

**State of Board of Health  
Agenda  
September 18, 2014 – 9:00 a.m.  
Four Points by Sheraton  
4700 South Laburnum Avenue  
Richmond, Virginia**

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| Call to Order and Welcome  | Bruce Edwards, Chair  |
| Pledge of Allegiance   | Dr. Steven Escobar  |
| Introductions  | Mr. Edwards   |
| Review of Agenda   | Joseph Hilbert<br>Director of Governmental and Regulatory Affairs |
| Approval of June 5, 2014 Minutes   | Mr. Edwards   |
| Commissioner’s Report  | Marissa J. Levine, MD, MPH, FAAFP<br>State Health Commissioner    |
| Budget Update  | Mike McMahon, Deputy Director<br>Office of Financial Management   |
| Regulatory Action Update   | Mr. Hilbert   |
| Break  |   |
| Abortion Facility Licensure Overview<br>and Status Report  | Erik Bodin, Director<br>Office of Licensure and Certification     |
| Public Comment Period  |   |
| <u>Regulatory Action Items</u>   |   |
| Virginia Emergency Medical Services Regulations<br>12VAC5-31<br>(Fast Track amendments)  | Gary Brown, Director<br>Office of Emergency Medical Services      |
| Regulations for Disease Reporting and Control<br>12VAC5-90<br>(Proposed amendments)  | Laurie Forlano, DO, MPH, Director<br>Office of Epidemiology       |
| Working Lunch  |   |
| Lunch Speaker – Paula Garrett, WIC Program Manager, VDH Division of Community Nutrition<br>Topic – Overview of WIC Food Packages |   |

Regulatory Action Items

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

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

Regulations Implementing the Virginia Organ  
and Tissue Donor Registry  
12VAC5-475  
(Final amendments)

Dr. Peake

Regulations Governing Virginia Newborn  
Screening Services  
12VAC5-71  
(Emergency regulations)

Dr. Peake

2015 Board Meeting Schedule

Mr. Edwards

Member Reports

Other Business

Adjourn

July 30, 2014

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

Dear Mr. Edwards:

The Code of Virginia § 32.1-111.5 establishes that the Board of Health shall prescribe by regulation the qualifications required for certification of emergency medical services (EMS) providers. The Board shall also prescribe by regulation procedures and the qualifications required for the recertification of EMS providers. Furthermore, § 32.1-111.4 of the Code of Virginia requires that the Board of Health shall prescribe by regulation requirements governing EMS personnel and vehicles, response times, enforcement provisions and civil penalties.

The most recent version of the Virginia EMS Regulations, 12 VAC5-31, was promulgated by the Board of Health effective October 12, 2012. In section 12VAC5-31-910 of the regulations which addresses criminal and enforcement history, the term “affiliation” was inadvertently removed from the text. The term “affiliation” had been included in the 2003 regulations that the revised 2012 regulations replaced.

The current 2012 text reads “application for or certification of individuals convicted of certain crimes present an unreasonable risk to public health and safety...” The proposed change is “application for affiliation or certification of individuals convicted of certain crimes present an unreasonable risk to public health and safety...” It is proposed that the term “affiliation” will be inserted as applicable in each paragraph of this section.

This language was in the 2003 version of the Virginia EMS regulations and is a technical revision for inclusion in the current version. This is a technical change to amend the current regulations to prohibit any individual, not just certified EMS providers, with an adverse criminal history from affiliating with an EMS agency, as was the case in the previous version of the regulations. Being able to restrict EMS affiliation and certification to those who have not committed heinous crimes adds a layer of protection to the health, safety and welfare of the citizens and visitors to the Commonwealth that EMS serves.

Mr. Bruce Edwards, Chair  
July 30, 2014  
Page Two

The Office of EMS (OEMS) has worked with the Rules and Regulations Committee, the State EMS Advisory Board and other EMS stakeholder groups and all agree with the need for this technical change and to insert the term “affiliation” as applicable. OEMS has developed the TH-04 Fast Track form to the Virginia Regulatory Town Hall for the purpose of amending the Virginia EMS Regulations accordingly.

Attached to this document is the TH-04 form and the regulatory text. As the Code of Virginia mandates, this regulatory action must be reviewed and approved by the State Board of Health. OEMS appreciates the opportunity to present this document to the Board, and values any input that the Board provides, as well as the input of any other stakeholder, or interested party.

Respectfully submitted,

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



Virginia  
Regulatory  
Town Hall

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

## Fast Track Proposed Regulation Agency Background Document

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|--|--|
| <b>Agency name</b>                                 | Virginia Department of Health  |
| <b>Virginia Administrative Code (VAC) citation</b> | 12VAC5-31  |
| <b>Regulation title</b>                            | Virginia Emergency Medical Services Regulations  |
| <b>Action title</b>                                | Amend 12VAC5-31-910 to add the term "affiliation" to the criteria for the general or presumptive denial for individuals applying for affiliation with an EMS agency or certification as an EMS provider. |
| <b>Date this document prepared</b>                 | July 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.*

This revision adds criteria that limit an individual's ability to become affiliated with an EMS agency if they have a prior history of committing certain crimes to an existing exclusion that prevents these individual's from becoming certified as a Virginia EMS provider. This language was in the 2003 version of the Virginia EMS Regulations but was inadvertently deleted when the current regulations were adopted in 2012. These amendments constitute a technical revision. In addition, minor revisions to the definition of "EMS Personnel" are necessary to correct grammar, without affecting the content of the definition.

### Statement of final agency action

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

The State Board of Health approved the fast track amendments to the Virginia Emergency Medical Services Regulations, 12VAC5-31-10 and 12VAC5-31-910, on September 18, 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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§ 32.1-111.4. Regulations; emergency medical services personnel and vehicles; response times; enforcement provisions; civil penalties.

A. The State Board of Health shall prescribe by regulation:

1. Requirements for record keeping, supplies, operating procedures and other agency operations;
2. Requirements for the sanitation and maintenance of emergency medical services vehicles and their medical supplies and equipment;
3. Procedures, including the requirements for forms, to authorize qualified emergency medical services personnel to follow Do Not Resuscitate Orders pursuant to § 54.1-2987.1;
4. Requirements for the composition, administration, duties and responsibilities of the State Emergency Medical Services Advisory Board;
5. Requirements, developed in consultation with the Emergency Medical Services Advisory Board, governing the training, certification, and recertification of emergency medical services personnel;
6. Requirements for written notification to the State Emergency Medical Services Advisory Board, the State Office of Emergency Medical Services, and the Financial Assistance and Review Committee of the Board's action, and the reasons therefore, on requests and recommendations of the Advisory Board, the State Office of Emergency Medical Services or the Committee, no later than five workdays after reaching its decision, specifying whether the Board has approved, denied, or not acted on such requests and recommendations;
7. Authorization procedures, developed in consultation with the Emergency Medical Services Advisory Board, which allow the possession and administration of epinephrine or a medically accepted equivalent for emergency cases of anaphylactic shock by certain levels of certified emergency medical services personnel as authorized by § 54.1-3408 and authorization procedures that allow the possession and administration of oxygen with the authority of the local medical director and a licensed emergency medical services agency;
8. A uniform definition of "response time" and requirements, developed in consultation with the Emergency Medical Services Advisory Board, for each agency to measure response times starting from the time a call for emergency medical care is received until (i) the time an appropriate emergency medical response unit is responding and (ii) the appropriate emergency medical response unit arrives on the scene, and requirements for agencies to collect and report such data to the Director of the Office of Emergency Medical Services who shall compile such information and make it available to the public, upon request; and

9. Enforcement provisions, including, but not limited to, civil penalties that the Commissioner may assess against any agency or other entity found to be in violation of any of the provisions of this article or any regulation promulgated under this article. All amounts paid as civil penalties for violations of this article or regulations promulgated pursuant thereto shall be paid into the state treasury and shall be deposited in the emergency medical services special fund established pursuant to § 46.2-694, to be used only for emergency medical services purposes.

B. The Board shall classify agencies and emergency medical services vehicles by type of service rendered and shall specify the medical equipment, the supplies, the vehicle specifications and the personnel required for each classification.

C. In formulating its regulations, the Board shall consider the current Minimal Equipment List for Ambulances adopted by the Committee on Trauma of the American College of Surgeons.

**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.*

This is a technical change to amend the current EMS Regulations to prohibit individuals with an adverse criminal history from affiliating with an EMS agency licensed by the Virginia Department of Health’s Office of Emergency Medical Services, as was the case in the previous version of the regulations. Individuals who provide care to patients in their time of need must meet high moral, ethical and legal standards in order to maintain the trust and confidence of the communities they serve. Being able to restrict EMS agency affiliation and certification to those who have not committed heinous crimes adds a layer of protection to the health, safety and welfare of the citizens and visitors of the Commonwealth.

**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.*

Changes to the regulations are not expected to be controversial. Key stakeholders groups and the general EMS community requested this technical change to reflect language that was previously in the 2003 version of the EMS Regulations but did not convey to the current version of the regulations.

**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.*

12VAC5-31-910 prohibits the certification of individuals who have been found guilty of certain crimes. The proposed technical changes add the term “affiliation” to this section in order to reflect the previous

version of the EMS Regulations. This change is designed to prohibit an individual who has committed crimes of a certain nature from affiliating with an EMS agency in addition to restricting their ability to apply for certification as an EMS provider. In addition, there are certain crimes, after a defined waiting period, which do not affect an individual’s ability to apply to become affiliated or certified as an EMS provider in Virginia.

EMS – Emergency Medical Services

**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.*

There are no disadvantages anticipated to the citizens, or businesses by amending these provisions. It will add an additional layer of scrutiny for those desiring to become affiliated with an EMS agency. For the Commonwealth, these recommended changes will work to assure a level of credibility for those seeking affiliation with or certification with an EMS agency providing service to the Commonwealth. There are no anticipated issues with this technical change. It restores the criteria as previously accepted by EMS system stakeholders in order to maintain the high standards the community expects for those providing emergency medical services in the Commonwealth.

**Requirements more restrictive than federal**

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

There are no requirements that exceed applicable federal requirements.

