

**State of Board of Health  
Agenda  
December 4, 2014 – 9:00 a.m.  
Perimeter Center, Boardroom 2  
9960 Mayland Drive  
Richmond, Virginia**

Note: There is limited seating within Boardroom 2, with seats available for 100 members of the public. The meeting will also be viewable in Boardroom 1. There is limited seating within Boardroom 1, with seats available for 80 members of the public. Seating will be available on a first-come, first served basis. The maximum occupancy of Boardroom 2 and 1 is enforced by the Fire Marshal, and cannot be exceeded.

Sign-up sheets for individuals wishing to address the Board during the public comment period will be available in Boardroom 2 and Boardroom 1. Each individual will be allowed to put only one name on the sign-up sheet.

Call to Order and Welcome	Bruce Edwards, Chair
Pledge of Allegiance	Dr. Steven Escobar
Introductions	Mr. Edwards
Review of Agenda	Joseph Hilbert Director of Governmental and Regulatory Affairs
Approval of September 18, 2014 Minutes	Mr. Edwards
Commissioner's Report	Marissa J. Levine, MD, MPH, FAAFP State Health Commissioner
Abortion Facility Licensure Overview and Status Report	Erik Bodin, Director Office of Licensure and Certification
Regulatory Action Update	Mr. Hilbert
Break	
Public Comment Period	
<u>Regulatory Action Items</u>	
Regulations for Licensure of Abortion Facilities 12VAC5-412 (Notice of Intended Regulatory Action)	Mr. Bodin

Working Lunch

Lunch Speaker – Adrienne McFadden, MD, JD, Director,  
Office of Minority Health and Health Equity,  
Topic – VDH Rural Health Program

Regulatory Action Items

Procedures for the Submission of Health  
Maintenance Organization Quality of  
Care Performance Information  
12VAC5-407  
(Fast track amendments)

Debbie Condrey  
Chief Information Officer

Regulations for the Conduct of Human Research  
12VAC5-20  
(Final amendments)

Lilian Peake, MD, MPH, Director  
Office of Family Health Services

Regulations Governing Virginia Newborn  
Screening Services  
12VAC5-71  
(Final amendments)

Dr. Peake

Member Reports

Other Business

Adjourn



# COMMONWEALTH of VIRGINIA

*Department of Health*

P O BOX 2448  
RICHMOND, VA 23218

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

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

## MEMORANDUM

DATE: November 3, 2014

TO: Virginia State Board of Health

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

SUBJECT: Regulations for Licensure of Abortion Facilities (12VAC5-412)

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Enclosed for your review is the Notice of Intended Regulatory Action (NOIRA) to amend the Regulations for Licensure of Abortion Facilities (12VAC5-412). On May 12, 2014, Governor McAuliffe issued Executive Directive 1 (2014), which directed the Board of Health to conduct a periodic review of 12VAC5-412. As a part of the periodic review, a 45-day public comment period was held. The Virginia Department of Health (VDH) reviewed and analyzed the 14,279 public comments submitted to VDH during the 45-day public comment period, conducted an internal review of the regulations, and reviewed recommendations for certain amendments from Office of Licensure and Certification survey staff based on their experience in abortion facilities conducting surveys. As a result of the review, VDH determined it was necessary to use the regulatory process to amend these regulations. This regulatory action will amend these regulations to: clarify the requirements for parental consent, insert additional best practices regarding medical testing and laboratory services, insert additional best practices regarding anesthesia service, align the requirements for administration, storage and dispensing of drugs more precisely with the Code of Virginia, align the requirements regarding emergency services more specifically with medical best practices and update the requirements for facility design and construction.

The Board of Health is requested to approve the NOIRA. Should the Board of Health approve the NOIRA, it will be submitted for executive branch review and, upon approval by the Governor, will be published in the Virginia Register of Regulations. Publication in the Virginia Register of Regulations will initiate a 30 day public comment period. Following the comment period, VDH will prepare proposed amendments which will be submitted for approval by the Board of Health at a future meeting.



Virginia  
Regulatory  
Town Hall

[townhall.virginia.gov](http://townhall.virginia.gov)

## Notice of Intended Regulatory Action (NOIRA) Agency Background Document

<b>Agency name</b>	Virginia Department of Health
<b>Virginia Administrative Code (VAC) citation</b>	12VAC5-412
<b>Regulation title</b>	Regulations for Licensure of Abortion Facilities
<b>Action title</b>	Amend the regulations following periodic review
<b>Date this document prepared</b>	November 3, 2014

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*.

### Purpose

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

On May 12, 2014, Governor McAuliffe issued Executive Directive 1 (2014), which directed the Board of Health to conduct a periodic review of 12VAC5-412. "Regulations for Licensure of Abortion Facilities." As a result of the review, the Department of Health determined it was necessary to use the regulatory process to amend these regulations. It is necessary to amend these regulations to: clarify the requirements for parental consent, insert additional best practices regarding medical testing and laboratory services, insert additional best practices regarding anesthesia service, align the requirements for administration, storage and dispensing of drugs more precisely with the Code of Virginia, align the requirements regarding emergency services more specifically with medical best practices and update the requirements for facility design and construction.

### Legal basis

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

The regulation is promulgated under the authority of § 32.1-127 of the Code of Virginia. Section 32.1-127 of the Code of Virginia requires the Board to promulgate regulations including minimum standards for (i) the construction and maintenance of hospitals, nursing homes and certified nursing facilities to ensure the environmental protection and the life safety of its patients, employees and the public, (ii) the operation, staffing and equipping of hospitals, nursing homes and certified nursing facilities, (iii) qualifications and training of staff of hospitals, nursing homes and certified nursing facilities, except those professionals licensed or certified by the Department of Health Professions, (iv) conditions under which a hospital or nursing home may provide medical and nursing services to patients in their places of residence, and (v) policies related to infection prevention, disaster preparedness, and facility security of hospitals, nursing homes and certified nursing facilities. Facilities in which five or more first trimester abortions are performed per month are classified as a category of hospital for the purposes of this requirement. (§ 32.1-127(B)(1))

### Need

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

The regulations are mandated by § 32.1-127 of the Code of Virginia. On May 12, 2014, Governor McAuliffe issued Executive Directive 1 (2014) which directed the Board of Health to conduct a periodic review of 12VAC5-412 "Regulations for Licensure of Abortion Facilities." As a result of the review, the Department of Health determined it was necessary to use the regulatory process to amend these regulations. The Department of Health has determined that the proposed regulatory action is essential to protect the health, safety and welfare of citizens as the regulatory action intends to update the regulations, align the regulations more precisely with the Code of Virginia, insert additional medical best practices and clarify certain provisions of the regulations as specified in the next section.

### Substance

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

No new regulatory sections are being proposed. The following amendments will be proposed:

#### Parental Consent

Clarify the requirements of parental consent. Ensure all requirements of parental consent are within the regulations.

#### Medical testing and laboratory services

Incorporate additional best practice standards. Remove an unnecessary mandate, which will allow the patient and physician to work together to determine the best course of action. Insert a new requirement which will allow tracking of lab results.

#### Anesthesia Service

Incorporate additional best practice standards. Add a documentation requirement.

#### Administration, storage and dispensing of drugs

Align these provisions more precisely with the Code of Virginia. Remove an unnecessary restriction that is not required by the Code of Virginia.

Emergency Services

Align these provisions more precisely with medical best practices. Remove an unnecessary provision that is not required due to federal requirements.

Facility Design and Construction

Update the design and construction requirements.

## Alternatives

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

Section 32.1-127 of the Code of Virginia mandates that the Board of Health regulate abortion facilities where five or more first trimester abortions per month are performed. Section 32.1-127 requires that the regulations include minimum standards for construction and maintenance, the operation, staffing and equipping of the facility, qualifications and training of staff, and policies related to infection prevention, disaster preparedness and facility security. On May 12, 2014, Governor McAuliffe issued Executive Directive 1 (2014), which directed the Board of Health to conduct a periodic review of 12VAC5-412 "Regulations for Licensure of Abortion Facilities." As a result of the review, the Department of Health determined it was necessary to use the regulatory process to amend these regulations. The regulations are mandated by law, the review of the regulations was mandated by Executive Directive, and there are no viable alternatives to the proposed regulatory action to achieve the necessary regulatory changes as determined by the regulatory review.

## Public participation

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

*Please also indicate pursuant to your Public Participation Guidelines whether a panel will be appointed to assist in the development of the proposed regulation. Please state one of the following: 1) a panel will be appointed and the agency's contact if you're interested in serving on the panel is \_\_\_\_\_; 2) a panel will not be used; or 3) public comment is invited as to whether to use a panel to assist in the development of this regulatory proposal.*

The agency is seeking comments on this regulatory action, including but not limited to 1) ideas to be considered in the development of this proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) the probable effect of the regulation on affected small businesses, and 3) the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (<http://www.townhall.virginia.gov>), or by mail, email, or fax to **Susan Horn, Policy Analyst, 9960 Mayland Drive, Richmond, VA 23233, phone number: 804-367-2157, fax number: 804-527-4502, and**

**susan.horn@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 day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (<http://www.townhall.virginia.gov>) and on the Commonwealth Calendar website (<http://www.virginia.gov/cmsportal3/cgi-bin/calendar.cgi>). Both oral and written comments may be submitted at that time.

**Family impact**

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

As the amendments being considered will clarify the requirements of parental consent, the regulatory action will strengthen the authority and rights of parents in the education, nurturing, and supervision of their children. The regulatory action shall have no other impact on the institution of the family and family stability.

