71-190. Confidentiality of information.

The department's newborn screening services and its contractors shall maintain, store, and safeguard client records from unauthorized access as required by law.



COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448
RICHMOND, VA 23218

Cynthia C. Romero, MD, FAAFP
State Health Commissioner

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

MEMORANDUM

DATE: May 13, 2013

TO: Virginia Board of Health

FROM: Lauri Kalanges, MD, MPH
Acting Director, Office of Family Health Services

SUBJECT: Proposed Amendments to 12VAC5-20 et seq. "Regulations for the Conduct of Human Research"

Enclosed for your review are proposed amendments to 12VAC5-20 et seq. "Regulations for the Conduct of Human Research". The Virginia State Board of Health is requested to approve the proposed amendments. Should the State Board of Health approve these amendments, the regulatory package will then be submitted for executive branch review. Following executive review and approval, the proposed amendments will be published in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall for a 60-day public comment period.

A periodic review of 12VAC5-20 et seq. "Regulations for the Conduct of Human Research" was conducted pursuant to Executive Order 14 (2010). This review was conducted in. The public comment period was between February 2, 2012 and March 21, 2012. No public comments were received. The findings of the review were to propose amendments for clarity, efficiency, and effectiveness. The proposed amendments are designed to update the regulations which were originally promulgated in 1993 and last amended in 2010.

The Notice of Intended Regulatory Action (NOIRA) was published on October 8, 2012 in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall. One comment was received during the public comment period which ended November 7, 2012. Following review the comment was found not applicable to the current regulation.

Thank you for your consideration. I look forward to discussing these proposed amendments with you at the June meeting.



Virginia
Regulatory
Town Hall

townhall.virginia.gov

Proposed Regulation Agency Background Document

Agency name	State Board of Health
Virginia Administrative Code (VAC) citation	12VAC5-20 et seq.
Regulation title	Regulations for the Conduct of Human Research
Action title	Amend the Virginia regulations for the Conduct of Human Research for clarity, efficiency and effectiveness
Date this document prepared	April 3, 2013

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 14 (2010) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

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

The proposed amendments update and clarify the current regulations regarding the conduct of human research to more closely reflect current practice and to achieve improvements that will be reasonable, prudent and will not impose an unnecessary burden on human subjects and researchers. The current regulations were originally promulgated and effective July 1, 1993 under statutory authority granted by the 1992 session of the Virginia General Assembly. The regulations were last amended in 2010. Based on findings from the most recent periodic review, the proposed regulations will: amend the definitions of 'human research', 'informed consent', and 'legally authorized representative' to be consistent with Code of Virginia § 32.1-162.16 et seq. and federal regulations 45 CFR Part 46; provide additional clarity on committee review procedures; add the requirement that the committee ensure compliance with the Health Insurance Portability and Accountability Act (HIPAA) and federal and state regulations regarding disclosure of Personal Health Information (PHI); provide additional clarification of the informed consent requirements; and revise the required reporting dates for the human subject research committee to report yearly activities and the commissioner to report the listing of institutions that are subject to federal regulations regarding human subject research and are exempt from 12VAC5-20 et seq.

Acronyms and Definitions

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

No acronyms are used.

Legal basis

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

Section 32.1-12.1 of the Code of Virginia states that "the State Board of Health shall promulgate regulations pursuant to the Administrative Process Act (§ 2.2-4000 et seq.) to effectuate the provisions of Chapter 5.1 (§ 32.1-162.16 et seq.) of this title for human research, as defined in § 32.1-162.16, to be conducted or authorized by the Department or any facilities or other entities operated, funded, or licensed by the Department." The imperative form of the verb "shall" is used in § 32.1-12.1 making the Board's authority to regulate the provisions of Chapter 5.1 (§ 32.1-162.16 et seq.) for human research mandatory rather than discretionary.

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.

To fulfill the statutory mandate to review regulations and to protect the citizens of the Commonwealth, the Virginia Department of Health conducted a periodic review of 12VAC5-20 et seq. "Regulations for the Conduct of Human Research" pursuant to Executive Order (EO) 14 (2010). As a result of this review, the Virginia Department of Health is providing proposed amendments to the regulations. It is necessary to amend these regulations to make corrections to outdated citations, provide consistency in language, and enhance the clarity of the regulations in order to achieve improvements that will be reasonable, prudent and will not impose an unnecessary burden on users of the Virginia Department of Health's Institutional Review Board, human subject researchers or the public.

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 proposed amendments to the regulations include:

- 1) Updating the definition of "Human Research."
- 2) Adding a definition of "Subject" or "human subject."
- 3) Replacing the term "participants" with "subjects" in various sections.
- 4) Eliminating the detail elements of informed consent in the definition section (12VAC5-20-10). This information is duplicated in Section 100.