**Localities particularly affected**

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

This proposed amendment affects all localities and EMS agencies in the Commonwealth of Virginia.

**Regulatory flexibility analysis**

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

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

This recommended change re-establishes previously identified screening criteria for applicants who wish to be certified or affiliated with an EMS agency in Virginia. There are no viable alternative regulatory methods that will accomplish the statutory objectives contained in the Code of Virginia.

**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.*

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| <b>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source / fund detail, and (b) a delineation of one-time versus on-going expenditures</b>   | No anticipated additional costs.  |
| <b>Projected cost of the <i>new regulations or changes to existing regulations</i> on localities.</b>  | No anticipated additional costs.  |
| <b>Description of the individuals, businesses or other entities likely to be affected by the <i>new regulations or changes to existing regulations</i>.</b>  | This change aligns with national criteria for certification and re-establishes the two main criteria for screening an applicant for affiliation or certification in Virginia. |
| <b>Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected.</b> Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.  | This affects the licensed EMS agencies in Virginia, 681 as of March 4, 2014.  |
| <b>All projected costs of the <i>new regulations or changes to existing regulations</i> for affected individuals, businesses, or other entities. Please be specific and include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.</b> | No anticipated additional costs.  |
| <b>Beneficial impact the regulation is designed to produce.</b>  | Provides additional screening criteria for individuals seeking to become affiliated with an EMS agency or certified as a provider.  |

**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 identified that would be less intrusive or least burdensome.

**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.*

There is no impact on the institution of 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), use this chart:

| Current section number | Proposed new section number, if applicable | Current requirement   | Proposed change, intent, rationale, and likely impact of proposed requirements   |
|------------------------|--|---|--|
| 10                     |  | “Emergency medical services personnel” or “EMS personnel” means a person, affiliated with an EMS agency, responsible for the provision of emergency medical services including any or all persons who could be described as an attendant, | “Emergency medical services personnel” or “EMS personnel” means a person <u>who is</u> affiliated with an EMS agency, <u>or is</u> responsible for the provision of emergency medical services including any or all persons who could be described as an attendant, attendant-in-charge, operator or operational medical director. |

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| <p>910</p> |  | <p>attendant-in-charge, operator or operational medical director.</p> <p>A. General denial. Application for or certification of individuals convicted of certain crimes present an unreasonable risk to public health and safety. Thus, applications for certification by individuals convicted of the following crimes will be denied in all cases:</p> <p>B. Presumptive denial. Application for or current certification by individuals in the following categories will be denied except in extraordinary circumstances, and then will be granted only if the applicant or provider establishes by clear and convincing evidence that certification will not jeopardize public health and safety.</p> <ol style="list-style-type: none"> <li>1. Application for certification by individuals who have been convicted of any crime and who are currently incarcerated, on work release, on probation, or on parole.</li> <li>2. Application for or certification by individuals convicted of crimes in the following categories unless at least five years have passed since the conviction or five years have passed since release from custodial confinement whichever occurs later:             <ol style="list-style-type: none"> <li>a. Crimes involving controlled substances or synthetics, including unlawful possession or distribution or intent to distribute unlawfully Schedule I through V drugs as defined by the Virginia Drug Control Act (§ 54.1-3400 seq. of the Code of Virginia).</li> <li>b. Serious crimes against</li> </ol> </li> </ol> | <p>Rationale: provides clarification of who is affiliated with or provides services on behalf of an EMS agency.</p> <p>A. General denial. Application for <u>affiliation</u> or certification of individuals convicted of certain crimes present an unreasonable risk to public health and safety. Thus, applications for <u>affiliation or certification</u> by individuals convicted of the following crimes will be denied in all cases:</p> <p>B. Presumptive denial. Application for <u>affiliation</u> or current certification by individuals in the following categories will be denied except in extraordinary circumstances, and then will be granted only if the applicant or provider establishes by clear and convincing evidence that affiliation or certification will not jeopardize public health and safety.</p> <ol style="list-style-type: none"> <li>1. Application for <u>affiliation or certification</u> by individuals who have been convicted of any crime and who are currently incarcerated, on work release, on probation, or on parole.</li> <li>2. Application for <u>affiliation or certification</u> by individuals convicted of crimes in the following categories unless at least five years have passed since the conviction or five years have passed since release from custodial confinement whichever occurs later:</li> <li>3. Is currently under any disciplinary or enforcement action from another state EMS office or other recognized state or national healthcare provider licensing or certifying body. Personnel subject to these disciplinary or enforcement actions may be eligible for <u>affiliation or certification</u> provided there have been no further disciplinary or enforcement actions for five years prior to application for certification in Virginia.</li> </ol> <p>Rationale: Amends the regulation to clarify the exclusionary criteria for not only EMS certification, but also those who desire to become affiliated with an EMS agency.</p> |
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|  |  | <p>property, such as grand larceny, burglary, embezzlement, or insurance fraud.</p> <p>c. Any other crime involving sexual misconduct.</p> <p>3. Is currently under any disciplinary or enforcement action from another state EMS office or other recognized state or national healthcare provider licensing or certifying body. Personnel subject to these disciplinary or enforcement actions may be eligible for certification provided there have been no further disciplinary or enforcement actions for five years prior to application for certification in Virginia.</p> |  |
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**Project 3991 - none**

**DEPARTMENT OF HEALTH**

**Amend Criminal or Enforcement History**

Part I

General Provisions

Article 1

Definitions

**12VAC5-31-10. Definitions.**

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

"Abandonment" means the termination of a health care provider-patient relationship without assurance that an equal or higher level of care meeting the assessed needs of the patient's condition is present and available.

"Accreditation" means approval granted to an entity by the Office of Emergency Medical Services (EMS) after the institution has met specific requirements enabling the institution to conduct basic or advanced life support training and education programs. There are four levels of accreditation: interim, provisional, full, and probationary.

"Accreditation cycle" means the term or cycle at the conclusion of which accreditation expires unless a full self-study is performed. Accreditation cycles are typically quinquennial (five-year) but these terms may be shorter, triennial (three-year) or biennial (two-year), if the Office of EMS deems it necessary.

"Accreditation date" means the date of the accreditation decision that is awarded to an entity following its full site visit and review.

"Accreditation decision" means the conclusion reached about an entity status after evaluation of the results of the onsite survey, recommendations of the site review team, and any other relevant information such as documentation of compliance with standards, documentation of plans to correct deficiencies, or evidence of recent improvements.

"Accreditation denied" means an accreditation decision that results when an entity has been denied accreditation. This accreditation decision becomes effective only when all available appeal procedures have been exhausted.

"Acute" means a medical condition having a rapid onset and a short duration.

"Acute care hospital" means any hospital that provides emergency medical services on a 24-hour basis.

"Administrative Process Act" or "APA" means Chapter 40 (§ 2.2-4000 et seq.) of Title 2.2 of the Code of Virginia.

"Advanced life support" or "ALS" means the provision of care by EMS personnel who are certified as an Emergency Medical Technician (EMT) - Enhanced, Advanced EMT, Intermediate, or Paramedic or equivalent as approved by the Board of Health.

Advanced life support in the air medical environment is a mission generally defined as the transport of a patient who receives care during a transport that includes an invasive medical procedure or the administration of medications, including IV infusions, in addition to any noninvasive care that is authorized by the Office of EMS.

"Advanced life support certification course" means a training program that allows a student to become eligible for a new ALS certification level. Programs must meet the educational

requirements established by the Office of EMS as defined by the respective advanced life support curriculum. Initial certification courses include:

1. Emergency Medical Technician-Enhanced;
2. Advanced EMT;
3. Advanced EMT to Intermediate Bridge;
4. EMT-Enhanced to Intermediate Bridge;
5. Intermediate;
6. Intermediate to Paramedic Bridge;
7. Paramedic;
8. Registered Nurse to Paramedic Bridge; and
9. Other programs approved by the Office of EMS.

"Advanced life support (ALS) coordinator" means a person who has met the criteria established by the Office of EMS to assume responsibility for conducting ALS training programs.

"Advanced life support transport" means the transportation of a patient who is receiving ALS level care.

"Affiliated" means a person who is employed by or a member of an EMS agency.

"Air medical specialist" means a person trained in the concept of flight physiology and the effects of flight on patients through documented completion of a program approved by the Office of EMS. This training must include but is not limited to aerodynamics, weather, communications, safety around aircraft/ambulances, scene safety, landing zone operations, flight physiology, equipment/aircraft familiarization, basic flight navigation, flight documentation, and survival training specific to service area.

"Ambulance" means (as defined by § 32.1-111.1 of the Code of Virginia) any vehicle, vessel or craft that holds a valid permit issued by the Office of EMS and that is specially constructed, equipped, maintained and operated, and intended to be used for emergency medical care and the transportation of patients who are sick, injured, wounded, or otherwise incapacitated or helpless. The word "ambulance" may not appear on any vehicle, vessel or aircraft that does not hold a valid EMS vehicle permit.

"Approved locking device" means a mechanism that prevents removal or opening of a drug kit by means other than securing the drug kit by the handle only.

"Assistant director" means the Assistant Director of the Office of Emergency Medical Services.

"Attendant-in-charge" or "AIC" means the certified or licensed person who is qualified and designated to be primarily responsible for the provision of emergency medical care.

"Attendant" means a certified or licensed person qualified to assist in the provision of emergency medical care.

"Basic life support" or "BLS" means the provision of care by EMS personnel who are certified as First Responder, Emergency Medical Responder (EMR), or Emergency Medical Technician or equivalent as approved by the Board of Health.

Basic life support in the air medical environment means a mission generally defined as the transport of a patient who receives care during a transport that is commensurate with the scope of practice of an EMT. In the Commonwealth of Virginia care that is provided in the air medical environment must be assumed at a minimum by a Virginia certified Paramedic who is a part of the regular air medical crew. (fixed wing excluded)

"BLS certification course" means a training program that allows a student to become eligible for a new BLS certification level. Programs must meet the educational requirements established

by the Office of EMS as defined by the respective basic life support curriculum. Initial certification courses include:

1. EMS First Responder;
2. EMS First Responder Bridge to EMT;
3. Emergency Medical Responder;
4. Emergency Medical Responder Bridge to EMT;
5. Emergency Medical Technician; and
6. Other programs approved by the Office of EMS.