**Periodic review and small business impact review report of findings**

*If this NOIRA is the result of a periodic review/small business impact review, please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and (2) indicate whether the regulation meets the criteria set out in Executive Order 17 (2014), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable.*

*In addition, please include, pursuant to Code of Virginia § 2.2-4007.1 E and F, a discussion of the agency’s consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.*

The Department of Health received a total of 14,279 comments during the public comment period of the periodic review.

Comment	Agency response
Jill Abbey on behalf of Richmond Medical Center for Women, Rosemary Codding on behalf of Falls Church Healthcare Center, Dr. David Peters on behalf of A Tidewater Women’s Health Clinic and Elisabeth Van Der Woude on behalf of Amethyst Health Center for Women, Inc. commented the regulations should be repealed, or in the alternative	The Regulations are required by § 32.1-127 and are required to include minimum standards for the construction and maintenance of abortion facilities.

<p>amended so that the facility design and construction requirements are removed or amended so that the facility design and construction requirements are not applied to existing facilities.</p>	
<p>CeCe Heil on behalf of the American Center for Law and Justice commented that Governor McAuliffe’s Executive Directive 1 and the resulting review of the regulations was inappropriate, and the regulations are required by statute and are necessary for the protection of public health, safety and welfare.</p>	<p>On May 12, 2014 Governor McAuliffe issued Executive Directive 1 (2014), which directed the Board of Health to conduct a periodic review of 12VAC5-412 “Regulations for Licensure of Abortion Facilities.” The Governor may at any time request a periodic review of any regulation promulgated by an agency (§ 2.2-4017 of the Code of Virginia).</p>
<p>Holly Puritz on behalf of the American Congress of Obstetricians and Gynecologists commented that: 1) the provision requiring that medications to induce a termination of a pregnancy be administered by a physician (12VAC5-412-260) be modified to indicate that such medications may be administered by a licensed independent practitioner, as under the Code of Virginia nurse practitioners can administer medication under the supervision of a physician and there is no medical reason for this medication to be regulated differently; 2) the provision requiring pathologic examination in the event of the absence of placental villi or fetal tissue within the uterine contents (12VAC5-412-240) be amended to allow the physician to notify the patient that pregnancy tissue was not identified, explain the possibility of ectopic pregnancy and offer a pathologic examination of the tissue including a disclosure of the cost, allowing the patient to be made aware of the potential and presented with all options but not be forced to undergo such procedures, 3) that the provision requiring a written emergency services agreement with a licensed general hospital (12VAC5-412-290) be amended as such an agreement is not necessary as EMTALA requires the emergency room of a licensed general hospital to provide a presenting patient with a medical screening exam and any necessary treatment. ACOG suggests the provision be amended to require the physician at the abortion facility provide direct communication to the emergency department staff regarding the status of the patient and the suspected complication; and 4) that the facility design and construction requirements are medically unnecessary and should be removed to be replaced with less restrictive requirements.</p>	<p>The Virginia Department of Health (VDH) is considering amendments to the regulations to address this comment. VDH is considering the following changes:</p> <ul style="list-style-type: none"> <li>• Aligning the requirements for administration, storage and dispensing of drugs more precisely with the Code of Virginia</li> <li>• Inserting additional best practices regarding medical testing and laboratory services</li> <li>• Aligning the requirements regarding emergency services more specifically with medical best practices</li> </ul> <p>§ 32.1-127 of the Code of Virginia requires the regulations to include minimum standards for the construction and maintenance of abortion facilities..</p>
<p>42 commenters requested non-specific amendment to the regulations. A majority of these comments requested that existing</p>	<p>These comments do not provide any suggested amendments to specific sections of the Regulations. VDH is considering certain changes to the regulations based on:</p>



<p>facilities be “grandfathered in” to the facility and construction guidelines.</p>	<ul style="list-style-type: none"> <li>• Review and analysis of the public comments submitted to VDH during the 45-day public comment period on the Periodic Review, which contained some specific recommendations for amendments; and</li> <li>• The Office of Licensure and Certification (OLC)’s review of the regulations and recommendations for certain amendments from OLC survey staff based on their experience conducting surveys of abortion facilities.</li> </ul>
<p>2,716 commenters expressed general support for the regulations and requested the regulations be retained</p>	<p>These comments do not provide any suggested amendments to specific sections of the Regulations. VDH is considering certain changes to the regulations based on:</p> <ul style="list-style-type: none"> <li>• Review and analysis of the public comments submitted to VDH during the 45-day public comment period on the Periodic Review, which contained some specific recommendations for amendments; and</li> <li>• The OLC’s review of the regulations and recommendations for certain amendments from OLC survey staff based on their experience conducting surveys of abortion facilities.</li> </ul>
<p>10,654 commenters expressed general opposition to the regulations and requested the regulations be repealed</p>	<p>These comments do not provide any suggested amendments to specific sections of the Regulations. VDH is considering certain changes to the regulations based on:</p> <ul style="list-style-type: none"> <li>• Review and analysis of the public comments submitted to VDH during the 45-day public comment period on the Periodic Review, which contained some specific recommendations for amendments; and</li> <li>• The OLC’s review of the regulations and recommendations for certain amendments from OLC survey staff based on their experience in abortion facilities conducting surveys.</li> </ul>
<p>867 of the comments did not express support or opposition or request a specific amendment to the regulations. These comments were ambiguous and did not speak to the regulations. Some of these comments expressed a desire for a complete ban on abortion or expressed that the writer was pro-choice.</p>	<p>VDH believes that no response is necessary for these comments, because they do not speak to the regulations.</p>

Executive Order 17 (2014) requires that regulatory activity should be undertaken with the least possible intrusion into the lives of the citizens of the Commonwealth. Executive Order 17 (2014) requires that agencies consider 1) The use of economic incentives to encourage the desired outcomes, 2) The use of information disclosure requirements, rather than regulatory mandates, so that the public can make more informed choices, 3) The use of performance standards in place of mandating specific techniques or behavior and 4) The consideration of reasonably available alternatives in lieu of regulation. Section 32.1-127 of the Code of Virginia mandates that the Board of Health regulate abortion facilities where five or more first trimester abortions per month are performed. Section 32.1-127 requires that the regulations include minimum standards for construction and maintenance, the operation, staffing and equipping of the facility, qualifications and training of staff, and policies related to infection prevention, disaster preparedness and facility security. The regulations are mandated by law; the alternatives proposed in

Executive Order 17 (2014) are not viable as VDH has been directed by the General Assembly to promulgate regulations. VDH is confident that the regulations are necessary for the protection of public health, safety, and welfare and will be clearly written and, with the intended amendments, easily understandable. The regulations are written simply and do not overlap, duplicate or conflict with federal or state law or regulation. They were drafted based upon the best reasonably available and reliable information.

There is a continued need for the regulation as the regulation is mandated by law, § 32.1-127 of the Code of Virginia.

The nature of complaints regarding the regulation from the public are predominantly related to the facility design and construction requirements. Specifically that the facility design and construction requirements are medically inappropriate, unnecessary, financially burdensome and not required by the Code of Virginia. Facilities requesting a variance to the regulations reported that the cost to renovate the facility to comply with the regulations would be between \$19,500 to \$1,500,000, which represented between 43% and 4,500% of the facilities' annual revenue. Section 32.1-127.001 of the Code of Virginia requires that the Board of Health promulgate regulations pursuant to § 32.1-127 for the licensure of hospitals and nursing homes that shall include minimum standards for the design and construction of hospitals, nursing homes, and certified nursing facilities consistent with the current edition of the Guidelines for Design and Construction of Hospital and Health Care Facilities issued by the American Institute of Architects Academy of Architecture for Health (now the Facility Guidelines Institute).

The Emergency Regulations for Licensure of Abortion Facilities became Effective on December 29, 2011. The Final Regulations for Licensure of Abortion Facilities became effective on June 20, 2013. The Periodic Review of the Regulations for Abortion Facilities was filed on May 15, 2014 and was completed October 1, 2014. The regulatory chapter has been reviewed frequently enough that technology, economic and other conditions have not changed in the area affected by the regulation.



# COMMONWEALTH of VIRGINIA

Department of Health

P O BOX 2448  
RICHMOND, VA 23218

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

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

## MEMORANDUM

DATE: November 5, 2014

TO: Virginia State Board of Health

FROM: Debbie Condrey, Chief Information Officer

SUBJECT: Procedures for the Submission of Health Maintenance Organization Quality of Care Performance Information (12VAC5-407)

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Enclosed for your review are the Fast-Track amendments to the Regulations for the Procedures for the Submission of Health Maintenance Organization Quality of Care Performance Information (12VAC5-407).

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 12 VAC 5-407 *et seq.* "Procedures for the Submission of Health Maintenance Organization Quality of Care Performance Information" pursuant to Executive Order (EO) 14 (2010). As a result of this review, the Department determined it was necessary to use the regulatory process to amend these regulations. The proposed amendments make corrections to the regulations, remove unnecessary sections and bring greater clarity to the regulations. The amendments are essential to protect the health, safety and welfare of citizens because they make improvements that are reasonable, prudent and do not impose any unnecessary burdens on the Virginia Department of Health or the public.

The Board of Health is requested to approve the Fast Track amendments. Should the Board of Health approve the Fast Track amendments, they will be submitted to the Office of the Attorney General to begin the Executive Branch review process, as specified by the Administrative Process Act. Following Executive Branch review and approval, the appropriate House and Senate committees, as well as the Joint Committee on Administrative Rulemaking (JCAR), will be notified of the Fast Track amendments. The Fast Track amendments will then be published in the Virginia Register of Regulations and on the Virginia Regulatory Town Hall website and a 30 day public comment period will begin. The amendments will become effective fifteen days after the close of the public comment period.