- 5) Amending the definition of “Legally Authorized Representative” to be consistent with § 32.1-162.16.
- 6) Add a definition of “Protected Health Information (PHI)”.
- 7) In Section 30, replace the term “human participants” with “human subjects” to be consistent with language used in § 32.1-162.16.
- 8) Add subsection F in Section 40 to clarify that no official or employee of the institution or agency conducting or authorizing the research is qualified to act as a legally authorized representative.
- 9) In Section 50, the committee reporting requirement is changed from January 31 to March 31st each year.
- 10) In Sections 50 and 60 the term “chairman” is amended to “chair.”
- 11) Section 70 is amended to require that the committee have at least 5 members instead of at least 7 members.
- 12) In Section 80, a new subsection A is added to clarify that no human research shall be conducted unless a research committee has reviewed and approved the project. The section is also amended to provide details as to the elements of the project that are to be considered in the review.
- 13) Section 80 is amended to delete the requirement that the committee approve a written procedure for when a subject has a complaint regarding the research. The requirement that the committee develop a procedure is retained.
- 14) In Section 80, a new subsection F requires that the committee chair provide a written report to the head of the institution regarding any violation that led to either a suspension or termination of the research.
- 15) In Section 80, a new subsection H requires that the committee ensure compliance with the Health Insurance Portability and Accountability Act (HIPAA) and federal and state regulations regarding disclosure of Personal Health Information (PHI).
- 16) In Section 80, a new section I provides that cooperating institutions conducting research may enter into a joint review, rely on another qualified committee or come to an agreement that avoids duplication of review effort.
- 17) Section 90 is amended and new subsections B and C are added to provide additional clarification on when and how an expedited review can be completed and clarifies the authority to suspend or terminate approval for a project.
- 18) Section 100 is amended and new subsections B, C, D, E and G are added to further clarify the informed consent requirements and when the committee may waive the informed consent requirement.
- 19) In Section 110 the reference to the Alzheimer’s Disease and Related Disorders Registry is eliminated along with the reference to § 32.1-116.1:2.
- 20) In Section 130 the reporting date is changed from January 31 to March 31 annually.

Issues

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

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

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

-
- 1) There are no disadvantages to the public.
 - 2) There are no disadvantages to the agency or the Commonwealth. An advantage to the agency and the Commonwealth is that the amended regulations will provide greater clarification on the requirements for human research and clarification on the protection of research subjects.
 - 3) There are no other pertinent matters of interest related to this action.

Requirements more restrictive than federal

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

These regulations are no more restrictive than the federal regulations governing conduct of human research (45 CFR Part 46).

Localities particularly affected

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

There are no localities that bear any identified disproportionate material impact from these amended regulations.

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 Town Hall website (<http://www.townhall.virginia.gov>), or by mail, email or fax to Dev Nair, Virginia Department of Health, 109 Governor Street, 10th Floor, Richmond, VA 23219, TEL: (804) 864-7662, EMAIL: Dev.Nair@vdh.virginia.gov, FAX: (804) 864-7380. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on 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 requirements 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 Board does not anticipate any additional incurred cost to implement or enforce this proposed amended regulation</p>
<p>Projected cost of the <i>new regulations or changes to existing regulations</i> on localities.</p>	<p>None</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>No additional impact on individuals, businesses or other entities.</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>N/A</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 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>No additional costs will be incurred related to clarifying the Conduct of Human Research regulations</p>
<p>Beneficial impact the regulation is designed to produce.</p>	<p>Protection of the rights and welfare of participants in any research projects conducted or authorized by the department and any facility operated, funded, or licensed by the department.</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 two alternatives to the present action are to leave the current regulations intact or to make fewer changes to the regulations. However, in reviewing these regulations it has been decided to make all the changes included in this package to provide greater clarity and bring the regulations in line with current practice and the federal regulations.

Regulatory flexibility analysis

Please describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum:

1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

The regulatory change impacts the operation of the Virginia Department of Health Institutional Review Board, which does not meet the statutory definition of a small business. Therefore, the adverse impact on small businesses does not apply in the development of this regulatory action.

Public comment

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

Commenter	Comment	Agency response
Vinita Johnson	Personnel complaint against state agency (not VDH).	Comment reviewed and found not applicable to this specific regulation.

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 changes do not strengthen or erode the authority or rights of parents in the education, nurturing and supervision of their children; or 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.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action.

If the proposed regulation is intended to replace an emergency regulation, please list separately (1) all differences between the **pre-emergency** regulation and this proposed regulation, and (2) only changes made since the publication of the emergency regulation.

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

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
Section 10: Definitions	N/A	Definition of "Human Research"	The definition is amended to be consistent with the § 32.1-162.16.
Section 10: Definitions	N/A	Definition of "Informed Consent"	The definition is amended to eliminate the detailed elements of informed consent that are duplicated in 12VAC5-20-100.
Section 10: Definitions	N/A	Definition of "Legally authorized representative"	This definition is amended to be consistent with § 32.1-162.16.
Section 10: Definitions	N/A		Add definition of "Protected health information (PHI)".
Section 10: Definitions	NA		Add definition of "Subject or Human Subject"
Section 10: Definitions	N/A	Current regulations use the term "participants".	The term "participants" is amended to "subjects" to be consistent with language used in § 32.1-162.16 et seq.
Section 30: Applicability	N/A	Current regulations use the term "human participants".	The term "participants" is amended to "subjects" to be consistent with language used in § 32.1-162.16 et seq.
Section 40: Policy	NA	Current regulations use the term "may".	The term "may" is amended to "shall" to require that no human research be conducted without informing the subject of risks.
Section 40: Policy	N/A	Current regulations reference 12VAC5-20-100 F and H of this chapter.	Remove reference to "F and H of this chapter".
Section 40: Policy	N/A		New subsection F clarifies that no official or employee of the institution or agency conducting or authorizing the research is qualified to act as a legally authorized representative.
Section 40: Policy	N/A	Current regulations use the term "participant."	The term "participant" is amended to "subject."
Section 40: Policy	N/A	Current regulations use the term "research."	The term "research" is amended to "human research" for consistency.
Section 50: Review Process for Department	N/A	Current regulations use the term "participant."	The term "participant" is amended to "subject."
Section 50: Review Process for Department	N/A	Current regulations require the committee to report yearly activities by January of each year.	The reporting requirement is amended to March 31 of each year.
Section 50: Review Process for Department	N/A	Current regulations reference "chairman".	The term "chairman" is amended to "chair".