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

"Candidate" means any person who is enrolled in or is taking a course leading toward initial certification.

"Candidate status" means the status awarded to a program that has made application to the Office of EMS for accreditation but that is not yet accredited.

"CDC" means the United States Centers for Disease Control and Prevention.

"Certification" means a credential issued by the Office of EMS for a specified period of time to a person who has successfully completed an approved training program.

"Certification candidate" means a person seeking EMS certification from the Office of EMS.

"Certification candidate status" means any candidate or provider who becomes eligible for certification testing but who has not yet taken the certification test using that eligibility.

"Certification examiner" means an individual designated by the Office of EMS to administer a state certification examination.

"Certification transfer" means the issuance of certification through reciprocity, legal recognition, challenge or equivalency based on prior training, certification or licensure.

"Chief executive officer" means the person authorized or designated by the agency or service as the highest in administrative rank or authority.

"Commercial mobile radio service" or "CMRS" as defined in §§ 3 (27) and 332 (d) of the Federal Telecommunications Act of 1996, 47 USC § 151 et seq., and the Omnibus Budget Reconciliation Act of 1993, Public Law 103-66, 107 USC § 312. It includes the term "wireless" and service provided by any wireless real time two-way voice communication device, including radio-telephone communications used in cellular telephone service or personal communications service (e.g., cellular telephone, 800/900 MHz Specialized Mobile Radio, Personal Communications Service, etc.).

"Commissioner" means the State Health Commissioner, the commissioner's duly authorized representative, or in the event of the commissioner's absence or a vacancy in the office of State Health Commissioner, the Acting Commissioner or Deputy Commissioner.

"Continuing education" or "CE" means an instructional program that enhances a particular area of knowledge or skills beyond compulsory or required initial training.

"Course" means a basic or advanced life support training program leading to certification or award of continuing education credit hours.

"Course coordinator" means the person identified on the course approval request as the coordinator who is responsible with the physician course director for all aspects of the program including but not limited to assuring adherence to the rules and regulations, office policies, and any contract components.

"Critical care" or "CC" in the air medical environment is a mission defined as an interfacility transport of a critically ill or injured patient whose condition warrants care commensurate with the scope of practice of a physician or registered nurse.

"Critical criteria" means an identified essential element of a state practical certification examination that must be properly performed to successfully pass the station.

"Defibrillation" means the discharge of an electrical current through a patient's heart for the purpose of restoring a perfusing cardiac rhythm. For the purpose of these regulations, defibrillation includes cardioversion.

"Defibrillator -- automated external" or "AED" means an automatic or semi-automatic device, or both, capable of rhythm analysis and defibrillation after electronically detecting the presence of ventricular fibrillation and ventricular tachycardia, approved by the United States Food and Drug Administration.

"Defibrillator -- manual" means a monitor/defibrillator that has no capability for rhythm analysis and will charge and deliver a shock only at the command of the operator. For the purpose of compliance with these regulations, a manual defibrillator must be capable of synchronized cardioversion and noninvasive external pacing. A manual defibrillator must be approved by the United States Food and Drug Administration.

"Designated infection control officer" means a liaison between the medical facility treating the source patient and the exposed employee. This person has been formally trained for this position and is knowledgeable in proper post exposure medical follow up procedures and current regulations and laws governing disease transmission.

"Designated emergency response agency" means an EMS agency recognized by an ordinance or a resolution of the governing body of any county, city or town as an integral part of

the official public safety program of the county, city or town with a responsibility for providing emergency medical response.

"Director" means the Director of the Office of Emergency Medical Services.

"Diversion" means a change in the normal or established pattern of patient transport at the direction of a medical care facility.

"Emergency medical services" or "EMS" means the services used in responding to an individual's perceived needs for immediate medical care in order to prevent loss of life or aggravation of physiological or psychological illness or injury including any or all of the services that could be described as first response, basic life support, advanced life support, neonatal life support, communications, training and medical control.

"EMS Advisory Board" means the Emergency Medical Services Advisory Board as appointed by the Governor.

"EMS education coordinator" means any EMS provider, registered nurse, physician assistant, doctor of osteopathic medicine, or doctor of medicine who possesses Virginia certification as an EMS education coordinator. Such certification does not confer authorization to practice EMS.

"Emergency medical services agency" or "EMS agency" means a person licensed by the Office of EMS to engage in the business, service, or regular activity, whether or not for profit, of transporting or rendering immediate medical care to persons who are sick, injured, or otherwise incapacitated.

"EMS agency status report" means a report submitted on forms specified by the Office of EMS that documents the operational capabilities of an EMS agency including data on personnel, vehicles and other related resources.

"Emergency medical services personnel" or "EMS personnel" means a person, who is affiliated with an EMS agency, or is responsible for the provision of emergency medical services including any or all persons who could be described as an attendant, attendant-in-charge, operator or operational medical director.

"Emergency medical services physician" or "EMS physician" means a physician who holds current endorsement from the Office of EMS and may serve as an EMS agency operational medical director or training program physician course director.

"Emergency medical services provider" or "EMS provider" means a person who holds a valid certification issued by the Office of EMS.

"Emergency medical services system" or "EMS system" means a system that provides for the arrangement of personnel, facilities, equipment, and other system components for the effective and coordinated delivery of emergency medical services in an appropriate geographical area that may be local, regional, state or national.

"Emergency medical services vehicle" or "EMS vehicle" means any vehicle, vessel, aircraft, or ambulance that holds a valid emergency medical services vehicle permit issued by the Office of EMS that is equipped, maintained or operated to provide emergency medical care or transportation of patients who are sick, injured, wounded, or otherwise incapacitated or helpless.

"Emergency medical services vehicle permit" means an authorization issued by the Office of EMS for any vehicle, vessel or aircraft meeting the standards and criteria established by regulation for emergency medical services vehicles.

"Emergency medical technician instructor" means an EMS provider who holds a valid certification issued by the Office of EMS to announce and coordinate BLS programs.

"Emergency vehicle operator's course" or "EVOOC" means an approved course of instruction for EMS vehicle operators that includes safe driving skills, knowledge of the state motor vehicle code affecting emergency vehicles, and driving skills necessary for operation of emergency vehicles during response to an incident or transport of a patient to a health care facility. This course must include classroom and driving range skill instruction. An approved course of instruction includes the course objectives as identified within the U.S. Department of Transportation Emergency Vehicle Operator curriculum or as approved by OEMS.

"Exam series" means a sequence of opportunities to complete a certification examination with any allowed retest.

"FAA" means the U.S. Federal Aviation Administration.

"FAR" means Federal Aviation Regulations.

"FCC" means the U.S. Federal Communications Commission.

"Financial Assistance Review Committee" or "FARC" means the committee appointed by the EMS Advisory Board to administer the Rescue Squad Assistance Fund.

"Full accreditation" means an accreditation decision awarded to an entity that demonstrates satisfactory compliance with applicable Virginia standards in all performance areas.

"Fund" means the Virginia Rescue Squad Assistance Fund.

"Institutional self study" means a document whereby training programs seeking accreditation answer questions about their program for the purpose of determining their level of preparation to conduct initial EMS training programs.

"Instructor" means the teacher for a specific class or lesson of an EMS training program.

"Instructor aide" means providers certified at or above the level of instruction.

"Interfacility transport" in the air medical environment means as a mission for whom an admitted patient (or patients) was transported from a hospital or care giving facility (clinic, nursing home, etc) to a receiving facility or airport.

"Interim accreditation" means an accreditation decision that results when a previously unaccredited EMS entity has been granted approval to operate one training program, for a period not to exceed 120 days, during which its application is being considered and before a provisional or full accreditation is issued, providing the following conditions are satisfied: (i) a complete application for accreditation is received by the Office of EMS and (ii) a complete institutional self study is submitted to the Office of EMS. Students attending a program with interim accreditation will not be eligible to sit for state testing until the entity achieves official notification of accreditation at the provisional or full level.

"Invasive procedure" means a medical procedure that involves entry into the living body, as by incision or by insertion of an instrument.

"License" means an authorization issued by the Office of EMS to provide emergency medical services in the state as an EMS agency.

"Local EMS resource" means a person recognized by the Office of EMS to perform specified functions for a designated geographic area. This person may be designated to perform one or more of the functions otherwise provided by regional EMS councils.

"Local EMS response plan" means a written document that details the primary service area and responding interval standards as approved by the local government and the operational medical director.

"Local governing body" or "governing body" means members of the governing body of a city, county, or town in the Commonwealth who are elected to that position or their designee.

"Major medical emergency" means an emergency that cannot be managed through the use of locally available emergency medical resources and that requires implementation of special procedures to ensure the best outcome for the greatest number of patients as determined by the EMS provider in charge or incident commander on the scene. This event includes local emergencies declared by the locality's government and states of emergency declared by the Governor.

"Medical care facility" means (as defined by § 32.1-102.1 of the Code of Virginia) any institution, place, building or agency, whether licensed or required to be licensed by the board or the Department of Behavioral Health and Developmental Services, whether operated for profit or nonprofit and whether privately owned or privately operated or owned or operated by a local governmental unit, by or in which health services are furnished, conducted, operated or offered for the prevention, diagnosis or treatment of human disease, pain, injury, deformity or physical condition, whether medical or surgical.

"Medical control" means the direction and advice provided through a communications device (on-line) to on-site and in-transit EMS personnel from a designated medical care facility staffed by appropriate personnel and operating under physician supervision.

"Medical direction" means the direction and supervision of EMS personnel by the Operational Medical Director of the EMS agency with which he is affiliated.

"Medical emergency" means the sudden onset of a medical condition that manifests itself by symptoms of sufficient severity, including severe pain, that the absence of immediate medical attention could reasonably be expected by a prudent layperson who possesses an average knowledge of health and medicine to result in (i) serious jeopardy to the mental or physical health of the individual, (ii) danger of serious impairment of the individual's bodily functions, (iii) serious dysfunction of any of the individual's bodily organs, or (iv) in the case of a pregnant woman, serious jeopardy to the health of the fetus.