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## Fast Track Proposed Regulation Agency Background Document

<b>Agency name</b>	Virginia Department of Health
<b>Virginia Administrative Code (VAC) citation</b>	12VAC5-407
<b>Regulation title</b>	Procedures for the Submission of Health Maintenance Organization Quality of Care Performance Information
<b>Action title</b>	Amend regulation for clarity, efficiency and effectiveness following periodic review
<b>Date this document prepared</b>	July 8, 2014

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

### Brief summary

*Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes.*

The State Board of Health (board) proposes to amend 12VAC5-407, Procedures for the Submission of Health Maintenance Organization Quality of Care Performance following a periodic review of the regulatory chapter. The proposed amendments make corrections to the regulations, for example: updating the correct definition of the acronym "HEDIS"; more accurately describing the process between the board and the nonprofit organization with regard to data submission; and updating the title of the Commissioner of Behavioral Health and Developmental Services. The proposed amendments also remove unnecessary sections, including sections 12VAC5-407-30 and 12VAC5-407-40, in order to make the regulation less lengthy and burdensome without having a great impact. Lastly, the proposed amendments include rearranging, editing, and rewording various language in order to bring greater clarity to the regulations.

### Acronyms and Definitions

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

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The following acronyms are used in this Agency Background Document and have the following meanings: "HMO" means "Health maintenance organization"

"HEDIS" means the "Health Employer Data and Information Set" also known as the "Healthcare Effectiveness Data and Information Set"

"NCQA" mean the National Committee for Quality Assurance

**Statement of final agency action**

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

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The Fast Track action for the Procedures for the Submission of Health Maintenance Organization Quality of Care Performance Information was approved by the Board of Health on December 4, 2014.

**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.*

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The regulation is promulgated under the authority of §32.1-12 and §32.1-276.5 of Chapter 7.2 of Title 32.1 of the Code of Virginia (Code). Section 32.1-12 grants the board the legal authority "to make, adopt, promulgate, and enforce such regulations necessary to carry out the provisions of Title 32.1 of the Code. Section 32.1-276.5 (B) requires health maintenance organizations (HMOs) to submit annually to the Commissioner audited data consistent with the latest version of HEDIS as collected by NCQA. Section 32.1-276.5 (B) requires that the Board promulgate regulations to implement this requirement.

**Purpose**

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

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To fulfill the statutory mandate to review regulations and to protect the citizens of the Commonwealth, the Department conducted a periodic review of 12 VAC 5-407 *et seq.* "Procedures for the Submission of Health Maintenance Organization Quality of Care Performance Information" pursuant to Executive Order 14 (2010). As a result of this review, the Department determined it was necessary to use the regulatory process to amend these regulations. The amendments are essential to protect the health, safety and welfare of citizens because they enhance the clarity of the regulations in order to achieve improvements

that will be reasonable, prudent and will not impose an unnecessary burden on the Virginia Department of Health or the public.

### Rationale for using fast track process

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

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

These amendments simply clarify confusing language, eliminate unnecessary sections within the existing regulations and correct the Statutory Authority of the Regulatory Chapter. This regulatory action does not propose any substantive changes. These amendments have also been created with input from stakeholders. Therefore, the Department does not expect that this regulatory action will be controversial.

### Substance

*Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. (Provide more detail about these changes in the "Detail of changes" section.) Please be sure to define any acronyms.*

12VAC5-407-10. Definitions -- Remove the unnecessary definition of Code. Correct the definitions of HEDIS and Nonprofit Organization.

12VAC5-407-20. Applicability -- Correct the Statutory Authority.

12VAC5-407-30 Reporting requirements for HMO -- Removal of an unnecessary section

12VAC5-407-40 Exceptions to HEDIS reporting -- Removal of an unnecessary section

12VAC5-407-50 Reporting methods and exemption from reporting -- Restructuring of the section for greater clarity.

12VAC5-407-60 Audited data required -- Changed the section into active voice. Removed unnecessary language from the section.

12VAC5-407-70 Process for data submission -- Clarifying language.

12VAC-407-80 Fees -- Clarifying language. Updating of terminology.

12VAC5-407-90 Late charge -- Change of terminology for consistency across the regulations.

12VAC5-407-100 Duties of the nonprofit organization. Clarifying language.

12VAC5-407-110 Biennial evaluation -- Correct the Statutory Authority.

12VAC5-407-120 Other duties of the board -- Removal of an unnecessary section.

**Issues**

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

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

*If there are no disadvantages to the public or the Commonwealth, please indicate.*

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The primary advantage to the agency, the Commonwealth and the public of the proposed regulatory action will be clearer and less burdensome regulations. There are no known disadvantages to the agency, the Commonwealth or the public.

**Requirements more restrictive than federal**

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

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There are no requirements in this proposal that exceed federal requirements.

**Localities particularly affected**

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

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

**Regulatory flexibility analysis**

*Pursuant to §2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.*

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The alternative regulatory methods are not applicable. The regulations are required by the Code and the proposed amendments are attempting to clarify and simplify the existing requirements.

**Economic impact**

*Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact. Please keep in mind that we are looking at the impact of the proposed changes to the status quo.*

<b>Description of the individuals, businesses or other entities likely to be affected (positively or negatively) by this regulatory proposal.</b> Think broadly, e.g., these entities may or may not be regulated by this board	HMOs with an active license to operate in the Commonwealth of Virginia, Virginia Health Information and the Virginia Department of Health.
<b>Agency’s best estimate of the number of (1) entities that will be affected, including (2) small businesses affected.</b> Small business means a business, including affiliates, that is independently owned and operated, employs fewer than 500 full-time employees, or has gross annual sales of less than \$6 million.	There are ten HMOs with an active license to operate in the Commonwealth of Virginia. None of these HMOs are small businesses.
<b>Benefits expected as a result of this regulatory proposal.</b>	Greater clarity of the regulations
<b>Projected cost to the <u>state</u> to implement and enforce this regulatory proposal.</b>	Negligible.
<b>Projected cost to <u>localities</u> to implement and enforce this regulatory proposal.</b>	None
<b>All projected costs of this regulatory proposal for affected individuals, businesses, or other entities.</b> Please be specific and include all costs, including projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses, and costs related to real estate development.	These amendments will simply clarify the regulations to current practice and therefore will not have an economic impact on affected entities.

**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.*

There are no viable alternatives other than the proposed amendments to clarify the current regulations to be clearer and less burdensome, while also continuing to fulfill the board's statutory mandate to regulate to implement the provisions of Section 32.1-276.5 (B) of the Code.

**Periodic review and small business impact review report of findings**



***If this fast-track regulation is not the result of a periodic review and/or small business impact review report of the regulation, please delete this entire section.***

*If this fast-track regulation is the result of a periodic review, please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and (2) indicate whether the regulation meets the criteria set out in Executive Order 14 (2010), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable.*

*If this fast-track regulation is also a small business impact review report of the regulation, pursuant to § 2.2-4007.1 E and F, a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation is required.*

No comments were received from the public during the recent periodic review. There is a continued need for the regulation as it is mandated by law. The Department has not received any complaints or comments concerning the regulation from the public. With the proposed amendments in this regulatory action, the regulation is clearly written and easily understandable and the Department is confident based on this most recent review that the regulation does not overlap, duplicate or conflict with federal or state law or 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 board has assessed the impact the proposed amendments will have on the institution of the family and family stability. The board anticipates no impact to the family or family stability.

**Detail of changes**

*Please list all changes that are being proposed and the consequences of the proposed changes. 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) or regulations that are being repealed and replaced, use this chart:

Throughout the regulatory action the Statutory Authority of the Regulations has been corrected. Previously Section 32.1-276.6 of the Code was listed as the Statutory Authority of the Regulatory Chapter. The correct Statutory Authority of Section 32.1-276.5 has been noted throughout.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
12VAC5-407-10 - Definitions		<p>The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:</p> <p>"Board" means State Board of Health.</p> <p>"Code" means the Code of Virginia.</p> <p>"Commissioner" means the State Health Commissioner.</p> <p>"Consumer" means any person (i) whose occupation is other than the administration of health activities or the provision of health services, (ii) who has no fiduciary obligation to a health care institution or other health agency or to any organization, public or private, whose principal activity is an adjunct to the provision of health services, or (iii) who has no material financial interest in the rendering of health services.</p> <p>"Department" means the State Department of Health.</p> <p>"Health maintenance organization" or "HMO" means any person who undertakes to provide or to arrange for one or more health care plans pursuant to Chapter 43 (§ 38.2-4300 et seq.) of Title 38.2 of the Code of Virginia.</p>	<p>The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:</p> <p>"Board" means State Board of Health.</p> <p><del>"Code" means the Code of Virginia.</del></p> <p>"Commissioner" means the State Health Commissioner.</p> <p>"Consumer" means any person (i) whose occupation is other than the administration of health activities or the provision of health services, (ii) who has no fiduciary obligation to a health care institution or other health agency or to any organization, public or private, whose principal activity is an adjunct to the provision of health services, or (iii) who has no material financial interest in the rendering of health services.</p> <p>"Department" means the State Department of Health.</p> <p>"Health maintenance organization" or "HMO" means any person who undertakes to provide or to arrange for one or more health care plans pursuant to Chapter 43 (§ 38.2-4300 et seq.) of Title 38.2 of the Code of Virginia.</p> <p>"HEDIS" means the Health Plan Employer Data and Information Set <u>also known as the Healthcare Effectiveness Data and Information Set</u>, a set of standardized performance measures <del>sponsored, supported</del> <u>collected</u> and maintained by the National Committee for Quality Assurance.</p> <p>"NCQA" means the National Committee for Quality Assurance.</p>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
		<p>"HEDIS" means the Health Plan Employer Data and Information Set, a set of standardized performance measures sponsored, supported and maintained by the National Committee for Quality Assurance.</p> <p>"NCQA" means the National Committee for Quality Assurance.</p> <p>"Nonprofit organization" means a nonprofit, tax-exempt health data organization with the characteristics, expertise, and capacity to execute the powers and duties set forth for such entity in this chapter.</p>	<p>"Nonprofit organization" means a nonprofit, tax-exempt health data organization with the characteristics, expertise, and capacity to execute the powers and duties set forth for such entity in <u>Chapter 7.2 of Title 32.1 of the Code of Virginia</u>.<del>this chapter.</del></p> <p>Intent: Remove an unnecessary definition. Update the definition of HEDIS to reflect the current terminology utilized by NCQA. Update the definition of nonprofit organization to reflect the Code of Virginia. Rationale: Greater clarity. No impact.</p>
<p>12VAC5-407-30-Reporting requirements for HMO data.</p>		<p>A. Every HMO shall make available to the commissioner those HEDIS or any other quality of care or performance information set, or a subset thereof.</p> <p>B. The board may contract directly with NCQA to purchase the selected HEDIS measures on behalf of the HMOs.</p>	<p><del>A. Every HMO shall make available to the commissioner those HEDIS or any other quality of care or performance information set, or a subset thereof.</del></p> <p><del>B. The board may contract directly with NCQA to purchase the selected HEDIS measures on behalf of the HMOs.</del></p> <p>Intent: Repeal an unnecessary section. Rationale: Less burdensome and lengthy regulation. Greater clarity. No impact.</p>
<p>12VAC5-407-40 - Exception to HEDIS reporting.</p>		<p>A. The board may approve and require quality of care data other than the HEDIS measures provided that reasonable notice is given to the HMOs in writing.</p>	<p><del>A. The board may approve and require quality of care data other than the HEDIS measures provided that reasonable notice is given to the HMOs in writing.</del></p> <p>Intent: Repeal an unnecessary section. Rationale: Less burdensome and lengthy regulation. Greater clarity. No impact.</p>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
<p>12VAC5-407-50. Reporting <u>methods</u> and exemption from reporting.</p>		<p>A. Every HMO with an active license in the Commonwealth shall be required to submit the HEDIS or any other quality of care or performance information set approved by the board unless granted a written exemption by the commissioner.</p> <p>B. An HMO may, in writing, petition the commissioner for an exemption. The commissioner, at his discretion, may grant a waiver from reporting the HEDIS or any other approved quality of care or performance information set. In considering a petition for waiver, the commissioner may give due consideration to the HMO's (i) sample size; (ii) number of covered lives; (iii) length of operating experience in Virginia; (iv) accreditation status with respect to NCQA or other national accrediting organizations; or (v) any other relevant factors he deems appropriate.</p> <p>C. An HMO that can demonstrate that it does not meet NCQA's minimum sample size requirements to collect statistically valid information on at least 50% of the HEDIS effectiveness of care measures or performance information sets approved by the board shall be exempt from reporting the HEDIS quality of care or performance sets during the reporting period. The HMO shall submit documentation to the commissioner each reporting period to</p>	<p>A. Every HMO with an active license in the Commonwealth shall be required to submit the HEDIS or any other quality of care or performance information set approved by the board unless granted a written exemption by the commissioner.</p> <p><u>B. The following methods shall be used for data submission.</u></p> <p><u>1. If the HMO submits data to NCQA, the commissioner may purchase HEDIS data or any other quality of care or performance information set from NCQA.</u></p> <p><u>2. If the HMO does not submit data to NCQA, or the commissioner elects not to purchase HEDIS data from the NCQA, then the HMO shall submit the performance information sets approved by the board to the nonprofit organization in accordance with the timeframes established in 12VAC5-407-70.</u></p> <p><del>B</del>C. An HMO may, in writing, petition the commissioner for an exemption. The commissioner, at his discretion, may grant a waiver from reporting the HEDIS or any other approved quality of care or performance information set. In considering a petition for waiver, the commissioner may give due consideration to the HMO's (i) sample size; (ii) number of covered lives; (iii) length of operating experience in Virginia; (iv) accreditation status with respect to NCQA or other national accrediting organizations; or (v) any other relevant factors he deems appropriate.</p> <p><del>C</del>D. An HMO that can demonstrate that it does not meet NCQA's minimum sample size requirements to collect statistically valid information on at least 50% of the HEDIS effectiveness of care measures or performance information sets</p>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
		<p>demonstrate that it meets the criteria for obtaining an exemption from reporting.</p> <p>D. Options for data submission.</p> <ol style="list-style-type: none"> <li>1. The commissioner may purchase HEDIS data or any other quality of care or performance information set from NCQA that includes all HMOs operating in the Commonwealth that submit HEDIS data to NCQA.</li> <li>2. HMOs that do not submit data directly to NCQA must submit the performance information sets approved by the board to the nonprofit organization in accordance with the timeframes established in 12VAC5-407-70.</li> <li>3. If the budget pursuant to 12VAC5-407-100 E includes a cost benefit for direct submission of HEDIS data or any other quality of care or performance information set, the commissioner may thereafter require direct submission.</li> </ol>	<p>approved by the board shall be exempt from reporting the HEDIS quality of care or performance sets during the reporting period. The HMO shall submit documentation to the commissioner each reporting period to demonstrate that it meets the criteria for obtaining an exemption from reporting.</p> <p><del>D. Options for data submission.</del></p> <ol style="list-style-type: none"> <li><del>1. The commissioner may purchase HEDIS data or any other quality of care or performance information set from NCQA that includes all HMOs operating in the Commonwealth that submit HEDIS data to NCQA.</del></li> <li><del>2. HMOs that do not submit data directly to NCQA must submit the performance information sets approved by the board to the nonprofit organization in accordance with the timeframes established in 12VAC5-407-70.</del></li> <li><del>3. If the budget pursuant to 12VAC5-407-100 E includes a cost benefit for direct submission of HEDIS data or any other quality of care or performance information set, the commissioner may thereafter require direct submission.</del></li> </ol> <p>Intent Greater clarity of the regulations. Rationale: Grouping the reporting requirement and the method of submission leads to greater clarity. No impact.</p>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
<p>12VAC5-407-60 Audited data required</p>		<p>A. Data submitted by HMOs is required to be verified by an independent auditing organization with no financial interest in or managerial association with the HMO.</p> <p>B. HMOs whose performance information set is audited by an NCQA-certified HEDIS compliance auditor will have a notice to that effect published with their HEDIS data.</p> <p>C. HMOs whose performance information set is not audited by NCQA-certified auditors will have a notice to that effect published with their HEDIS data.</p>	<p><del>A. Data submitted by HMOs is required to shall submit data that has been verified by an independent auditing organization with no financial interest in or managerial association with the HMO. The HMO shall submit an audit report with the data.</del></p> <p><del>B. HMOs whose performance information set is audited by an NCQA-certified HEDIS compliance auditor will have a notice to that effect published with their HEDIS data.</del></p> <p><del>C. HMOs whose performance information set is not audited by NCQA-certified auditors will have a notice to that effect published with their HEDIS data.</del></p> <p>Intent: Remove unnecessary language and more clearly identify the auditing requirement. Rationale: Greater clarity. No impact.</p>
<p>12VAC5-407-70 Process for data submission</p>		<p>A. Before January 1 of each year, the commissioner shall submit to each HMO in writing the process required for data submission, obtaining a waiver from reporting and the amount of the fee to be paid. HMOs providing HEDIS or any other quality of care or performance information set directly to the commissioner shall submit the data by September 15 of each year.</p> <p>B. The nonprofit organization shall publish annually the quality information data before December 31.</p>	<p>A. Before January 1 of each year, the commissioner shall submit to each HMO in writing the process required for data submission, <u>the fee associated with data submission, and the process for obtaining a waiver</u> <del>obtaining a waiver from reporting and the amount of the fee to be paid.</del> HMOs providing HEDIS or any other quality of care or performance information set directly to the <del>commissioner</del> <u>nonprofit organization</u> shall submit the data by September 15 of each year.</p> <p>B. <del>The nonprofit organization board</del> <u>direct the nonprofit organization to</u> publish annually the quality information data before December 31.</p> <p>Intent: Clarifying confusing language. Rationale: Greater clarity. No impact.</p>
<p>12VAC5-407-80- Fees</p>		<p>A. For each HMO required to provide information pursuant to this chapter, the board shall prescribe a reasonable fee to cover the cost of collecting and making available such data. The commissioner may purchase</p>	<p>A. For each HMO required to provide information pursuant to this chapter, the board shall prescribe a reasonable fee to cover the cost of collecting and making available such data. The commissioner may purchase HEDIS data or other quality of care or performance information set on behalf of all the</p>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
		<p>HEDIS data or other quality of care or performance information set on behalf of all the actively licensed HMOs in the Commonwealth that are participating in HEDIS and divide the cost among the HMOs. Each HMO shall pay an equal share of the cost to the board for purchase of the HEDIS data directly from NCQA. The remainder of the cost associated with making the data available shall be divided among the participating HMOs in a tiered format based on the number of enrollees per HMO.</p> <p>B. Fees described in subsection A of this section shall not exceed \$3,000 per HMO per year.</p> <p>C. The payment of such fees shall be on September 15 of each year. The nonprofit organization providing services pursuant to an agreement or contract as provided in § 32.1-276.4 of the Code of Virginia shall be authorized to charge and collect the fees prescribed by the board in this section when the data are provided directly to the nonprofit organization. Such fees shall not exceed the amount authorized by the board.</p> <p>D. The nonprofit organization providing services pursuant to an agreement or contract as provided in § 32.1-276.4 of the Code of Virginia shall be authorized to charge and collect reasonable fees approved by the board for</p>	<p>actively licensed HMOs in the Commonwealth that are participating in HEDIS and divide the cost among the HMOs. Each HMO shall pay an equal share of the cost to the board for purchase of the HEDIS data directly from NCQA. The remainder of the cost associated with making the data available shall be divided among the participating HMOs in a tiered format based on the number of enrollees per HMO.</p> <p>B. Fees described in subsection A of this section shall not exceed \$3,000 per HMO per year.</p> <p>C. The payment of such fees shall be on September 15 of each year <u>or later if determined by the nonprofit</u>. The nonprofit organization <del>providing services pursuant to an agreement or contract as provided in § 32.1-276.4 of the Code of Virginia</del> shall be authorized to charge and collect the fees prescribed by the board in <u>this subsection A</u> when the data are provided directly to the nonprofit organization. Such fees shall not exceed the amount authorized by the board.</p> <p>D. The nonprofit organization <del>providing services pursuant to an agreement or contract as provided in § 32.1-276.4 of the Code of Virginia</del> shall be authorized to charge and collect reasonable fees approved by the board for making available <u>to any individual or entity who requests</u> the HEDIS data or other approved quality of care data; however, the commissioner, the State Corporation Commission, and the Commissioner of <u>Behavioral Health and Developmental Services Mental Health, Mental Retardation and Substance Abuse Services</u> shall be entitled to receive relevant and appropriate data from the nonprofit organization at no charge.</p> <p>E. <del>HMOs shall be entitled to receive relevant and appropriate HMO data as defined by and from the nonprofit</del></p>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
		<p>making available the HEDIS data or other approved quality of care data; however, the commissioner, the State Corporation Commission, and the Commissioner of Mental Health, Mental Retardation and Substance Abuse Services shall be entitled to receive relevant and appropriate data from the nonprofit organization at no charge.</p> <p>E. HMOs shall be entitled to receive relevant and appropriate HMO data as defined by and from the nonprofit organization, with input from the HMO industry at no charge.</p>	<p><del>organization, with input from the HMO industry at no charge.</del> <u>The board shall direct the nonprofit organization to solicit input from the HMO industry to determine relevant and appropriate data that the industry shall receive at no charge.</u></p> <p>Intent: Removal of unnecessary language due to the update of the definition of nonprofit organization. Insertion of clarifying language to clarify the nature of the different fees. Update the title of the Commissioner of Behavioral Health and Developmental Services. Provide clarifying language. Rationale: Greater clarity of the regulations. No impact.</p>
<p>12VAC5-207-90- Late Charge</p>		<p>A. A late charge of \$25 per working day shall be paid to the board by an HMO that has not received an exemption from the commissioner as provided for in 12VAC5-407-50 and that has not paid the assessed fees by September 15. The late fee may not be assessed until completion of a 30-day grace period for submitting the data.</p> <p>B. Late charges may be waived by the board, in its discretion, if an HMO can show that an extenuating circumstance exists. Examples of an extenuating circumstance may include, but are not limited to, the installation of a new computerized system, a bankruptcy proceeding, or change of ownership in the HMO.</p>	<p>A. A late charge of \$25 per working day shall be paid to the board by an HMO that has not received an exemption from the commissioner as provided for in 12VAC5-407-50 and that has not paid the assessed fees by September 15 <u>or later if determined by an agreement between the board and the nonprofit.</u> The late <del>fee</del> <u>charge</u> may not be assessed until completion of a 30-day grace period for submitting the data.</p> <p>B. Late charges may be waived by the board, in its discretion, if an HMO can show that an extenuating circumstance exists. Examples of an extenuating circumstance may include, but are not limited to, the installation of a new computerized system, a bankruptcy proceeding, or change of ownership in the HMO.</p> <p>Intent: Consistency of terminology and of date fees are due. Rationale: Greater clarity of the regulations. No impact.</p>



Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
<p>12VAC5-407-100. <u>Contract with Duties of the nonprofit organization.</u></p>		<p>A. The commissioner shall negotiate and contract with a nonprofit organization pursuant to § 32.1-276.4 of the Code of Virginia for compiling, storing, and making available to consumers the data submitted by HMOs pursuant to 12VAC5-407-30 and 12VAC5-407-40.</p> <p>B. The nonprofit organization shall assist the board in developing a summary plan and budget to collect and make available HMO HEDIS or any other quality of care performance information set results for consumers. The nonprofit organization shall present the summary plan and budget on a biennial basis to the board for approval. The commissioner, at his discretion, shall also review the summary plan on a periodic basis to determine its effectiveness.</p> <p>C. The nonprofit organization shall collect the HEDIS data in the most cost-effective manner available.</p> <p>D. The nonprofit organization will prepare a biennial summary plan in identifying the measures selected for reporting. The summary plan shall include:</p> <ol style="list-style-type: none"> <li>1. The rationale for selecting each measure to be made available to consumers;</li> <li>2. The goal of reporting each measure;</li> <li>3. The cost and benefit of</li> </ol>	<p><u>The contract entered into by the board and the nonprofit organization pursuant to Chapter 7.2 of Title 32.1 of the Code of Virginia shall provide:</u></p> <p><del>A. The commissioner shall negotiate and contract with a nonprofit organization pursuant to § 32.1-276.4 of the Code of Virginia for compiling, storing, and making</del> <u>The nonprofit organization shall compile, store and make available to consumers the data submitted by HMOs pursuant to 12VAC5-407-30 and 12VAC5-407-40.</u></p> <p>B. The nonprofit organization shall assist the board in developing a summary plan and budget to collect and make available HMO HEDIS or any other quality of care performance information set results for consumers. The nonprofit organization shall present the summary plan and budget on a biennial basis to the board for approval. The commissioner, at his discretion, shall also review the summary plan on a periodic basis to determine its effectiveness.</p> <p>C. The nonprofit organization shall collect the HEDIS data in the most cost-effective manner available.</p> <p>D. The nonprofit organization <del>shall will</del> prepare a biennial summary plan in identifying the measures selected for reporting. The summary plan shall include:</p> <ol style="list-style-type: none"> <li>1. The rationale for selecting each measure to be made available to consumers;</li> <li>2. The goal of reporting each measure;</li> <li>3. The cost and benefit of collecting the measures and making them available to consumers; and</li> <li>4. The scope of dissemination of information in paper or electronic format and the target audience.</li> </ol>

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change, intent, rationale, and likely impact of proposed requirements
		<p>collecting the measures and making them available to consumers; and</p> <p>4. The scope of dissemination of information in paper or electronic format and the target audience.</p> <p>E. The nonprofit organization shall prepare a biennial budget that includes a cost-benefit analysis of purchasing HEDIS data from NCQA or obtaining the information performance sets directly from the HMOs.</p> <p>F. The nonprofit organization will present the summary plan and budget to the board for review and approval on a biennial basis.</p> <p>G. The nonprofit organization shall organize, present and make available to consumers all data required by the board to be reported to the commissioner.</p>	<p>E. The nonprofit organization shall prepare a biennial budget that includes a cost-benefit analysis of purchasing HEDIS data from NCQA or obtaining the information performance sets directly from the HMOs.</p> <p>F. The nonprofit organization <del>shall</del>will present the summary plan and budget to the board for review and approval on a biennial basis.</p> <p>G. The nonprofit organization shall organize, present and make available to consumers on its website all data required by the board to be reported to the commissioner.</p> <p>Intent: Add clarifying language. Rationale: Greater clarity of the regulations. No impact.</p>
<p>12VAC5-407-120 Other duties of the board.</p>		<p>The board shall (i) maintain records of its activities relating to the dissemination of data reported by HMOs and (ii) collect and account for all fees, as described in this chapter, and deposit the moneys so collected into a special fund from which the expenses attributed to this chapter shall be paid.</p>	<p><del>The board shall (i) maintain records of its activities relating to the dissemination of data reported by HMOs and (ii) collect and account for all fees, as described in this chapter, and deposit the moneys so collected into a special fund from which the expenses attributed to this chapter shall be paid.</del></p> <p>Intent: Repeal an unnecessary section. Rationale: Less burdensome and lengthy regulation. Greater clarity. No impact.</p>

Project 3763 - none

**DEPARTMENT OF HEALTH**  
**Action to Amend Chapter 407 as result of a Periodic Review**

CHAPTER 407  
PROCEDURES FOR THE SUBMISSION OF HEALTH MAINTENANCE ORGANIZATION  
QUALITY OF CARE PERFORMANCE INFORMATION

Part I  
Definitions and General Information

**12VAC5-407-10. Definitions.**

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

"Board" means State Board of Health.

~~"Code" means the Code of Virginia.~~

"Commissioner" means the State Health Commissioner.

"Consumer" means any person (i) whose occupation is other than the administration of health activities or the provision of health services, (ii) who has no fiduciary obligation to a health care institution or other health agency or to any organization, public or private, whose principal activity is an adjunct to the provision of health services, or (iii) who has no material financial interest in the rendering of health services.

"Department" means the State Department of Health.

"Health maintenance organization" or "HMO" means any person who undertakes to provide or to arrange for one or more health care plans pursuant to Chapter 43 (§ 38.2-4300 et seq.) of Title 38.2 of the Code of Virginia.