Section 60: Review for Institutions or Agencies Funded or Licensed by the Department	N/A	Current regulations use the term "participant."	The term "participant" is amended to "subject."
Section 60: Review Process for Institutions or Agencies Funded or Licensed by the Department	N/A	Current regulations reference "chairman".	The term "chairman" is amended to "chair".
Section 70: Composition of Research Review Committee	N/A	Current regulations use the term "participant."	The term "participant" is amended to "subject."
Section 70: Composition of Research Review Committee	N/A	Current regulation requires that the committee have at least seven members.	The requirement that the committee have at least seven members is amended to be at least 5 members in order to be consistent with the federal regulations (45 CFR § 46.107) and provide greater efficiency
Section 80: Elements of Committee Review Process	N/A		New subsection A clarifies that no human research shall be conducted unless a research review committee has reviewed and approved the project and provides details as to the elements of the project that are to be considered in the review.
Section 80: Elements of Committee Review Process	N/A	Current regulation requires that the committee approve or develop a written procedure for when a subject has a complaint regarding the research.	Deletes the requirement that the committee approve a written procedure and retains the requirement that the committee develop a procedure to be followed when a research subject has a complaint.
Section 80: Elements of Committee Review Process	N/A		New subsection F provides that the committee shall have the authority to suspend or terminate approval of research that is not conducted according to committee requirements or that is associated with unexpected serious harm to subjects.
Section 80: Elements of Committee Review Process	N/A		New subsection G requires that the committee chair provide a written report to the head of the institution of any violation that led to either a suspension or termination of human research.

Section 80: Elements of Committee Review Process	N/A		New subsection I requires that the committee ensure compliance with the HIPAA and federal and state regulations regarding disclosure of PHI.
Section 80: Elements of Committee Review Process	N/A		New subsection J provides that cooperating institutions conducting research may enter into joint review, rely upon the review of another qualified committee or come to an agreement that will avoid duplication of effort. The section provides details on the content of any such agreements and the approval process.
Section 90: Expedited Review of Human Research Projects	N/A	Current regulations authorize the committee to conduct an expedited review of a human research project which involves no more than minimal risk to the subjects.	Amends section to add that the research shall involve procedures that are in one or more categories established by the U.S. Secretary of Health and Human Services and published in the Federal Register.
Section 90: Expedited Review of Human Research Projects	N/A		New subsection B clarifies when the expedited review procedure may be used.
Section 90: Expedited Review of Human Research Projects	N/A		New subsection C clarifies that the expedited review may be carried out by the chair or by one or more reviewers designated by the chair. The reviewers may exercise all the authority of the IRB except that they may not disapprove the research. A research project can only be disapproved after review in accordance with 12VAC5-20-80.
Section 100: Informed Consent	N/A	Current regulations address the basic information necessary for an informed consent to participate as a research subject.	Subsection A. 1 is amended to add the requirement that information on how the results of the human research will be disseminated, and how the identity of the individual will be protected.
Section 100: Informed Consent	N/A	Current regulations address the basic information necessary for an informed consent to participate as a research subject.	Subsection A. 2 is amended to add the requirement that information on side effects, risks and benefits of any appropriate alternative procedures or therapies be disclosed.
Section 100: Informed Consent	N/A		New subsection A.3 requires that a description of any adverse consequences and risks to be expected and an indication whether there may be other significant risks not yet identified be disclosed as an element of informed consent.

Section 100: Informed Consent	N/A	Current regulations address the basic information necessary for an informed consent to participate as a research subject	Subsection A.4 is amended to include that a person may withdraw consent or discontinue participation from the research without fear of reprisal.
Section 100: Informed Consent	N/A	Current regulations address the basic information necessary for an informed consent to participate as a research subject	Subsection A.5 is amended to include in the elements of informed consent information on any medical care that may be available if an injury occurs.
Section 100: Informed Consent	N/A	Current regulations address the basic information necessary for an informed consent to participate as a research subject	Subsection A.6 is amended to include in the elements of informed consent an offer to answer any inquiries if applicable for the legally authorized representative and a description of the ways that any concerns may be raised or questions asked.
Section 100: Informed Consent	N/A		A new subsection B clarifies that no human research shall be conducted in the absence of informed consent and clarifies the conditions under which informed consent must be obtained.
Section 100: Informed Consent	N/A		New subsection C clarifies that informed consent shall not include any language through which the individual waives legal rights including any release of any person, institution or agency from liability for negligence. Also, no individual shall be forced to participate in human research if the investigator knows that participation is protested by the individual.
Section 100: Informed Consent	N/A		New subsection D clarifies that a legally authorized representative may not consent to human research unless it will present no more than a minor increase over minimal risk and that no aspect of the research is contrary to the religious beliefs or basic values of the individual.
Section 100: Informed Consent	N/A		New subsection E. and subsection E. 1-4 clarifies when the research review committee may approve a consent procedure that does not include or that alters some of the elements of informed consent. These include when the risk is no more than minimal; the alteration will not adversely affect the rights and welfare of the individual; the research cannot be practicably carried out without the omission, wavier or alteration; and the individuals are provided with additional pertinent information after their participation.