"Medical practitioner" means a physician, dentist, podiatrist, licensed nurse practitioner, licensed physician's assistant, or other person licensed, registered or otherwise permitted to distribute, dispense, prescribe and administer, or conduct research with respect to, a controlled substance in the course of professional practice or research in this Commonwealth.

"Mutual aid agreement" means a written document specifying a formal understanding to lend aid to an EMS agency.

"Neonatal" or "neonate" means, for the purpose of interfacility transportation, any infant who is deemed a newborn within a hospital, has not been discharged since the birthing process, and is currently receiving medical care under a physician.

"Nonprofit" means without the intention of financial gain, advantage, or benefit as defined by federal tax law.

"OSHA" means the U.S. Occupational Safety and Health Administration or Virginia Occupational Safety and Health, the state agency designated to perform its functions in Virginia.

"Office of EMS" means the Office of Emergency Medical Services within the Virginia Department of Health.

"Operational medical director" or "OMD" means an EMS physician, currently licensed to practice medicine or osteopathic medicine in the Commonwealth, who is formally recognized and responsible for providing medical direction, oversight and quality improvement to an EMS agency and personnel.

"Operator" means a person qualified and designated to drive or pilot a specified class of permitted EMS vehicle.

"Patient" means a person who needs immediate medical attention or transport, or both, whose physical or mental condition is such that he is in danger of loss of life or health impairment, or who may be incapacitated or helpless as a result of physical or mental condition

or a person who requires medical attention during transport from one medical care facility to another.

"Person" means (as defined in the Code of Virginia) any person, firm, partnership, association, corporation, company, or group of individuals acting together for a common purpose or organization of any kind, including any government agency other than an agency of the United States government.

"Physician" means an individual who holds a valid, unrestricted license to practice medicine or osteopathy in the Commonwealth.

"Physician assistant" means an individual who holds a valid, unrestricted license to practice as a physician assistant in the Commonwealth.

"Physician course director" or "PCD" means an EMS physician who is responsible for the clinical aspects of emergency medical care training programs, including the clinical and field actions of enrolled students.

"Prehospital patient care report" or "PPCR" means a document used to summarize the facts and events of an EMS incident and includes, but is not limited to, the type of medical emergency or nature of the call, the response time, the treatment provided and other minimum data items as prescribed by the board. "PPCR" includes any supplements, addenda, or other related attachments that document patient information or care provided.

"Prehospital scene" means, in the air medical environment, the direct response to the scene of incident or injury, such as a roadway, etc.

"Prescriber" means a practitioner who is authorized pursuant to §§ 54.1-3303 and 54.1-3408 of the Code of Virginia to issue a prescription.

"Primary retest status" means any candidate or provider who failed his primary certification attempt. Primary retest status expires 90 days after the primary test date.

"Primary service area" means the specific geographic area designated or prescribed by a locality (county, city or town) in which an EMS agency provides prehospital emergency medical care or transportation. This designated or prescribed geographic area served must include all locations for which the EMS agency is principally dispatched (i.e., first due response agency).

"Private Mobile Radio Service" or "PMRS" as defined in § 20.3 of the Federal Communications Commission's Rules, 47 CFR 20.3. (For purposes of this definition, PMRS includes "industrial" and "public safety" radio services authorized under Part 90 of the Federal Communications Commission's Rules, 47 CFR 90.1 et seq., with the exception of certain for-profit commercial paging services and 800/900 MHz Specialized Mobile Radio Services that are interconnected to the public switched telephone network and are therefore classified as CMRS.)

"Probationary status" means the Office of EMS will place an institution on publicly disclosed probation when it has not completed a timely, thorough, and credible root cause analysis and action plan of any sentinel event occurring there. When the entity completes an acceptable root cause analysis and develops an acceptable action plan, the Office of EMS will remove the probation designation from the entity's accreditation status.

"Provisional accreditation" means an accreditation decision that results when a previously unaccredited entity has demonstrated satisfactory compliance with a subset of standards during a preliminary on-site evaluation. This decision remains in effect for a period not to exceed 365 days, until one of the other official accreditation decision categories is assigned based upon an a follow-up site visit against all applicable standards.

"Public safety answering point" or "PSAP" means a facility equipped and staffed on a 24-hour basis to receive requests for emergency medical assistance for one or more EMS agencies.

"Quality management program" or "QM" means the continuous study of and improvement of an EMS agency or system including the collection of data, the identification of deficiencies through continuous evaluation, the education of personnel and the establishment of goals, policies and programs that improve patient outcomes in EMS systems.

"Reaccreditation date" means the date of the reaccreditation decision that is awarded to an entity following a full site visit and review.

"Recertification" means the process used by certified EMS personnel to maintain their training certifications.

"Reentry" means the process by which EMS personnel may regain a training certification that has lapsed within the last two years.

"Reentry status" means any candidate or provider whose certification has lapsed within the last two years.

"Regional EMS council" means an organization designated by the board that is authorized to receive and disburse public funds in compliance with established performance standards and whose function is to plan, develop, maintain, expand and improve an efficient and effective regional emergency medical services system within a designated geographical area pursuant to § 32.1-111.11 of the Code of Virginia.

"Regional trauma triage plan" means a formal written plan developed by a regional EMS council or local EMS resource and approved by the commissioner that incorporates the region's geographic variations, trauma care capabilities and resources for the triage of trauma patients pursuant to § 32.1-111.3 of the Code of Virginia.

"Registered nurse" means a person who is licensed or holds a multistate privilege under the provisions of Chapter 30 (§ 54.1-3000 et seq.) of Title 54.1 of the Code of Virginia to practice professional nursing.

"Regulated medical device" means equipment or other items that may only be purchased or possessed upon the approval of a physician and that the manufacture or sale of which is regulated by the U.S. Food and Drug Administration (FDA).

"Regulated waste" means liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or potentially infectious materials and are capable of releasing these materials during handling; items dripping with liquid product; contaminated sharps; pathological and microbiological waste containing blood or other potentially infectious materials.

"Regulations" means (as defined in the Code of Virginia) any statement of general application, having the force of law, affecting the rights or conduct of any person, promulgated by an authorized board or agency.

"Rescue" means a service that may include the search for lost persons, gaining access to persons trapped, extrication of persons from potentially dangerous situations and the rendering of other assistance to such persons.

"Rescue vehicle" means a vehicle, vessel or aircraft that is maintained and operated to assist with the location and removal of victims from a hazardous or life-threatening situation to areas of safety or treatment.

"Responding time" means the elapsed time in minutes between the time a call for emergency medical services is received by the PSAP until the appropriate emergency medical response unit arrives on the scene.

"Responding time standard" means a time standard in minutes, established by the EMS agency, the locality and OMD, in which the EMS agency will comply with 90% or greater reliability.

"Response obligation to locality" means a requirement of a designated emergency response agency to lend aid to all other designated emergency response agencies within the locality or localities in which the EMS agency is based.

"Revocation" means the permanent removal of an EMS agency license, vehicle permit, training certification, ALS coordinator endorsement, EMS education coordinator, EMS physician endorsement or any other designation issued by the Office of EMS.

"Safety apparel" means personal protective safety clothing that is intended to provide conspicuity during both daytime and nighttime usage and that meets the Performance Class 2 or 3 requirements of the ANSI/ISEA 107–2010 publication entitled "American National Standard for High-Visibility Safety Apparel and Headwear."

"Secondary certification status" means any candidate or provider who is no longer in primary retest status.

"Secondary retest status" means any candidate or provider who failed their secondary certification attempt. Secondary retest status expires 90 days after the secondary test date.

"Sentinel event" means any significant occurrence, action, or change in the operational status of the entity from the time when it either applied for candidate status or was accredited. The change in status can be based on but not limited to one or all of the events indicated below:

Entering into an agreement of sale of an accredited entity or an accreditation candidate.

Entering into an agreement to purchase or otherwise directly or indirectly acquire an accredited entity or accreditation candidate.

Financial impairment of an accredited entity or candidate for accreditation, which affects its operational performance or entity control.

Insolvency or bankruptcy filing.

Change in ownership or control greater than 25%.

Disruption of service to student body.

Discontinuance of classes or business operations.

Failure to report a change in program personnel, location, change in training level or Committee on Accreditation of Educational Programs for the Emergency Medical Services Professions (CoAEMSP) accreditation status.

Failure to meet minimum examination scores as established by the Office of EMS.

Loss of CoAEMSP or Commission on Accreditation of Allied Health Education Programs (CAAHEP) accreditation.

Company fine or fines of greater than \$100,000 for regulatory violation, marketing or advertising practices, antitrust, or tax disputes.

"Special conditions" means a notation placed upon an EMS agency or registration, variance or exemption documents that modifies or restricts specific requirements of these regulations.

"Specialized air medical training" means a course of instruction and continuing education in the concept of flight physiology and the effects of flight on patients that has been approved by the Office of EMS. This training must include but is not limited to aerodynamics, weather, communications, safety around aircraft/ambulances, scene safety, landing zone operations, flight physiology, equipment/aircraft familiarization, basic flight navigation, flight documentation, and survival training specific to service area.

"Specialty care mission" in the air medical environment means the transport of a patient requiring specialty patient care by one or more medical professionals who are added to the regularly scheduled medical transport team.

"Specialty care provider" in the air medical environment means a provider of specialized medical care, to include but not limited to neonatal, pediatric, and perinatal.

"Standard of care" means the established approach to the provision of basic and advanced medical care that is considered appropriate, prudent and in the best interests of patients within a geographic area as derived by consensus among the physicians responsible for the delivery and oversight of that care. The standard of care is dynamic with changes reflective of knowledge gained by research and practice.

"Standard operating procedure" or "SOP" means preestablished written agency authorized procedures and guidelines for activities performed by affiliated EMS agency.

"Supplemented transport" means an interfacility transport for which the sending physician has determined that the medically necessary care and equipment needs of a critically injured or ill patient is beyond the scope of practice of the available EMS personnel of the EMS agency.