"HEDIS" means the Health Plan Employer Data and Information Set also known as the Healthcare Effectiveness Data and Information Set, a set of standardized performance measures ~~sponsored, supported~~ collected and maintained by the National Committee for Quality Assurance.

"NCQA" means the National Committee for Quality Assurance.

"Nonprofit organization" means a nonprofit, tax-exempt health data organization with the characteristics, expertise, and capacity to execute the powers and duties set forth for such entity in Chapter 7.2 of Title 32.1 of the Code of Virginia and that enters into a contract for the compilation, storage, analysis, and evaluation of data pursuant to Chapter 7.2 of Title 32.1 of the Code of Virginia. ~~this chapter.~~

**12VAC5-407-20. Applicability.**

This chapter shall apply to all HMOs with an active license to operate in this Commonwealth.

Part II  
Quality of Care Data Reporting

**12VAC5-407-30. Reporting requirements for HMO data. (Repealed.)**

~~A. Every HMO shall make available to the commissioner those HEDIS or any other quality of care or performance information set, or a subset thereof.~~

~~B. The board may contract directly with NCQA to purchase the selected HEDIS measures on behalf of the HMOs.~~

**12VAC5-407-40. ~~Exception to HEDIS reporting. (Repealed.)~~**

~~A. The board may approve and require quality of care data other than the HEDIS measures provided that reasonable notice is given to the HMOs in writing.~~

**12VAC5-407-50. Reporting methods and exemption from reporting.**

A. Every HMO with an active license in the Commonwealth shall be required to submit the HEDIS or any other quality of care or performance information set approved by the board unless granted a written exemption by the commissioner.

B. The following methods shall be used for data submission.

1. If the HMO submits data to NCQA, the commissioner may purchase HEDIS data or any other quality of care or performance information set from NCQA.

2. If the HMO does not submit data to NCQA, or the commissioner elects not to purchase HEDIS data from the NCQA, then the HMO shall submit the performance information sets approved by the board to the nonprofit organization in accordance with the timeframes established in 12VAC5-407-70.

~~B.C.~~ An HMO may, in writing, petition the commissioner for an exemption. The commissioner, at his discretion, may grant a waiver from reporting the HEDIS or any other approved quality of care or performance information set. In considering a petition for waiver, the commissioner may give due consideration to the HMO's (i) sample size; (ii) number of covered lives; (iii) length of operating experience in Virginia; (iv) accreditation status with respect to NCQA or other national accrediting organizations; or (v) any other relevant factors he deems appropriate.

~~B.D.~~ An HMO that can demonstrate that it does not meet NCQA's minimum sample size requirements to collect statistically valid information on at least 50% of the HEDIS effectiveness of care measures or performance information sets approved by the board shall be exempt from reporting the HEDIS quality of care or performance sets during the reporting period. The HMO shall submit documentation to the commissioner each reporting period to demonstrate that it meets the criteria for obtaining an exemption from reporting.

~~D. Options for data submission:~~

~~1. The commissioner may purchase HEDIS data or any other quality of care or performance information set from NCQA that includes all HMOs operating in the Commonwealth that submit HEDIS data to NCQA.~~

~~2. HMOs that do not submit data directly to NCQA must submit the performance information sets approved by the board to the nonprofit organization in accordance with the timeframes established in 12VAC5-407-70.~~

~~3. If the budget pursuant to 12VAC5-407-100 E includes a cost benefit for direct submission of HEDIS data or any other quality of care or performance information set, the commissioner may thereafter require direct submission.~~

**12VAC5-407-60. Audited data required.**

~~A. Data submitted by HMOs is required to~~ shall submit HEDIS or other quality of care or performance information set approved by the Board that has been verified by an independent auditing organization with no financial interest in or managerial association with the HMO. The HMO shall submit an audit report with the data.

~~B. HMOs whose performance information set is audited by an NCQA-certified HEDIS compliance auditor will have a notice to that effect published with their HEDIS data.~~

~~C. HMOs whose performance information set is not audited by NCQA-certified auditors will have a notice to that effect published with their HEDIS data.~~

### **12VAC5-407-70. Process for data submission.**

A. Before January 1 of each year, the commissioner shall submit to each HMO in writing the process required for data submission, the fee associated with data submission, and the process for obtaining a waiver. ~~obtaining a waiver from reporting and the amount of the fee to be paid.~~ HMOs providing HEDIS or any other quality of care or performance information set directly to the ~~commissioner,~~ nonprofit organization shall submit the data by September 15 of each year.

B. ~~The nonprofit organization~~ board shall direct the nonprofit organization to publish annually the quality information data before December 31.

### **12VAC5-407-80. Fees.**

A. For each HMO required to provide information pursuant to this chapter, the board shall prescribe a reasonable fee to cover the cost of collecting and making available such data. The commissioner may purchase HEDIS data or other quality of care or performance information set on behalf of all the actively licensed HMOs in the Commonwealth that are participating in HEDIS and divide the cost among the HMOs. Each HMO shall pay an equal share of the cost to the board for purchase of the HEDIS data directly from NCQA. The remainder of the cost associated with making the data available shall be divided among the participating HMOs in a tiered format based on the number of enrollees per HMO.

B. Fees described in subsection A of this section shall not exceed \$3,000 per HMO per year.

C. The payment of such fees shall be on September 15 of each year or later if determined by an agreement between the board and the nonprofit. ~~The nonprofit organization providing services pursuant to an agreement or contract as provided in § 32.1-276.4 of the Code of Virginia shall be authorized to charge and collect the fees prescribed by the board in this subsection A when the data are provided directly to the nonprofit organization.~~ Such fees shall not exceed the amount authorized by the board.

D. ~~The nonprofit organization providing services pursuant to an agreement or contract as provided in § 32.1-276.4 of the Code of Virginia shall be authorized to charge and collect reasonable fees approved by the board for making available to any individual or entity who requests the HEDIS data or other approved quality of care data; however, the commissioner, the State Corporation Commission, and the Commissioner of Behavioral Health and Developmental Services Mental Health, Mental Retardation and Substance Abuse Services shall be entitled to receive relevant and appropriate data from the nonprofit organization at no charge.~~

E. ~~HMOs shall be entitled to receive relevant and appropriate HMO data as defined by and from the nonprofit organization, with input from the HMO industry at no charge. The board shall direct the nonprofit organization to solicit input from the HMO industry to determine relevant and appropriate data that the industry shall receive at no charge.~~

### **12VAC5-407-90. Late charge.**

A. A late charge of \$25 per working day shall be paid to the board by an HMO that has not received an exemption from the commissioner as provided for in 12VAC5-407-50 and that has not paid the assessed fees by September 15 or later if determined by an agreement between the board and the nonprofit. The late ~~fee~~ charge may not be assessed until completion of a 30-day grace period for submitting the data.

B. Late charges may be waived by the board, in its discretion, if an HMO can show that an extenuating circumstance exists. Examples of an extenuating circumstance may include, but are not limited to, the installation of a new computerized system, a bankruptcy proceeding, or change of ownership in the HMO.

Part III

Duties of the Board and the Nonprofit Organization

**12VAC5-407-100. ~~Contract with~~Duties of the nonprofit organization.**

The contract entered into by the board and the nonprofit organization pursuant to Chapter 7.2 of Title 32.1 of the Code of Virginia shall provide:

A. ~~The commissioner shall negotiate and contract with a nonprofit organization pursuant to § 32.1-276.4 of the Code of Virginia for compiling, storing, and making~~The nonprofit organization shall compile, store and make available to consumers the data submitted by HMOs pursuant to 12VAC5-407-30 and 12VAC5-407-40.

B. The nonprofit organization shall assist the board in developing a summary plan and budget to collect and make available HMO HEDIS or any other quality of care performance information set results for consumers. The nonprofit organization shall present the summary plan and budget on a biennial basis to the board for approval. The commissioner, at his discretion, shall also review the summary plan on a periodic basis to determine its effectiveness.

C. The nonprofit organization shall collect the HEDIS data in the most cost-effective manner available.

D. The nonprofit organization ~~shall~~will prepare a biennial summary plan in identifying the measures selected for reporting. The summary plan shall include:

1. The rationale for selecting each measure to be made available to consumers;
2. The goal of reporting each measure;
3. The cost and benefit of collecting the measures and making them available to consumers; and
4. The scope of dissemination of information in paper or electronic format and the target audience.

E. The nonprofit organization shall prepare a biennial budget that includes a cost-benefit analysis of purchasing HEDIS data from NCQA or obtaining the information performance sets directly from the HMOs.

F. The nonprofit organization ~~shall~~will present the summary plan and budget to the board for review and approval on a biennial basis.

G. The nonprofit organization shall organize, present and make available to consumers on its website all data required by the board to be reported to the commissioner.

**12VAC5-407-110. Biennial evaluation.**

A. The board shall evaluate biennially the impact and effectiveness of collecting and making available HEDIS or any other quality of care or performance information set and the appropriateness of the fee structure. This evaluation shall be completed by January 15.

B. As part of the biennial evaluation, the board may consult with the HMOs and the nonprofit organization to determine whether changes should be made to the HEDIS or any other quality of care or performance information set requirements.