Section 100: Informed Consent	N/A		New subsection G provides additional clarification of when the research review committee may waive the requirement for informed consent which includes if the only record linking the individual and the research would be the consent document and the risk would be potential harm from a breach of confidentiality. In this case, each individual will be asked whether they want documentation linking them with the research and their wishes govern. The committee may require the investigator to provide individuals with a written statement explaining the research.
Section 110: Categories of Human Research Exempt from Regulation	N/A	Current regulations exempt research designed to study large scale anonymous vital records and registry data including the Statewide Alzheimer's Disease and Related Disorders Registry (32.1-71.1) and references section 32.116.1:2 relating to Emergency Medical Services Patient Care Information System.	Amend subsection 2 to delete The Alzheimer's Disease and Related Disorders Registry as Section 32.1-71.1 of the Code of Virginia was repealed in 1994. Section 32.116.1:2 relating to the Emergency Medical Services Patient Care Information System has expired.
Section 120: Committee Records	N/A	Current regulations require that an overview of approved human research projects and the results be made public on the department's website.	Amend subsection C to specify that each research review committee of a state institution or agency shall provide an overview of approved projects and results on their website.
Section 130: Applicability of Federal Policies	N/A	Current regulations require institutions whose human research is subject to federal regulations to notify the commissioner annually that they are exempt from this chapter and they are in compliance with the federal regulations. The commissioner is required to report this information in an annual report to the Governor and the General Assembly by January 31.	Amend Section 130 to change the reporting date from January 31 to March 31 annually.

Project 3674 - none

DEPARTMENT OF HEALTH

Update Following Periodic Review

(Amending 12VAC5-20-10, 12VAC5-20-30, 12VAC5-20-40, 12VAC5-20-50, 12VAC5-20-60, 12VAC5-20-70, 12VAC5-20-80, 12VAC5-20-90, 12VAC5-20-100, 12VAC5-20-110, 12VAC5-20-120, 12VAC5-20-130)

CHAPTER 20

REGULATIONS FOR THE CONDUCT OF HUMAN RESEARCH

12VAC5-20-10. Definitions.

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

"Affiliated with the institution" means employed by or contracting with the institution or directly or indirectly involved in the management thereof.

"Commissioner" means the Commissioner of the Department of Health.

"Committee" means human research committee assembled pursuant to 12VAC5-20-70 of this chapter by any institution defined herein.

"Department" means the Department of Health.

"Human research" means any systematic investigation ~~utilizing human participants who may be exposed to physical or psychological injury as a consequence of participation and which departs from the application of established and accepted therapeutic methods appropriate to meet the participants' needs,~~ including research development, testing and evaluation, utilizing human subjects, that is designed to develop or contribute to generalized knowledge. Human research shall not be deemed to include research exempt from federal research regulation pursuant to 45 C.F.R. § 46.101 (b).

"Informed consent" means the knowing and voluntary agreement, without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion, of a person who is capable of exercising free power of choice. For the purposes of human research, the basic elements of information necessary to such consent shall include:

- ~~1. A reasonable and comprehensible explanation to the person of the proposed procedures or protocols to be followed, their purposes, including descriptions of any attendant discomforts, and risks and benefits reasonably to be expected;~~
- ~~2. A disclosure of any appropriate alternative procedures or therapies that might be advantageous for the individual;~~
- ~~3. An instruction that the person may withdraw his consent and discontinue participation in the human research at any time without prejudice to him;~~
- ~~4. An explanation of any costs or compensation which may accrue to the person and, if applicable, the availability of third party reimbursement for the proposed procedures or protocols; and~~
- ~~5. An offer to answer any inquiries by any individual concerning the procedures and protocols.~~

In addition to the required elements, the information provided to the individual should also include the following:

- ~~1. A statement that the study involves research, and an explanation that includes identification of any procedures which are experimental; the expected duration of the individual's participation; and a statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained; and if any data from this study are published, the individual will not be identified without his written permission;~~

- ~~2. A statement that there may be other risks not yet identified;~~
- ~~3. A disclosure of any appropriate alternative procedures or therapies that might be advantageous for the individual;~~
- ~~4. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the individual is otherwise entitled, and the individual may discontinue participation at any time without penalty or loss of benefits to which he is otherwise entitled;~~
- ~~5. An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury; and~~
- ~~6. For research involving more than minimal risk, an explanation as to whether any compensation or medical care is available if injury occurs and, if so, what is included or where further information may be obtained.~~

~~Information should be provided in a manner that is understandable to the individual with regard to his educational level and language of greatest fluency.~~

"Institution" or "agency" means any facility, program, or organization owned or operated by the Commonwealth, by any political subdivision, or by any person, firm, corporation, association, or other legal entity.

"Legally authorized representative" means in the following specified order of priority, (i) the parent or parents having custody of a prospective participant subject of human research who is a minor, (ii) the agent appointed under an advance directive as defined in § 54.1-2982 of the Code of Virginia, executed by the individual who is the prospective subject of human research, provided the advance directive authorizes the agent to make decisions regarding the individual's participation in human, (iii) the legal guardian of a prospective participant subject of human

research, (iv) the spouse of a prospective subject of human research, except where a suit for divorce has been filed and the divorce decree is not yet final, (v) an adult child of a prospective subject of human research, (vi) a parent of a prospective subject of human research when the individual is an adult, (vii) an adult brother or sister of a prospective subject of human research, or (viii) any person or judicial or other body authorized by law or regulation to consent on behalf of a prospective participant ~~subject of human research~~ to such person's participation in the particular human research. For the purposes of this chapter, any person authorized by law or regulation to consent on behalf of a prospective participant ~~subject~~ to his such subject's participation in the particular human research shall include an attorney-in-fact appointed under a durable power of attorney, to the extent the power grants the authority to make such a decision. The attorney-in-fact shall not be employed by the person, institution or agency conducting the human research. No official or employee of the institution or agency conducting or authorizing the research shall be qualified to act as a legally authorized representative.