"Suspension" means the temporary removal of an EMS agency license, vehicle permit, training certification, ALS coordinator endorsement, EMS education coordinator, EMS physician endorsement or any other designation issued by the Office of EMS.

"Test site coordinator" means an individual designated by the Office of EMS to coordinate the logistics of a state certification examination site.

"Training officer" means an individual who is responsible for the maintenance and completion of agency personnel training records and who acts as a liaison between the agency, the operational medical director, and a participant in the agency and regional quality assurance process.

"Trauma center" means a specialized hospital facility distinguished by the immediate availability of specialized surgeons, physician specialists, anesthesiologists, nurses, and resuscitation and life support equipment on a 24-hour basis to care for severely injured patients

or those at risk for severe injury. In Virginia, trauma centers are designated by the Virginia Department of Health as Level I, II or III.

"Trauma center designation" means the formal recognition by the board of a hospital as a provider of specialized services to meet the needs of the severely injured patient. This usually involves a contractual relationship based on adherence to standards.

"Triage" means the process of sorting patients to establish treatment and transportation priorities according to severity of injury and medical need.

"USDOT" means the United States Department of Transportation.

"Vehicle operating weight" means the combined weight of the vehicle, vessel or craft, a full complement of fuel, and all required and optional equipment and supplies.

"Virginia Statewide Trauma Registry" or "Trauma Registry" means a collection of data on patients who receive hospital care for certain types of injuries. The collection and analysis of such data is primarily intended to evaluate the quality of trauma care and outcomes in individual institutions and trauma systems. The secondary purpose is to provide useful information for the surveillance of injury morbidity and mortality.

#### **12VAC5-31-910. Criminal or enforcement history.**

A. General denial. Application for affiliation or certification of individuals convicted of certain crimes present an unreasonable risk to public health and safety. Thus, applications for affiliation or certification by individuals convicted of the following crimes will be denied in all cases:

1. Felonies involving sexual misconduct where the victim's failure to affirmatively consent is an element of the crime, such as forcible rape.
2. Felonies involving the sexual or physical abuse of children, the elderly or the infirm, such as sexual misconduct with a child, making or distributing child pornography or

using a child in a sexual display, incest involving a child, or assault on an elderly or infirm person.

3. Any crime in which the victim is an out-of-hospital patient or a patient or resident of a healthcare facility including abuse of, neglect of, theft from, or financial exploitation of a person entrusted to the care or protection of the applicant.

4. Serious crimes of violence against persons such as assault or battery with a dangerous weapon, aggravated assault and battery, murder or attempted murder, manslaughter except involuntary manslaughter, kidnapping, robbery of any degree, or arson.

5. Has been subject to a permanent revocation of license or certification by another state EMS office or other recognized state or national healthcare provider licensing or certifying body.

B. Presumptive denial. Application for affiliation or current certification by individuals in the following categories will be denied except in extraordinary circumstances, and then will be granted only if the applicant or provider establishes by clear and convincing evidence that certification will not jeopardize public health and safety.

1. Application for affiliation or certification by individuals who have been convicted of any crime and who are currently incarcerated, on work release, on probation, or on parole.

2. Application for affiliation or certification by individuals convicted of crimes in the following categories unless at least five years have passed since the conviction or five years have passed since release from custodial confinement whichever occurs later:

a. Crimes involving controlled substances or synthetics, including unlawful possession or distribution or intent to distribute unlawfully Schedule I through V

drugs as defined by the Virginia Drug Control Act (§ 54.1-3400 seq. of the Code of Virginia).

b. Serious crimes against property, such as grand larceny, burglary, embezzlement, or insurance fraud.

c. Any other crime involving sexual misconduct.

3. Is currently under any disciplinary or enforcement action from another state EMS office or other recognized state or national healthcare provider licensing or certifying body. Personnel subject to these disciplinary or enforcement actions may be eligible for affiliation or certification provided there have been no further disciplinary or enforcement actions for five years prior to application for certification in Virginia.

C. Permitted vehicle operations. Agencies are responsible for the monitoring of compliance with all driving criteria set forth in these regulations.

1. Personnel operating OEMS permitted vehicles shall possess a valid operator's or driver's license from his state of residence.

2. Personnel operating OEMS permitted vehicles shall not have been convicted on any charge as described in subsections A and B of this section.

3. Personnel who as the proximate result of having operated an OEMS permitted vehicle are (i) convicted of driving under the influence of alcohol or drugs or (ii) sentenced or assigned to any alcohol safety action program or any driver alcohol rehabilitation program pursuant to the Code of Virginia shall be prohibited from operating any OEMS permitted vehicle. Personnel or agencies shall be required to report these situations to OEMS.

4. Agencies shall develop and maintain policies that address driver eligibility, record review, and vehicle operation. Such policies must minimally address:

- a. Driving education or training required for personnel to include information on the agency's policy content;
- b. Safe operation of vehicles;
- c. Agency driving record review procedures;
- d. Requirement for immediate agency notification by personnel regarding any convictions, regardless of the state where an infraction occurred or changes to his operator's or driver's license. The immediate agency notification shall be defined as no more than 10 calendar days following the conviction date; and
- e. Identification of internal mechanisms regarding agency level actions for driver penalties (i.e., probation or suspension of driving privileges).

D. All references to criminal acts or convictions under this section refer to substantially similar laws or regulations of any other state or the United States. Convictions include prior adult convictions, juvenile convictions and adjudications of delinquency based on an offense that would have been, at the time of conviction, a felony conviction if committed by an adult within or outside Virginia.

E. Agencies shall submit a report regarding items in this section to OEMS upon request.



# COMMONWEALTH of VIRGINIA

## Department of Health

MARISSA J. LEVINE, MD, MPH  
INTERIM STATE HEALTH COMMISSIONER

PO BOX 2448  
RICHMOND, VA 23218

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

### MEMORANDUM

DATE: August 13, 2014

TO: Virginia State Board of Health

FROM: Laurie Forlano, DO, MPH  
Director, Office of Epidemiology

SUBJECT: Proposed Amendment and Repeal within the Regulations for Disease Reporting and Control Relating to Testing Children for Elevated Blood Lead Levels

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The proposed regulatory action affects 12VAC5-120, the requirements for *testing* children's blood to determine if they have been exposed to lead in the environment. The action also affects 12VAC5-90, the requirements for *reporting* elevated blood lead levels in children.

The Regulations for Disease Reporting and Control (12VAC5-90) currently include provisions for physicians and laboratories to report children with elevated blood lead levels to the health department. Having a separate set of regulations (12VAC5-120) that describe which children should be tested is confusing to the regulated community.

The agency is proposing to combine both the testing and the reporting requirements into one set of regulations to make the process clearer to medical care providers. This would be done by adding a section numbered 12VAC5-90-**215** (incorporating the testing requirements) and simultaneously repealing 12VAC5-120 (testing children for elevated blood lead levels).

The previously proposed amendment pertaining to the testing of gametes for HIV infection, which was discussed at the last Board of Health meeting, has been stricken from this proposed regulatory action.

The Board of Health is asked to approve this proposed amendment at its September 2014 meeting. Following approval, the proposed amendment would be submitted to the Virginia Regulatory Town Hall to initiate Executive Branch review of the proposal.



Virginia  
Regulatory  
Town Hall

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

## Proposed Regulation Agency Background Document

|  |   |
|--|---|
| <b>Agency name</b>                                 | State Board of Health   |
| <b>Virginia Administrative Code (VAC) citation</b> | 12VAC5-90 and 12VAC5-120  |
| <b>Regulation title</b>                            | Regulations for Disease Reporting and Control and Regulations for Testing Children for Elevated Blood Lead Levels |
| <b>Action title</b>                                | Updating Disease Reporting Regulations and Repealing Lead Testing Regulation                                      |
| <b>Date this document prepared</b>                 | August 13, 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

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

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

The agency proposes to incorporate the testing and risk determination criteria for identifying children with elevated blood lead levels into 12VAC5-90 and to repeal the 12VAC5-120, the existing regulation pertaining to blood lead testing of children.

The amendments to the cancer reporting and gamete donor testing requirements that were included in the Notice of Intended Regulatory Action will not be pursued at this time.

## 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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No acronyms are used without being defined in context.

## 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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Title 32.1 of the *Code of Virginia*, §§ 32.1-12 and 32.1-35 through 32.1-73, contains mandatory language authorizing the State Board of Health to promulgate the proposed regulations. Specifically, § 32.1-35 directs the Board of Health to promulgate regulations specifying which diseases occurring in the Commonwealth are to be reportable and the method by which they are to be reported. §32.1-46.1 authorizes the Board to establish a protocol for the identification of children with elevated blood lead levels. The Board of Health is empowered to adopt such regulations as are necessary to carry out provisions of laws of the Commonwealth administered by the state health commissioner by § 32.1-12 of the *Code of Virginia*.

## Purpose

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

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The proposed amendment will improve the ability of the Virginia Department of Health to conduct surveillance and implement disease control for detectable blood lead levels in children. The changes will position the agency to better detect and respond to these illnesses to protect the health of the public.

## Substance

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

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The section on testing children to determine their blood lead levels is new to the Regulations for Disease Reporting and Control but reflects minor amendments to existing requirements that are currently included in another set of agency regulations, 12VAC5-120. The agency decided it was a logical and efficient change to incorporate the lead testing requirements into the set of regulations that addresses the

reporting of elevated blood lead levels. Having one set of regulations on this topic should reduce confusion among the regulated community.

12VAC5-120, the existing regulation pertaining to the identification of children with elevated blood lead levels, is being repealed as its content is being incorporated into 12VAC5-90. Some changes to the requirements are proposed as well. The changes simplify and clarify the requirements, remove unnecessary references to guidelines and non-mandatory actions, and reflect current Centers for Disease Control and Prevention recommendations. The proposed amendment to 12VAC5-90 pertaining to blood lead levels in children reflects a similar schedule of testing, risk factors for testing, criteria for determining low risk, and need for confirmatory testing as is currently provided in 12VAC5-120.