**12VAC5-407-120. ~~Other duties of the board.~~ (Repealed.)**

~~The board shall (i) maintain records of its activities relating to the dissemination of data reported by HMOs and (ii) collect and account for all fees, as described in this chapter, and deposit the moneys so collected into a special fund from which the expenses attributed to this chapter shall be paid.~~

## MEMORANDUM

DATE: November 13, 2104

TO: Virginia State Board of Health

FROM: Lilian Peake, MD, MPH  
Director, Office of Family Health Services

SUBJECT: Final Amendments to 12VAC5-20, "Regulations for the Conduct of Human Research"

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The Virginia State Board of Health (Board) is asked to review and approve the enclosed amendments to 12VAC5-20, "Regulations for the Conduct of Human Research" so that they may be submitted for the final stage of regulatory review. The Board previously approved the amendments for the proposed stage of regulatory review, and they were submitted for Executive Branch review and public comment. The public comment period closed on March 14, 2014 with no comments submitted. The Board most recently reviewed these final amendments at the September 18 meeting; and indefinitely postponed action to allow VDH to respond to several questions that were raised by the Board.

Following the questions from the Board, VDH has considered the following issues:

- Defining the term "undue inducement" under the definition of informed consent.

VDH was unable to find clear guidance through the Office of Human Research Protections or in other federal guidelines or regulations addressing this issue. The Office of the Attorney General advised that it was not necessary to define this term further.

- Clarifying the term "...minor increase over minimal risk..." as it pertains to informed consent in 12VAC5-20-100 D.

VDH reviewed 45 CFR § 46.406 (Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition) and minutes from a 2005 meeting of the Secretary's Advisory Committee on Human Research Protections. Based on this

review, VDH has added a definition of “Minor increase over minimal risk” and has added clarifying language to 12VAC5-20-100 D, which is consistent with the federal regulations.

- Specifying the composition of the research review committee as it pertains to the protection of vulnerable subjects in 12VAC5-20-70.

VDH modified the language to indicate that consideration will be given to the inclusion of individuals experienced with vulnerable populations that are regularly reviewed by the committee. This is consistent with the federal regulations. The vulnerable populations that are regularly reviewed by the VDH Internal Review Board include pregnant women and children. VDH does not generally review studies involving research with prisoners or handicapped or mentally disabled persons.

- Addressing redundant language in 12VAC5-20-100 A stating that informed consent include a statement that there may be risks that are not yet identified.

12VAC5-20-100 A.7 “A statement that there may be other risks not yet identified” has been deleted, as it is redundant with amended language.

Should the Board approve these amendments, the regulatory package will be submitted for final stage executive branch review. Following executive review and approval, the amendments will be published in the Virginia Register of Regulations and will, after a 30-day final adoption period, take effect.

Thank you for your consideration.





Virginia  
Regulatory  
Town Hall

[townhall.virginia.gov](http://townhall.virginia.gov)

## Final Regulation Agency Background Document

<b>Agency name</b>	State Board of Health (Virginia Department of Health)
<b>Virginia Administrative Code (VAC) citation</b>	12VAC5-20
<b>Regulation title</b>	Regulations for the Conduct of Human Research
<b>Action title</b>	Amend regulations for clarity, efficiency and effectiveness following periodic review.
<b>Date this document prepared</b>	November 18, 2014

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

### Brief summary

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

The final 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 final 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 for the commissioner to report the listing of institutions that are subject to federal regulations regarding human subject research and are exempt from 12VAC5-20.

## Statement of final agency action

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

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The Virginia State Board of Health approved the text of the final amendments for the “Regulations for the Conduct of Human Research,” 12VAC5-20 on December 4, 2014.

## 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.*

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Section 32.1-12.1 of the *Code of Virginia* charges the State Board of Health with promulgating 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. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.*

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Several aspects of the regulations regarding the Conduct of Human Research need updating and clarifying. As a result of the Periodic Review, it was noted that the 2010 regulation amendments did not include a revised definition of “human research”. The changes add a definition for this term and a definition for “protected health information.” The changes amend the definitions for “informed consent” and “legally authorized representative” to provide greater clarity to the regulations. In addition, the regulations amend the requirements of the composition of the human research review committee. The current state regulations require that each committee have at least seven members, however, the federal regulations require that each committee have at least five members (45 CFR 46.107 (a)). Reducing the number of members will reduce the burden on the state while continuing to provide the protection of human research subjects. The amendments provide additional details regarding the elements of the committee review process to ensure consistency with § 32.1-162.19 of the *Code of Virginia*. The amendments provide greater clarity to the informed consent process, and eliminate repealed Code sections in the categories of human research exempt from regulation. The amendments are updates that will assist in ensuring the public health, safety and welfare of the citizens of the Commonwealth.

## Substance

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

The final amendments to the regulations include:

- 1) Updating the definition of "Human Research."
- 2) Adding a definition of "Minor Increase over Minimal Risk."
- 3) Adding a definition of "Subject" or "Human Subject."
- 4) Replacing the term "participants" with "subjects" in various sections.
- 5) Eliminating the detail elements of informed consent in the definition section (12VAC5-20-10). This information is duplicated in Section 100.
- 6) Amending the definition of "Legally Authorized Representative" to be consistent with § 32.1-162.16.
- 7) Add a definition of "Protected Health Information (PHI)".
- 8) In Section 30, replace the term "human participants" with "human subjects" to be consistent with language used in § 32.1-162.16.
- 9) 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 of a subject in human research.
- 10) In Section 50, the committee reporting requirement is changed from January 31 to March 31<sup>st</sup> each year.
- 11) In Sections 50 and 60 the term "chairman" is amended to "chair."
- 12) Section 70 is amended to require that the committee have at least 5 members instead of at least 7 members.
- 13) Section 70 is amended to indicate that consideration will be given to the inclusion of members experienced in working with categories of vulnerable subjects that are regularly reviewed by the committee.
- 14) 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.
- 15) Section 80(D) 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.
- 16) In Section 80, a new subsection G 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.
- 17) In Section 80, a new subsection I 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).
- 18) In Section 80, a new section J 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.
- 19) Section 90(A) 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.
- 20) 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.

- 21) 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.
- 22) 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 there are 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 is that the amended regulations will provide greater clarity on the committee review process.
- 3) There are no other pertinent matters of interest related to this action.

**Changes made since the proposed stage**

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

<b>Section number</b>	<b>Requirement at proposed stage</b>	<b>What has changed</b>	<b>Rationale for change</b>
10: Definitions	N/A	Added a definition of “minor increase over minimal risk”	Provides greater clarity to the term as used in 12VAC5-20-100.
70 : Composition of Research Review Committee	If the committee regularly reviews research that has an impact on vulnerable subjects, the committee shall have in its membership one or more individuals primarily concerned with the welfare of these subjects.	If the committee regularly reviews research that has an impact on vulnerable subjects, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.	Provides greater consistency with federal regulations
80: Elements of Committee Review Process	Refers to “undue influence”	“Influence” is deleted and replaced with “inducement”	Provides consistency with the term used in the definition of Informed Consent in Section 10.
100: Informed Consent	N/A	Delete number 8.”A statement that there may be other risks not yet identified.”	This is redundant with number 3 in the final amendments.



**Public comment**

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

No comments were received during the public comment period following the publication of the proposed stage.

Commenter	Comment	Agency response
N/A	N/A	N/A

**All changes made in this regulatory action**

*Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections.*

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
Section 10: Definitions	N/A	Definition of "Human Research"	The definition is amended to be consistent with the definition in § 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 "minor increase over minimal risk"
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

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
			qualified to act as a legally authorized representative of a subject in human research.
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 regulations state If the committee regularly reviews research that has an impact on vulnerable subjects, the committee shall have in its membership one or more	To provide greater consistency with federal regulations, this is amended to state that consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these vulnerable subjects.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
		individuals primarily concerned with the welfare of these subjects.	
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(a)) 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 in subsection D 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 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	N/A	Current regulations authorize the committee to conduct an expedited review of a human research	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

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
Research Projects		project which involves no more than minimal risk to the subjects.	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 informed consent to participate as a research subject.	Subsection A(1) is amended to add the requirement that information be provided 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 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 a description of any adverse consequences and risks to be expected and an indication whether there may be other significant risks not yet identified as an element of informed consent.
Section 100: Informed Consent	N/A	Current regulations address the basic information necessary for 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 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 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) from the legally authorized representative and a description of the ways that any concerns may be raised or questions asked.



Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
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 subsections E(1)-(4) clarify 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, waiver 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. This 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.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
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 the 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.

Action:

Amend Regulations Based on Results of Periodic Review

Stage: Final

12VAC5-20-10

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 CFR 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 person who is the prospective subject of human research, provided the advance directive authorizes the agent to make decisions regarding the person's participation in human research; (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.~~

**["Minor increase over minimal risk" means there is only slightly more than minimal risk; any potential harms are transient and reversible with respect to any harm; and there is an extremely small probability that the subject will experience severe pain, discomfort, stress or harm]**

"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 person about whom an investigator (whether professional or student) conducting research obtains (i) data through intervention or interaction with the person or (ii) identifiable private information.

12VAC5-20-30

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 that~~ conducts or ~~which~~ proposes to conduct or authorize research ~~which uses~~ using human participants subjects.

12VAC5-20-40

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~~ shall not present greater than minimal risk.

E. The ~~individual person, institution, or agency~~ conducting the human research shall ~~be required to~~ notify all ~~participants subjects~~ of human research of the risks caused by the research ~~which that~~ 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

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 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.

C. The ~~chairman~~ chair of the committee shall report as soon as possible to the commissioner any violation of the research protocol ~~which that~~ 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

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

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, **[such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these 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

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

A. No human research shall be conducted or authorized by a person, 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 (i) by using procedures that are consistent with sound human research design and that do not unnecessarily expose subjects to risk and (ii) 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 inducement**, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons;

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.

~~A. B.~~ 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 for 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.

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

~~C. D.~~ 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.

~~D.~~ E. 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.