"Minimal risk" means that the risks of harm or discomfort anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations ~~or tests~~ or treatments.

"Nontherapeutic research" means human research in which there is no reasonable expectation of direct benefit to the physical or mental condition of the ~~participant~~ subject.

"Protected health information or PHI" means individually identifiable health information that is created or received by or on behalf of the institution or agency that is maintained or transmitted in any medium, including electronic media. PHI excludes individually identifiable health information in:

1. Education records covered by the Family Educational Rights and Privacy Act, as amended, 20 USC § 1232g;

2. Records described at 20 USC §1232g(a)(4)(B)(iv) (educational records not otherwise covered under the Family Educational Rights and Privacy Act in subdivision 1 of this definition); or

3. Employment records held by a covered entity in its role as an employer.

“Subject” or “human subject” means a living individual about whom an investigator (whether professional or student) conducting research obtains 1) data through intervention or interaction with the individual, or 2) identifiable private information.

“Quorum” means a simple majority of the number of voting members of the committee.

12VAC5-20-20. [Reserved]

12VAC5-20-30. Applicability.

This chapter shall apply to the department, including any local health department and to any facility operated, funded or licensed by the department which conducts or which proposes to conduct or authorize research ~~which uses human participants~~ subjects.

12VAC5-20-40. Policy.

A. No human research ~~may~~ shall be conducted without informing the ~~participant~~ subject or his legally authorized representative of the procedures, risks, and discomforts of the research. The consent of the ~~participant~~ subject or his legally authorized representative to participate in the research shall be subscribed to in writing by the ~~participant~~ subject or his legally authorized representative and supported by the signature of a witness not involved in the conduct of the research, except as provided for in 12VAC5-20-100 ~~F and H of this chapter~~. Special arrangements shall be made for those who need assistance in understanding the consequences of participating in the research.

B. Each human research activity shall be reviewed and approved by a committee as set forth in 12VAC5-20-70 ~~of this chapter~~ composed of representatives of varied backgrounds who shall assure the competent, complete, and professional review of human research activities.

C. Every person engaged in the conduct of human research or proposing to conduct human research shall associate himself with an institution or agency having a research review committee, and the human research which he conducts or proposes to conduct shall be subject to review and approval by such committee in the manner set forth in ~~these regulations~~ this chapter.

D. Nontherapeutic research using patients or residents within an institution as defined herein is forbidden unless it is determined by the research review committee that such nontherapeutic research will not present greater than minimal risk.

E. The individual conducting the human research shall ~~be required to~~ notify all ~~participants~~ subjects of human research of the risks caused by the research which are discovered after the research has concluded. If consent has been obtained by the signature of the legally authorized representative, the legally authorized representative shall also be notified.

F. No official or employee of the institution or agency conducting or authorizing the human research shall be qualified to act as a legally authorized representative for a subject of the particular human research.

12VAC5-20-50. Review process for department.

A. Prior to the initiation of a human research project by any component of the department, a description of the proposed human research project shall be submitted to a research review committee established by the department for review and approval. The description shall include a statement of the purpose of the proposed project and justification thereof, the criteria for

inclusion of a ~~participant~~ as a subject in the research project, a description of what will be done to the ~~participants~~ subjects, and a copy of the informed consent statement.

B. The committee shall report by ~~January~~ March 31 of each year to the commissioner on activities of the committee during the previous calendar year. Such reports shall include:

1. A description of each human research project reviewed and approved or disapproved;
2. Any significant deviations from proposals as approved;
3. A list of committee members, their qualifications for service on the committee, and their institutional affiliation; and
4. A copy of the minutes of any committee meetings conducted.

C. The ~~chairman~~ chair of the committee shall report as soon as possible to the commissioner any violation of the research protocol which led the committee to either suspend or terminate the research.

D. The commissioner may inspect the records of the committee.

E. The commissioner shall report at least annually to the Governor and General Assembly on the human research projects conducted by any component of the department as annually reported to the commissioner by the committee.

12VAC5-20-60. Review process for institutions or agencies funded or licensed by the department.

A. Prior to the initiation of a human research project by any institution or agency funded or licensed by the department, a description of the proposed human research project shall be submitted to a research review committee for review and approval. The description shall include a statement of the purpose of the proposed project and justification thereof, the criteria for

inclusion of a ~~participant~~ subject in the research project, a description of what will be done to the ~~participants~~ subjects, and a copy of the informed consent statement.

B. When more than one such institution or agency is involved in a research project, the cooperating entities may enter into joint review.

C. Such institutions or agencies having a committee shall report by ~~January~~ March 31 of each year to the commissioner on activities of the committee during the previous calendar year.

Such reports shall include:

1. A description of each human research project reviewed and whether it was approved or disapproved;
2. Any significant deviations from proposals as approved;
3. A list of committee members, their qualifications for service on the committee, and their institutional affiliation; and
4. A copy of the minutes of any committee meetings conducted.