**Issues**

*Please identify the issues associated with the proposed regulatory action, including:*  
1) *the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*  
2) *the primary advantages and disadvantages to the agency or the Commonwealth; and*  
3) *other pertinent matters of interest to the regulated community, government officials, and the public.*

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

The primary advantages to the public will be clearer rules for testing children for exposure to lead and less confusion that is inherent in maintaining two sets of regulations pertaining to the same subject and procedures.

The primary advantages to the agency are the same as for the public. That is, elimination of the confusion caused by needing to track multiple sets of regulations or the potential for inconsistent requirements in different regulations.

No disadvantages or other pertinent matters of interest to the regulated community have been identified.

**Requirements more restrictive than federal**

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

None of these requirements is more restrictive than federal requirements.

**Localities particularly affected**

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

The impact of these changes is anticipated to be similar for all localities.

**Public participation**

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

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

Anyone wishing to submit written comments may do so via the Regulatory Town Hall website (<http://www.townhall.virginia.gov>), or by mail, email or fax to Diane Woolard, Director, Division of Surveillance and Investigation, Virginia Department of Health, P.O. Box 2448, Room 516E, Richmond VA 23218; phone 804-864-8141; fax 804-864-8139; email [diane.woolard@vdh.virginia.gov](mailto:diane.woolard@vdh.virginia.gov). Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last date of the public comment period.

**Economic impact**

*Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in 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  | The proposed amendment regarding testing children’s blood lead levels pertain to physicians and other medical care providers and are anticipated to have minimal impact on their practices or procedures. |
| <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. | Any physician who diagnoses or treats children could be affected by the lead regulation. This would include 1,200 pediatricians and 3,300 family practitioners in Virginia.                               |
| <b>Benefits expected as a result of this regulatory proposal.</b>  | Proposed changes to the lead testing requirement clarifies existing language and consolidates two regulations pertaining to the same topic into one regulation.   |
| <b>Projected cost to the <u>state</u> to implement and enforce this regulatory proposal.</b>   | No costs are anticipated.   |
| <b>Projected cost to <u>localities</u> to implement and enforce this regulatory proposal.</b>  | No costs are anticipated.   |
| <b>All projected costs of this regulatory proposal for <u>affected individuals, businesses, or other entities</u>.</b> Please be specific and include all costs,   | No costs are anticipated.   |

|   |  |
|---|--|
| including projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses, and costs related to real estate development. |  |
|---|--|

**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.*

In light of the clear, specific and mandatory authority of the State Board of Health to promulgate the proposed amendments to the regulations, no alternatives have been considered, nor are there any that are advisable.

**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.*

No lessening of testing requirements is advisable given the need to detect elevated blood lead levels in children. The proposed changes do not increase the extent of existing requirements, the requirements are as necessary and as simple as possible, and the impact on small businesses is expected to be minimal.

**Public comment**

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

| Commenter | Comment  | Agency response |
|-----------|--|-----------------|
| None      | No comments were received following the publication of the NOIRA |                 |

**Family impact**

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

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

**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:

| <b>Current section number</b> | <b>Proposed new section number, if applicable</b> | <b>Current requirement</b>                                      | <b>Proposed change, intent, rationale, and likely impact of proposed requirements</b> |
|-------------------------------|---|---|---|
| 12VAC5-120                    |   | Regulations for testing children for elevated blood lead levels | Repealed and replaced with the new regulation, cited below.                           |

If a new regulation is being promulgated, use this chart:

| <b>Section number</b> | <b>Proposed requirements</b>  | <b>Other regulations and law that apply</b>   | <b>Intent and likely impact of proposed requirements</b>   |
|-----------------------|---|---|--|
| 12VAC5-90-215         | Testing children at 12 and 24 months of age for blood lead levels if they meet any of a list of criteria; confirming tests indicating elevated levels if the test was not a standard confirmatory test performed by a certified laboratory; providing test results to parents or guardians. | Similar requirement exists in 12VAC5-120, which is being repealed within this same regulatory action. | Physicians will need to assess children and determine if they meet criteria for testing for blood lead levels and provide the results and educational materials to parents/guardians for any laboratory results that indicate the child was exposed to lead. This is already a standard of practice for clinicians and a recommendation of the Centers for Disease Control and |

|  |  |  |   |
|--|--|--|---|
|  |  |  | <p>Prevention. Similar requirements are in effect in an existing agency regulation, except that the blood lead level that indicates that exposure to lead has occurred has been lowered so action will be necessary for children testing at a level lower than previously, which is again an existing standard of practice.</p> |
|--|--|--|---|

**Project 3897 - Proposed**

**DEPARTMENT OF HEALTH**

**Update Disease Reporting and Control Regulations and Repeal Blood Lead Testing  
Regulations**

**Part IX.**

**Protocol for identification of children with elevated blood lead levels**

**12VAC5-90-215. Schedule and criteria for and confirmation of blood lead testing and information to be provided.**

A. Schedule for testing. Every child shall be tested to determine the blood lead level at 12 months and 24 months of age if the health care provider determines that the child meets any of the criteria listed in subsection B of this section. Children 25 months through 72 months of age who present for medical care and meet any of criteria of subsection B of this section shall also be tested if they have either not previously been tested for blood lead level or were previously tested but experienced a change since testing that has resulted in an increased risk of lead exposure, based on the criteria listed in subsection B.

B. Criteria for testing.

1. The child is eligible for or receiving benefits from Medicaid or the Special Supplemental Nutrition Program for Women, Infants and Children (WIC);
2. The child is living in or regularly visiting a house, apartment, dwelling, structure, or child care facility built before 1960;

3. The child is living in or regularly visiting a house, apartment, dwelling, structure, or child care facility built before 1978 that has (i) peeling or chipping paint or (ii) recent (within the last six months) ongoing, or planned renovations;

4. The child is living in or regularly visiting a house, apartment, dwelling or other structure in which one or more persons have blood lead testing yielding evidence of lead exposure;

5. The child is living with an adult whose job, hobby, or other activity involves exposure to lead;

6. The child is living near an active lead smelter, battery recycling plant, or other industry likely to release lead;

7. The child's parent, guardian, or other person standing in loco parentis requests the child's blood be tested due to any suspected exposure; or

8. The child is a recent refugee, immigrant, or is adopted from outside of the U.S.

C. Exceptions. A child who does not meet any of the above schedule or criteria is considered to be at low risk, and testing is not required but may be conducted at the discretion of the health care provider. The testing requirement shall be waived if the parent, guardian or other person standing in loco parentis of a child objects to the testing on the basis that the procedure conflicts with his religious tenets or practices.

D. Confirmation of blood lead levels. Blood lead level testing shall be performed on venous or capillary blood. Tests of venous blood performed by a laboratory certified by the federal Centers for Medicare & Medicaid Services in accordance with Clinical Laboratory Improvement Amendment of 1988 (CLIA-certified) are considered confirmatory. Tests of venous blood performed by any other laboratory and tests of capillary blood shall be confirmed by a repeat

blood test, preferably venous, performed by a CLIA-certified laboratory. Such confirmatory testing shall be performed in accordance with the following schedule:

1. Within one to three months if the result of the capillary test is at or above the CDC's reference value and up to 9 micrograms of lead per deciliter of whole blood ( $\mu\text{g}/\text{dL}$ ).
2. Within one week to one month if the result of the capillary test is 10-44  $\mu\text{g}/\text{dL}$ . The higher this test result, the more urgent the need for a confirmatory test.
3. Within 48 hours if the result of the capillary test is 45-59  $\mu\text{g}/\text{dL}$ .
4. Within 24 hours if the result of the capillary test is 60-69  $\mu\text{g}/\text{dL}$ .
5. Immediately as an emergency laboratory test if the result of the capillary test is 70  $\mu\text{g}/\text{dL}$  or higher.

E. Information to be provided. As part of regular well-check visits for all children, the health care provider shall make available to parents, guardians, or other persons standing in loco parentis information on the dangers of lead poisoning, potential sources of lead and ways to prevent exposure, and a list of available lead-related resources. When blood lead level testing is performed, the health care provider shall share the child's blood lead level test result with the child's parent, guardian, or other person standing in loco parentis and report to the health department in accordance with the requirements of 12VAC5-90-80.

CHAPTER 120

REGULATIONS FOR TESTING CHILDREN FOR ELEVATED BLOOD-LEAD LEVELS

Part I

Definitions and General Information

**12VAC5-120-10. Definitions. (Repealed.)**

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

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

~~"Commissioner" means the Commissioner of Health.~~

~~"Elevated blood lead level" for children means 10 or more micrograms of lead per deciliter of whole blood in a child up to and including 72 months of age.~~

~~"Health care provider" means a physician or his designee or an official of a local health department.~~

~~"High-risk ZIP Code area" means a ZIP Code area listed in guidelines issued by the Virginia Department of Health in which 27% or more of the housing was built before 1950 or 12% or more of the children have elevated blood lead levels based on current available data.~~

~~"Physician" means a person licensed to practice medicine in any of the 50 states or the District of Columbia.~~

~~"Point of care testing" refers to testing by a health care provider that has a CLIA Certificate of Waiver.~~

~~"Qualified laboratory" means a laboratory that is certified by the Health Care Financing Administration in accordance with the Clinical Laboratory Improvement Amendments of 1988~~

~~(CLIA) (42 CFR Part 493) and is participating in the Centers for Disease Control and Prevention's (CDC) Blood Lead Laboratory Proficiency Program.~~

~~"µg/dL" means micrograms of lead per deciliter of whole blood.~~

**12VAC5-120-20. Statement of general policy. (Repealed.)**

~~The Commonwealth of Virginia has recognized the need for early identification of children with elevated blood lead levels to alert parents and guardians to the need for intervention to prevent physical, developmental, behavioral, and learning problems associated with elevated blood lead levels in children, and to prevent exposure of other children.~~

~~The purpose of this chapter is to provide a protocol for identifying children with elevated blood lead levels.~~

~~The department encourages health care providers, parents and guardians to exercise reasonable, but liberal judgment and discretion in implementing and applying the protocol set forth in this chapter, so that the health of all Virginia's children may be protected from lead poisoning.~~