~~E.~~ H. 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 (42 USC § 1320d et seq.), 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 CFR 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

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 that~~ 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 CFR 46.110.~~

B. The committee also is authorized to conduct an expedited review of a human research project that 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.

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

12VAC5-20-100

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 of whether there may be other significant risks not yet identified;

~~3- 4.~~ 4. 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;

~~4- 5.~~ 5. 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;

~~5- 6.~~ 6. 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;

~~6- 7.~~ 7. 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;

~~[7- 8. A statement that there may be other risks not yet identified];~~

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

9. 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;

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

11. 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 person 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 person or by the person's authorized representative except as provided for in subsection E of this section. If the person is capable of providing informed consent, written consent shall be provided by the person and witnessed. If the person 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 person's legally authorized representative and witnessed. If the person 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 person 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 person or, if applicable, the person's legally authorized representative shall be in language understandable to the person or representative.

C. No person 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 person 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 person 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 person.

D. No legally authorized representative shall consent to nontherapeutic human research unless it is determined by the research review committee that such nontherapeutic research will present no more than a minor increase over minimal risk to the subject~~], and (a) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations; and (b) the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition, which is of vital importance for the understanding or amelioration of the subjects' disorder or condition;~~]. A legally authorized representative may not consent to participation in human research on behalf of a subject 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 subject, 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 subjects;
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.

B. F. 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

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~~ subjects], 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

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 that~~ 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. ~~An~~ Each research review committee of a state institution or agency shall ensure that 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

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

Human research ~~at institutions which are~~ that 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 12VAC5-20-60 F.

## MEMORANDUM

DATE: November 10, 2014

TO: Virginia State Board of Health

FROM: Lilian Peake, MD, MPH  
Director, Office of Family Health Services

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

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The Virginia State Board of Health (Board) is asked to review and approve the enclosed amendments to 12VAC5-71, Regulations Governing Virginia Newborn Screening Services so that they may be submitted for the final stage of regulatory review. The amendments would add Severe Combined Immunodeficiency (SCID) to the Virginia newborn screening panel. The Board previously approved the amendments for the proposed stage of regulatory review, and they were submitted for Executive Branch review and public comment. The public comment period closed on September 12, 2014, with 30 comments submitted. All 30 comments were fully in favor of the amendments.

The Discretionary Advisory Committee on Heritable Disorders in Newborns and Children advises the Secretary of the U.S. Department of Health and Human Services on the most appropriate application of universal newborn screening tests, technologies, policies, guidelines and standards. In February 2010, the U.S. Secretary of Health and Human Resources approved adding SCID to the recommended uniform screening panel (RUSP).

Thereafter, 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. VDH convened a Virginia SCID Planning Workgroup on September 20-21, 2012 to formulate a plan and discuss issues surrounding the possible addition of this condition to the Virginia panel. On October 24, 2012, a regulatory advisory group met to provide input and changes to a draft version of regulatory changes.

The final amendments include only one change: adding SCID to the list of newborn screens that are included in 12VAC5-71-30. The conditions in that section are listed in alphabetical order, and SCID would be a new item number 23.

Section 32.1-65 of the Code of Virginia states that every infant who is born in the Commonwealth shall be subjected to screening tests for various disorders consistent with, but not necessarily identical to, the RUSP. Currently, the Virginia newborn screening regulations cover 29 of 31 disorders that are included in the RUSP. The Board considered emergency regulations at its meeting on September 18, 2014, which will add a 30<sup>th</sup> condition (critical congenital heart disease) to the panel. If the Board approves the SCID amendments, Virginia would screen for all 31 disorders in the RUSP.

Should the Board approve these amendments, the regulatory package will be submitted for final stage executive branch review. Following executive review and approval, the amendments will be published in the Virginia Register of Regulations and, following a 30-day final adoption period, will take effect.

Thank you for your consideration.



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V

## Final Regulation Agency Background Document

<b>Agency name</b>	State Board of Health (Virginia Department of Health)
<b>Virginia Administrative Code (VAC) citation</b>	12VAC5-71 <i>et seq.</i>
<b>Regulation title</b>	Regulations Governing Virginia Newborn Screening Services
<b>Action title</b>	Amend regulations to add Severe Combined Immunodeficiency (SCID) to the Virginia Newborn Screening System core panel of heritable disorders and genetic diseases.
<b>Date this document prepared</b>	November 10, 2014

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

### Brief summary

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

The final 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.

### Statement of final agency action

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

The Virginia State Board of Health approved the final amendments for the Regulations Governing Virginia Newborn Screening Services, 12VAC5-71 on December 4, 2014.

### 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 Section 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 Section 32.1-65.

### Purpose

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

All newborns in Virginia would be screened for SCID as a result of this final 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 opportunity for 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 2015.

## Substance

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

The 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 29 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 there are 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 is estimated to be \$8.50 per sample. (This is higher than the original estimate from June, 2013 that the cost would be \$7.50 a sample.)

The \$8.50 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 \$16.50 per panel. As a result, the total cost of the blood spot screening panel increased from \$53.00 to \$78.00. (This cost increase went into effect on January 1, 2014.) This cost is less than the national average fee of \$89.75 among 22 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.

The Division of Consolidated Laboratory Services (DCLS) at the Department of General Services, which conducts the tests, is installing the last of the SCID screening instrumentation now. Once in place, DCLS will run a complete validation study to insure all testing processes are in control and will consistently provide accurate and reproducible results across all instruments. At the same time, DCLS is stocking up on supplies and is recruiting for three additional scientists needed to test all newborn screening samples for SCID.

DCLS is also working with VDH staff to provide support for the educational materials that will be developed and distributed to parents and the healthcare community relate to SCID screening.

**Changes made since the proposed stage**

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

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

Section number	Requirement at proposed stage	What has changed	Rationale for change
N/A	N/A	N/A	N/A

**Public comment**

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

Commenter	Comment	Agency response
Nataly Jouseph	Wonderful	Comment noted.
Melba Atkinson	“Please add SCID Newborn Screening to the routine testing done in the state of Virginia for infants.”	Comment noted.
Virginia Rodriguez	“Please pass the necessary legislation to test for this disease.”	Comment noted.
Kristen Klaaren	“I am writing to urge you to add SCID testing to the list of routine testing done for newborns.”	Comment noted.
Paige Rannigan	“Please add SCID to newborn screening tests so that children’s lives can be saved.”	Comment noted.
Gail Mattocks	“Please vote for SCID screening for newborns.”	Comment noted.

Alexandra Brunst	This is an affordable test that will save the lives of affected babies through newborn screening.	Comment noted.
Jasey Snead	"This screening should be mandatory in the state of Va. It would save lives and I personally see no reason to NOT do this screening!"	Comment noted.
Kerri Madden	"I am in favor of SCID Newborn Screening. Early detection is key."	Comment noted.
Mary Cail	"If the parents of newborns who suffer this disease are recommending that it be added to newborn screenings, I suggest that we listen to them."	Comment noted.
Anne Gould	"Please add SCID to routine newborn screenings - it can save lives."	Comment noted.
Diana Bower	"Please amend this law to save lives and families. It will help keep medical costs down as well with early screening and treatment."	Comment noted.
Stephen Sielinski	"Getting regulations passed to test for Severe combined immunodeficiency (SCID) in newborns is critical."	Comment noted.
Jayne P Hollar	"I support the adding of SCID to newborn screenings."	Comment noted.
Jenny Dimasi	"This is a devastating condition and could be helped by infant screening. For minimal cost devastation could be possibly avoided."	Comment noted.
Charlotte Hisey	It is of vital importance to pass this in order to start screening for SCID."	Comment noted.
Patricia M. Rannigan	"Please pass this bill, as no one needs to go through the horror of losing a child."	Comment noted.
Marsha Meeks	"Please include SCID testing as a mandatory newborn test!"	Comment noted.
Kay Ferguson	Seems a simple matter to add testing for SCIDS to newborn screening and it has the potential to avert great suffering for affected infants and their families.	Comment noted.
Cheryl Hughes	"My heart breaks to think about the parents out there who could lose a child due to ignorance of their child's propensity for this condition, when screening could easily educate them."	Comment noted.
Judith Miller	"Every child deserves a chance."	Comment noted.
Clare Rannigan	"As the grandmother of a beautiful grandson who lost his	Comment noted.

	battle with SCID at 5 months of age I implore you to add this test to newborn screenings in Virginia.”	
Donna Varela	“I’m strongly in favor of SCID screening. It saves lives!”	Comment noted.
Laura Lilley-Bell	“This must be amended. Even 1 child lost to SCID is 1 too many.”	Comment noted.
Crystal Simmons	“If it could save 1 life it should be done.”	Comment noted.
Tammy Wood	“Our children NEED this screening.”	Comment noted.
Edward Rodriguez	“The test costs so little and can save so many lives. The sooner SCID is diagnosed, the easier it is to treat. This is a 100% no brainer that must, must, MUST, occur!!”	Comment noted.
Robert C Rannigan	“In favor of SCID testing.”	Comment noted.
Immune Deficiency Foundation	“Your approval of the pending regulations will save the lives of babies in Virginia. We hope that Virginia will join the 21 other states that are currently screening for SCID.”	Comment noted.
Barb Ballard	“This test makes sense as a health initiative, as a budgetary issue, and as an ethical issue.”	Comment noted.

**All changes made in this regulatory action**

*Please list all changes that are being proposed and the consequences of the proposed changes. Describe new provisions and/or all changes to existing sections.*

<b>Current section number</b>	<b>Proposed new section number, if applicable</b>	<b>Current requirement</b>	<b>Proposed change and rationale</b>
12VAC5-71-30	N/A	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.

## 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.