D. The ~~chairman~~ chair of the committee shall report as soon as possible to the head of such institution or agency and to the commissioner any violation of the research protocol which led the committee to ~~either~~ suspend or terminate the research.

E. The commissioner may inspect the records of the committee.

F. The commissioner shall report at least annually to the Governor and General Assembly on the human research projects conducted by such institutions or agencies as annually reported to the commissioner by the relevant research review committees.

12VAC5-20-70. Composition of research review committee.

A. Each committee shall have at least ~~seven~~ five members, appointed by the head of the institution, with varying backgrounds to provide complete and adequate review of activities

commonly conducted by the institution. The committee shall be sufficiently qualified through the maturity, experience, and diversity of its members, including consideration of race, gender and cultural background, to promote respect for its advice and counsel in safeguarding the rights and welfare of ~~participants~~ subjects in human research. In addition to possessing the professional competence necessary to review specific activities, the committee shall be able to ascertain the acceptability of applications and proposals in terms of institutional commitments and regulations, applicable law, standards of professional conduct and practice, and community attitudes. If a committee regularly reviews research that has an impact on patients or residents within an institution as defined herein or other vulnerable category of ~~participants~~ subjects, the committee shall have in its membership one or more individuals who are primarily concerned with the welfare of these ~~participants~~ subjects and who have appropriate experience to serve in that capacity.

B. No committee shall consist entirely of members of one profession, and at least one member ~~must~~ shall be an individual whose primary concerns are in nonscientific areas (e.g., lawyers, ethicists, members of the clergy).

C. Each committee shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

D. No member of a committee shall participate in the committee's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the committee. The committee has responsibility for determining whether a member has a conflicting interest. The committee size shall be maintained at no fewer than ~~seven~~ five persons by appointment of a substitute representative for each member with a conflicting interest.

E. A committee may, at its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the committee. These individuals ~~may~~ shall not vote with the committee.

F. A quorum of the committee shall consist of a majority of its members including at least one member whose primary concerns are in nonscientific areas.

G. The committee and the institution shall establish procedures and rules of operation necessary to fulfill the requirements of this chapter.

12VAC5-20-80. Elements of committee review process.

A. No human research shall be conducted or authorized by an institution or agency unless a research review committee has reviewed and approved the proposed human research project giving consideration to:

1. The adequacy of the description of the potential benefits and risks involved and the adequacy of the methodology of the human research;

2. The degree of the risk, and, if the human research is nontherapeutic, whether it presents greater than minimal risk;

3. Whether the rights and welfare of the human subjects involved are adequately protected;

4. Whether the risks to the human subjects are outweighed by the potential benefits to them;

5. Whether the risks to subjects are minimized by using procedures that are consistent with sound human research design and that do not unnecessarily expose subjects to risk, and whenever appropriate, by using currently accepted procedures for diagnostic or treatment purposes;

6. Whether additional safeguards have been included in the study to protect the rights and welfare of the subjects when some or all of the subjects are likely to be incapable of providing informed consent or are otherwise vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons or economically or educationally disadvantaged person;

7. Whether the informed consent is to be obtained by methods that are adequate and appropriate and whether the written consent form is adequate and appropriate in both content and language for the particular human research and for the particular subjects of the human research;

8. Whether the persons proposing to supervise or conduct the particular human research are appropriately competent and qualified;

9. Whether criteria for selection of subjects are equitable; and

10. Whether the human research conforms with other requirements of the department, where applicable.

AB. The committee shall consider a research ~~proposals~~ proposal within 45 days after its submission to the committee. In order for the research proposal to be approved, it shall receive the approval of a majority of ~~these~~ the committee members present at a meeting in which a quorum exists. A committee shall notify investigators and the institution in writing of its decision to approve or disapprove the ~~proposed research activity~~ proposal, or of modifications required to secure committee approval.

BC. During the committee review of research ~~projects~~ proposals, no personal identifiers of present or potential subjects shall be stated.

~~CD.~~ The committee shall ~~approve or~~ develop a written description of the procedure to be followed when a subject has a complaint about a research project in which he is participating or has participated.

~~DE.~~ Any subject who has a complaint about a research project in which he is participating or has participated shall be referred to the committee to determine if there has been a violation of the protocol.

F. The committee shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the committee requirements or that has been associated with unexpected serious harm to the subjects. Any suspension or termination of approval shall include a statement of the reasons for the committee's action and shall be reported promptly to the investigator, appropriate institutional officials, the department or agency head and the commissioner.

G. The chair of the committee shall provide a written report to the head of the institution of any violation of the human research protocol that led the committee to suspend or terminate the human research.

~~EH.~~ The committee shall require reports from approved research projects at least annually to ensure conformity with the approved proposal. The frequency of such reports shall be consistent with the nature and degree of risk of each research project. The committee shall also require a report ~~from the research project~~ at the conclusion of the research project.

I. The committee shall ensure compliance with the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191), if applicable, and federal and state regulations regarding the use and disclosure of PHI created for human research. In particular, authorization shall be obtained for the use and disclosure of PHI created for the purpose of human research, except as otherwise permitted by 45 C.F.R. § 164-512(i).

J. When cooperating institutions conduct some or all of the human research involving some or all of the subjects of the human research, each cooperating institution shall be responsible for safeguarding the rights and welfare of the subjects and for complying with this chapter, provided however, in complying with this chapter, institutions may enter into joint review, rely upon the review of another qualified committee, or come to similar agreements aimed at avoiding duplication of effort. Any such agreement shall be in writing and designate a lead institution, which shall be the institution responsible for reporting and handling any possible misconduct in the human research. Such agreements shall be entered into by the committee chair with the approval of a majority of the committee members. If an institution or agency does not have a research review committee, such agreements shall be approved and entered into by the chief executive officer of the institution, or his designee.