Part II

Protocol for Identification of Children with Elevated Blood-Lead Levels

**12VAC5-120-30. Schedule for testing. (Repealed.)**

~~Virginia health care providers should test all children up to and including 72 months of age for elevated blood lead levels according to the following schedule unless they are determined under 12VAC5-120-60 to be at low risk for elevated blood lead levels. All blood lead samples shall be analyzed by a qualified laboratory. The use of a CDC approved and CLIA-waived instrument for point-of-care testing, as a means of administering screening tests for elevated blood lead levels, is exempted from the requirement to have all blood lead samples analyzed by a qualified laboratory. However, any elevated blood lead level found through point-of-care~~

~~testing to be equal to or greater than 10 µg/dL shall be confirmed by a venous blood lead test performed by a qualified laboratory in accordance with the requirements of 12VAC5-120-40.~~

- ~~1. Children should be tested at ages one and two years.~~
- ~~2. Children from 36 through 72 months of age should be tested if they have never been tested.~~
- ~~3. Additional testing may be ordered by the health care provider.~~
- ~~4. Children should be tested at the request of a parent or guardian due to any suspected exposure.~~

**12VAC5-120-35. Information about lead poisoning. (Repealed.)**

~~The health care provider shall make available to parents information on the dangers of lead poisoning, along with a list of available resources, as part of regular well check visits for all children up to 72 months of age.~~

**12VAC5-120-40. Confirmation of blood-lead levels. (Repealed.)**

~~Testing may be performed on venous or capillary blood collected in tubes or on filter paper. If a test of capillary blood reveals an elevated blood lead level, the results shall be confirmed by a repeat blood test (preferably venous):~~

- ~~1. Within three months if the result of the capillary test is 10 µg/dL to 19 µg/dL.~~
- ~~2. Within one week to one month if the result of the capillary test is 20 µg/dL to 44 µg/dL.~~  
~~The higher this test result, the more urgent the need for a confirmation test.~~
- ~~3. Within 48 hours if the result of the capillary test is 45 µg/dL to 59 µg/dL.~~
- ~~4. Within 24 hours if the result of the capillary test is 60 µg/dL to 69 µg/dL.~~
- ~~5. Immediately as an emergency laboratory test if the result of the capillary test is 70 µg/dL or higher.~~

~~Elevated blood lead results from venous blood testing shall be deemed a confirmed test.~~

**12VAC5-120-50. Risk factors requiring testing. (Repealed.)**

~~A health care provider shall test any child for elevated blood lead level, or have such a child tested, if the provider determines, in the exercise of medical discretion, that such testing is warranted, and that the child meets one or more of the following criteria:~~

- ~~1. Eligible for or receiving benefits from Medicaid or the Special Supplemental Nutrition Program for Women, Infants and Children (WIC);~~
- ~~2. Living in a high-risk zip code area;~~
- ~~3. Living in or regularly visiting a house or child care facility built before 1950;~~
- ~~4. Living in or regularly visiting a house, apartment, dwelling or other structure, or a child care facility built before 1978, with peeling or chipping paint or with recent (within the last six months), ongoing, or planned renovations;~~
- ~~5. Living in or regularly visiting a house, apartment, dwelling or other structure in which one or more persons have elevated blood lead levels;~~
- ~~6. Living with an adult whose job or hobby involves exposure to lead as described in Preventing Lead Poisoning in Young Children (CDC, 1991);~~
- ~~7. Living near an active lead smelter, battery recycling plant, or other industry likely to release lead;~~
- ~~8. The child's parent or guardian requests the child's blood be tested due to any suspected exposure; or~~
- ~~9. A health care provider recommends the child's blood be tested due to any suspected exposure.~~

~~The Department of Health will maintain a list of high-risk zip code areas in Virginia.~~

**~~12VAC5-120-60. Determination of low risk for elevated blood-lead levels. (Repealed.)~~**

~~Blood-lead testing is not indicated for children determined by a health care provider to be at low risk for elevated blood-lead levels. A health care provider may determine a child to be at low risk for elevated blood-lead level if the child meets none of the criteria listed in 12VAC5-120-50, but is encouraged to cause a child to be tested if, in the exercise of discretion and consideration of the various means by which exposure to lead may occur, such exposure cannot be clearly ruled out.~~

**~~12VAC5-120-70. Samples submitted to a qualified laboratory. (Repealed.)~~**

~~A. All blood samples submitted to a qualified laboratory for analysis shall be accompanied by a completed laboratory requisition with all of the required data as determined by the Department of Health.~~

~~B. All qualified laboratories accepting blood samples for lead analysis under this chapter shall submit all required data to the board within 10 business days of analysis. The data shall be sent by a secure electronic means that has been approved by the Department of Health.~~

~~C. Any laboratory reporting under this section shall be deemed in compliance with the stipulations of § 32.1-36 of the Code of Virginia and 12VAC5-90-90 of the Board of Health Regulations for Disease Reporting and Control.~~

**~~12VAC5-120-80. Follow-up testing and information. (Repealed.)~~**

~~The Department of Health will establish guidelines for follow-up testing for children with confirmed elevated blood-lead levels, provide or recommend appropriate information for parents, and disseminate through various available means the protocol and other information to all relevant health care professionals. The department encourages health care professionals to conduct whatever follow-up testing is indicated or warranted in the exercise of medical or clinical judgment and discretion.~~

~~12VAC5-120-90. Exclusion from testing when risk is low and on religious grounds.~~

~~**(Repealed.)**~~

~~In accordance with § 32.1-46.2 of the Code of Virginia, every child in the Commonwealth should be tested for elevated blood-lead levels or determined to be at low risk for elevated blood-lead levels unless the parent, guardian or other person standing in loco parentis obtains a determination that the child is at low risk for elevated blood-lead levels or unless the parent, guardian or other person having control or charge of such child objects to such testing on the basis that the procedure conflicts with his religious tenets or practices.~~

## MEMORANDUM

DATE: May 13, 2104

TO: Virginia State Board of Health

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

SUBJECT: Proposed 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 regulatory changes were proposed after a periodic review of 12VAC5-20 "Regulations for the Conduct of Human Research" had been conducted pursuant to Executive Order 14 (2010). Amendments will correct outdated citations and enhance the clarity of the regulations.

The proposed amendments include a revised definition of "human research". Adding this definition and additional details regarding the elements of the committee review process and the informed consent process will provide greater clarity to the regulations and make them consistent with the applicable sections of the Code. In addition, 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.

Changes have been made in Section 10 (Definitions) to amend definition of "Human research" to make it consistent with the definition used in § 32.1-162.16 of the Code of Virginia. The

definitions of “Informed consent” and “Legally authorized representative” are amended to provide increased clarity and the definition of “Protected health information” is added. Section 40 was amended to clarify who may act as a legally authorized representative and Section 70 was amended to require review committees to have five members (consistent with federal regulations). Section 80 was amended to provide greater clarity on the elements that each review committee shall consider in conducting a review of a proposed human research project, consistent with the requirements of § 32.1-162.19 of the Code of Virginia. Section 90 was amended to provide clarity on the expedited review process including the committee’s authority to suspend or terminate approval of research. Section 100 was amended to provide increased clarity in the informed consent process. Lastly, Section 110 was amended to eliminate references to repealed Code sections and add a reference to the Virginia Immunization Information System.

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 take effect.

Thank you for your consideration.



Virginia

Regulatory  
Town Hall  
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 <i>et seq.</i>   |
| <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>                 | May 5, 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 the commissioner to report the listing of institutions that are subject to federal regulations regarding human subject research and are exempt from 12VAC5-20 *et seq.*

## 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 September 18, 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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The amendments will assist in ensuring the public health, safety and welfare of the citizens of the Commonwealth. 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.

## 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 proposed amendments to the regulations include:

- 1) Updating the definition of "Human Research."
- 2) Adding a definition of "Subject" or "human subject."
- 3) Replacing the term "participants" with "subjects" in various sections.
- 4) Eliminating the detail elements of informed consent in the definition section (12VAC5-20-10). This information is duplicated in Section 100.
- 5) Amending the definition of "Legally Authorized Representative" to be consistent with § 32.1-162.16.
- 6) Add a definition of "Protected Health Information (PHI)."
- 7) In Section 30, the term "human participants" is replaced with "human subjects" to be consistent with language used in § 32.1-162.16.
- 8) Subsection F in Section 40 is added 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.
- 9) In Section 50, the committee reporting requirement is changed from January 31 to March 31<sup>st</sup> each year.
- 10) In Sections 50 and 60 the term "chairman" is amended to "chair."
- 11) Section 70 is amended to require that the committee have at least 5 members instead of at least 7 members.
- 12) In Section 80, a new subsection A is added to clarify that no human research shall be conducted unless a research committee has reviewed and approved the project. The section is also amended to provide details as to the elements of the project that are to be considered in the review.
- 13) Section 80(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.
- 14) 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.
- 15) 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).
- 16) 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.
- 17) 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.
- 18) Section 100 is amended and new subsections B, C, D, E and G are added to further clarify the informed consent requirements and when the committee may waive the informed consent requirement.
- 19) In Section 110 the reference to the Alzheimer's Disease and Related Disorders Registry is eliminated along with the reference to § 32.1-116.1:2.
- 20) In Section 130 the reporting date is changed from January 31 to March 31 annually.