12VAC5-20-90. Expedited review of human research projects.

A. The committee is authorized to conduct an expedited review of a human research project which involves no more than minimal risk to the subjects if: and involves only research procedures listed in one or more categories established by the Secretary of Health and Human Services and published in the Federal Register, pursuant to 45 C.F.R. § 46.110.

B. The committee also is authorized to conduct an expedited review of a human research project which involves no more than minimal risk to the subjects if:

1. Another institution's or agency's human research review committee has reviewed and approved the project; or
2. The review involves only minor changes in previously approved research and the changes occur during the approved project period.

C. An expedited review may be carried out by the chair of the committee or by one or more experienced reviewers designated by the chair from among the committee members. In

reviewing the research project, the reviewers may exercise all of the authorities of the committee except that the reviewers may not disapprove the research project. A research project may be disapproved only after review by the full committee in accordance to the procedures set forth in 12VAC5-20-80.

~~BD.~~ Each committee which uses an expedited review procedure shall adopt a method for keeping all members advised of research ~~proposals~~ projects which have been approved under the procedure.

12VAC5-20-100. Informed consent.

A. "Informed consent" means the knowing and voluntary agreement, without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion, of a person who is capable of exercising free power of choice. For the purposes of human research, the basic elements of information necessary to determine the existence of such consent shall include the following:

1. A reasonable and comprehensible explanation to the person of the proposed procedures or protocols to be followed, their purposes, including descriptions of any attendant discomforts, and risks and benefits reasonably to be expected, how the results of the human research are disseminated, and how the identity of the person is protected;
2. A disclosure of any appropriate alternative procedures or therapies that might be advantageous for the ~~individual~~ person, together with their side effects, risks and benefits;
3. A description of any adverse consequences and risks to be expected and an indication whether there may be other significant risks not yet identified;

~~34~~. An instruction that the person may withdraw his consent and discontinue participation in the human research at any time without prejudice to him or fear of reprisal;

45. An explanation of any costs or compensation that may accrue to the person and, if applicable, the availability of third party reimbursement for the proposed procedures or protocols or any medical care that may be available if an injury occurs;

56. An offer to answer any inquiries by ~~any individual~~ the person or, if applicable, his legally authorized representative concerning the procedures and protocols and a description of the ways in which concerns may be raised or questions asked;

67. A statement that the study involves research, and an explanation that includes identification of any procedures that are experimental; the expected duration of the ~~individual's~~ person's participation; a statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained; and if any data from this study are published, the ~~individual~~ person will not be identified without his written permission;

78. A statement that there may be other risks not yet identified;

89. A disclosure of any appropriate alternative procedures or therapies that might be advantageous for the ~~individual~~ person;

910. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the ~~individual~~ person is otherwise entitled, and the ~~individual~~ person may discontinue participation at any time without penalty or loss of benefits to which he is otherwise entitled;

~~40~~11. An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury; and

4112. For research involving more than minimal risk, an explanation as to whether any compensation or medical care is available if injury occurs and, if so, what is included or where further information may be obtained.

Information shall be provided in a manner that is understandable to the individual with regard to his educational level and language of greatest fluency.

B. No human research shall be conducted in the absence of informed consent subscribed to in writing by the individual or by the individual's authorized representative except as provided for in subsection E of this section. If the individual is capable of providing informed consent, written consent shall be provided by the individual and witnessed. If the individual is incapable of making an informed decision, as defined in § 54.1-2982 of the Code of Virginia, at the time consent is required, written consent shall be provided by the individual's legally authorized representative and witnessed. If the individual is a minor otherwise capable of rendering informed consent, the consent shall be provided by both the minor and his legally authorized representative. An investigator shall seek such consent only under circumstances that provide the individual who is the prospective subject or the representative sufficient opportunity to consider whether to participate and that minimize the possibility of coercion or undue influence. The information that is given to the individual or, if applicable the individual's legally authorized representative shall be in language understandable to the individual or representative.

C. No individual shall participate in human research unless the informed consent requirement in this section is met. No informed consent shall include any language through which the individual waives or appears to waive any of his legal rights, including any release of any person, institution, or agency or any agents thereof from liability for negligence. No individual

shall be forced to participate in any human research if the investigator conducting the human research knows that participation in the human research is protested by the individual.

D. No legally authorized representative shall consent to non therapeutic human research unless it is determined by the research review committee that such non therapeutic research will present no more than a minor increase over minimal risk to the individual. A legally authorized representative may not consent to participation in human research on behalf of an individual if the legally authorized representative knows, or upon reasonable inquiry ought to know, that any aspect of the human research protocol is contrary to the religious beliefs or basic values of the individual, whether expressed orally or in writing.

E. The research review committee may approve a consent procedure that does not include or that alters some or all of the elements of informed consent set forth in this section, or that waives the requirements to obtain informed consent provided the committee finds and documents that:

1. The human research involves no more than minimal risk to the subjects;

2. The omission, waiver, or alteration will not adversely affect the rights and welfare of the individuals;

3. The human research could not practicably be performed without the omission, waiver, or alterations; and

4. After participation, the subjects shall be provided with additional pertinent information, whenever appropriate.

BF. Consent may take the form of either of the following:

1. A written consent document that embodies the elements of informed consent required by this section. This form may be read to the subject or the subject's legally authorized

representative, but, in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed and witnessed; or

2. A short form written consent document stating that the elements of informed consent required by this section have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the committee shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself written consent is to be signed by the subject or the representative. However, the witness shall sign both the short form written consent and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary and a copy of the short form written consent shall be given to the subject or the representative.

G. The research review committee may waive the requirement in subsection B of this section for the investigator to obtain a written informed consent form for some or all subjects if it finds that the only record linking the subject and the human research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject shall be asked whether the subject wants documentation linking the subject with the human research, and the subject's wishes shall govern. In cases where the documentation requirement is waived, the committee may require the investigator to provide subjects with a written statement explaining the human research.

12VAC5-20-110. Categories of human research exempt from regulation.

Research activities in which the only involvement of human participants ~~will be~~ subjects is in one or more of the following categories are exempt from this chapter:

1. The surveillance and investigation by the department into all preventable diseases and epidemics in the Commonwealth and into the means for the prevention of such diseases and epidemics conducted pursuant to § 32.1-39 of the Code of Virginia.
2. Research designed to study on a large scale anonymous vital records and registry data collected pursuant to the Code of Virginia, Chapter 7 (§ 32.1-249 et seq.) of Title 32.1 (Vital Records), § 32.1-64.1 (Virginia Hearing Impairment Identification and Monitoring System), § 32.1-69.1 (~~Virginia~~ Virginia Congenital Anomalies Reporting and Education System), § 32.1-70 (Statewide Cancer Registry), ~~§ 32.1-71.1 (Statewide Alzheimer's Disease and Related Disorders Registry), § 32.1-46.01 (Virginia Immunization Information System)~~ and ~~§§ § 32.116.1 and 32.116.1:2~~ (Emergency Medical Services Patient Care Information System).
3. Research or student learning outcomes assessment conducted in educational settings such as research involving:
 - a. Regular or special education instructional strategies; or
 - b. The effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods; or
 - c. The use of educational tests, whether cognitive, diagnostic, aptitude, or achievement, if the data from such tests are recorded in a manner so that ~~participants~~ subjects cannot be identified, directly or through identifiers linked to the ~~participants~~ subjects.
4. Research involving survey or interview procedures unless responses are recorded in such a manner that the ~~participants~~ subjects can be identified, directly or through identifiers linked to the ~~participants~~ subjects, and either:

- a. The ~~participant's~~ subject's responses, if they became known outside the research, could reasonably place the participant at risk of criminal or civil liability or be damaging to his financial standing, employability, or reputation; or
 - b. The research deals with sensitive aspects of the ~~participant's~~ subject's own behavior such as sexual behavior, drug or alcohol use, or illegal conduct.
5. Research involving survey or interview procedures, when the respondents are elected or appointed public officials or candidates for public office.
6. Research involving solely the observation of public behavior, including observation by participants, unless observations are recorded in such a manner that the ~~participants~~ subjects can be identified, directly or through identifiers linked to the ~~participants~~ subjects, and either:
- a. The observations recorded about the ~~individual~~ subject, if they became known outside the research, could reasonably place the ~~participant~~ subject at risk of criminal or civil liability or be damaging to his financial standing, employability, or reputation; or
 - b. The research deals with sensitive aspects of the ~~participant's~~ subject's own behavior, such as sexual behavior, drug or alcohol use, or illegal conduct.
7. Research involving the collection or study of existing data, documents, records, or pathological specimens, if these sources are publicly available or if the information is recorded by the investigator in a manner so that ~~participants~~ subjects cannot be identified, directly or through identifiers linked to the ~~participants~~ subjects.

12VAC5-20-120. Committee records.

A. Documentation of committee activities shall be prepared and maintained by each such committee and shall include the following:

1. Copies of all research proposals reviewed, scientific evaluations that may accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to ~~participants~~ subjects;
2. Minutes of committee meetings ~~which shall be~~ in sufficient detail to show attendance at the meetings; actions taken by the committee; the vote on ~~these actions~~ each action, including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution;
3. Records of continuing review activities;
4. Copies of all correspondence between the committee and the investigators;
5. A list of committee members;
6. Written procedures for the committee; and
7. Statements of significant new findings provided to ~~participants~~ subjects.

B. The records required by this chapter shall be retained for at least three years, and records relating to research which is conducted shall be retained for at least three years after completion of the research. All records shall be accessible for inspection and copying by authorized employees or agents of the department at reasonable times and in a reasonable manner.

C. Each research review committee of a state institution or agency shall ensure that ~~An~~ an overview of approved human research projects and the results of such projects ~~will be~~ are made public on ~~the department's~~ such institution's or agency's website unless otherwise exempt from disclosure under the Virginia Freedom of Information Act (§ 2.2-3700 et seq. of the Code of Virginia).

12VAC5-20-130. Applicability of federal policies.

Human research at ~~institutions~~ which are is subject to policies and regulations for the protection of human ~~participants~~ subjects promulgated by any agency of the federal government shall be exempt from this chapter. ~~Such institutions~~ Institutions where research is performed that is subject to federal policies and regulation shall notify the commissioner annually, by ~~January~~ March 31, of their compliance with the policies and regulations of federal agencies. The commissioner shall identify institutions exempt from this chapter as reported in accordance with this section in the annual report to the Governor and the General Assembly provided in accordance with 12VAC5-20-60F.