**Issues**

*Please identify the issues associated with the proposed regulatory action, including:*  
 1) *the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*  
 2) *the primary advantages and disadvantages to the agency or the Commonwealth; and*  
 3) *other pertinent matters of interest to the regulated community, government officials, and the public. If 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.*

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.*

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 "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  | N/A  | New subsection F clarifies that no official or employee of the institution or agency conducting or authorizing the research is qualified to act as a legally authorized representative 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.  |

| Current section number   | Proposed new section number, if applicable | Current requirement  | Proposed change and rationale   |
|--|--|--|---|
| Section 50: Review Process for Department  | N/A  | Current regulations use the term "participant."  | The term "participant" is amended to "subject."   |
| Section 50: Review Process for Department  | N/A  | Current regulations require the committee to report yearly activities by January of each year. | The reporting requirement is amended to March 31 of each year.  |
| Section 50: Review Process for Department  | N/A  | Current regulations reference "chairman."  | The term "chairman" is amended to "chair."  |
| Section 60: Review for Institutions or Agencies Funded or Licensed by the Department         | N/A  | Current regulations use the term "participant."  | The term "participant" is amended to "subject."   |
| Section 60: Review Process for Institutions or Agencies Funded or Licensed by the Department | N/A  | Current regulations reference "chairman."  | The term "chairman" is amended to "chair."  |
| Section 70: Composition of Research Review Committee   | N/A  | Current regulations use the term "participant."  | The term "participant" is amended to "subject."   |
| Section 70: Composition of Research Review Committee   | N/A  | Current regulation requires that the committee have at least seven members.                    | The requirement that the committee have at least seven members is amended to be at least 5 members in order to be consistent with the federal regulations (45 CFR § 46.107(a)) and provide greater efficiency.                                |
| Section 80: Elements of Committee Review Process   | N/A  | 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. |

| Current section number                                  | Proposed new section number, if applicable | Current requirement  | Proposed change and rationale  |
|---|--|--|--|
| 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  | 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  | 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  | N/A  | New subsection I requires that the committee ensure compliance with the HIPAA and federal and state regulations regarding disclosure of PHI.   |
| Section 80: Elements of Committee Review Process        | N/A  | N/A  | New subsection J provides that cooperating institutions conducting research may enter into joint review, rely upon the review of another qualified committee or come to an agreement that will avoid duplication of effort. The section provides details on the content of any such agreements and the approval process. |
| Section 90: Expedited Review of Human Research Projects | N/A  | Current regulations authorize the committee to conduct an expedited review of a human research project which involves no more than minimal risk to the subjects. | Amends section to add that the research shall involve procedures that are in one or more categories established by the U.S. Secretary of Health and Human Services and published in the Federal Register.  |
| Section 90: Expedited Review of Human Research Projects | N/A  | N/A  | New subsection B clarifies when the expedited review procedure may be used.  |

| Current section number                                  | Proposed new section number, if applicable | Current requirement   | Proposed change and rationale  |
|---|--|---|--|
| Section 90: Expedited Review of Human Research Projects | N/A  | N/A   | New subsection C clarifies that the expedited review may be carried out by the chair or by one or more reviewers designated by the chair. The reviewers may exercise all the authority of the IRB except that they may not disapprove the research. A research project can only be disapproved after review in accordance with 12VAC5-20-80. |
| Section 100: Informed Consent                           | N/A  | Current regulations address the basic information necessary for an informed consent to participate as a research subject. | Subsection A(1) is amended to add the requirement that information 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 an informed consent to participate as a research subject. | Subsection A(2) is amended to add the requirement that information on side effects, risks and benefits of any appropriate alternative procedures or therapies be disclosed.  |
| Section 100: Informed Consent                           | N/A  | 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 an informed consent to participate as a research subject. | Subsection A(4) is amended to include that a person may withdraw consent or discontinue participation from the research without fear of reprisal.  |
| Section 100: Informed Consent                           | N/A  | Current regulations address the basic information necessary for an informed consent to participate as a research subject. | Subsection A(5) is amended to include in the elements of informed consent information on any medical care that may be available if an injury occurs.   |
| Section 100: Informed Consent                           | N/A  | Current regulations address the basic information necessary for an informed consent to participate as a research subject. | Subsection A(6) is amended to include in the elements of informed consent an offer to answer any inquiries (if applicable) from the legally authorized representative and a description of the ways that any concerns may be raised or questions asked.  |
| Section 100: Informed Consent                           | N/A  | N/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.  |

| Current section number        | Proposed new section number, if applicable | Current requirement | Proposed change and rationale  |
|-------------------------------|--|---------------------|--|
| Section 100: Informed Consent | N/A  | 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  | 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  | 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  | 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 § 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 § 32.1-71.1 of the Code of Virginia was repealed in 1994. Section 32.116.1:2 relating to the Emergency Medical Services Patient Care Information System has expired. |
| Section 120: Committee Records                                   | N/A  | Current regulations require that an overview of approved human research projects and the results be made public on the department’s website.  | Amend subsection C to specify that each research review committee of a state institution or agency shall provide an overview of approved projects and results on their website.   |
| Section 130: Applicability of Federal Policies                   | N/A  | Current regulations require institutions whose human research is subject to federal regulations to notify the commissioner annually that they are exempt from this chapter and they are in compliance with the federal regulations. The commissioner is required to report this information in an annual report to the Governor and the General Assembly by January 31. | Amend Section 130 to change the reporting date from January 31 to March 31 annually.  |

**Project 3401 - Proposed**

**DEPARTMENT OF HEALTH**

**Amend Regulations Based on Results of Periodic Review**

**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.

"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. 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. 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. 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. Review process for institutions or agencies funded or licensed by the department.**

A. Prior to the initiation of a human research project by any institution or agency funded or licensed by the department, a description of the proposed human research project shall be submitted to a research review committee for review and approval. The description shall include a statement of the purpose of the proposed project and justification thereof, the criteria for inclusion of a ~~participant~~ subject in the research project, a description of what will be done to the ~~participants~~ subjects, and a copy of the informed consent statement.

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

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

Such reports shall include:

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

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

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

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

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

A. Each committee shall have at least ~~seven~~ five members, appointed by the head of the institution, with varying backgrounds to provide complete and adequate review of activities commonly conducted by the institution. The committee shall be sufficiently qualified through the maturity, experience, and diversity of its members, including consideration of race, gender and

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

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

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

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

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

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

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

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

A. No human research shall be conducted or authorized by 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,

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. 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. 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. 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. 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. 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. 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.~~ 9. A disclosure of any appropriate alternative procedures or therapies that might be advantageous for the ~~individual~~ person;

~~9.~~ 10. 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.~~ 11. An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury; and

~~44.~~ 12. 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. 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. 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 (~~Viginia~~ Virginia Congenital Anomalies Reporting and Education System), § 32.1-70 (Statewide Cancer Registry), ~~§ 32.1-71.1 (Statewide Alzheimer's Disease and Related Disorders Registry), § 32.1-46.01 (Virginia Immunization Information System),~~ and §§ § 32.116.1 and 32.116.1:2 (Emergency Medical Services Patient Care Information System).

3. Research or student learning outcomes assessment conducted in educational settings such as research involving:

- a. Regular or special education instructional strategies; or
- b. The effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods; or
- c. The use of educational tests, whether cognitive, diagnostic, aptitude, or achievement, if the data from such tests are recorded in a manner so that ~~participants~~ subjects cannot be identified, directly or through identifiers linked to the ~~participants~~ subjects.

4. Research involving survey or interview procedures unless responses are recorded in such a manner that the ~~participants~~ subjects can be identified, directly or through identifiers linked to the ~~participants~~ subjects, and either:

- a. The ~~participant's~~ subject's responses, if they became known outside the research, could reasonably place the participant at risk of criminal or civil liability or be damaging to his financial standing, employability, or reputation; or

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

**12VAC5-20-120. Committee records.**

- A. Documentation of committee activities shall be prepared and maintained by each such committee and shall include the following:
  1. Copies of all research proposals reviewed, scientific evaluations that may accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to ~~participants~~ subjects;

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

B. The records required by this chapter shall be retained for at least three years, and records relating to research ~~which~~ 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. 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: August 1, 2014

TO: Virginia State Board of Health

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

SUBJECT: Final Amendments to 12VAC5-475, Regulations Implementing the Virginia Organ and Tissue Donor Registry

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The Virginia State Board of Health (Board) is asked to review and approve the enclosed amendments to 12VAC5-475, Regulations Implementing the Virginia Organ and Tissue Donor Registry, 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 February 14, 2014 with no comments submitted.

The regulatory changes were proposed to more closely reflect the current practice of the Organ and Tissue Donor Registry. The current regulations were the first to be promulgated under statutory authority granted by the 2000 session of the Virginia General Assembly and have been in effect since March 27, 2002 without amendment.

The proposed amendments include changing the references to the Virginia Organ and Tissue Donor Registry to the "Virginia Donor Registry" as determined by the 2006 General Assembly amendments to §§ 32.1-292.2 and 32.1-297.1 of the Code of Virginia. The amendments will also replace references to §§ 32.1-289 et seq. and 32.1-290 (which were repealed by the 2007 General Assembly) with references to the Revised Uniform Anatomical Gift Act (§ 32.1-291.1 et seq.).

Changes have been made in Section 10 (Definitions) to make definitions consistent with the Revised Uniform Anatomical Gift Act (§ 32.1-291.1 et seq.); to delete definitions no longer

required or used in the text; to amend or add definitions to include donor registration processes available through the DonateLifeVirginia.org website; and to clarify other functions and entities. Section 30 (Administration) will be amended to cite data requirements to be maintained and reported annually to the Board of Health. Section 40 (Access) will be moved and become a new Section 75. This Section will be amended to include that designees may assist individuals to complete a signed application and that persons may indicate their willingness to donate through a donor registration process or mail-in form available on the DonateLifeVirginia.org website. The proposed amendment to Section 60 (Data to be recorded) will eliminate the recording of the telephone number in the Registry. References to the registry forms (VTC 1 and VTC 0) have been deleted.

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 take effect.



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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> | 12VAC5-475 et seq.  |
| <b>Regulation title</b>                            | Virginia Organ and Tissue Donor Registry  |
| <b>Action title</b>                                | Amend the Virginia Organ and Tissue Donor Registry regulation for clarity, efficiency and effectiveness |
| <b>Date this document prepared</b>                 | March 4, 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 Virginia Organ and Tissue Donor Registry to more closely reflect current registry practice and to achieve improvements that will be reasonable, prudent and will not impose an unnecessary burden on users of the registry or the public. The amendments include changing the references to the Virginia Organ and Tissue Donor Registry to the "Virginia Donor Registry" as determined by the 2006 General Assembly amendments to §§ 32.1-292.2 and 32.1-297.1 of the Code of Virginia. The amendments will also replace references to §§ 32.1-289 et seq. and 32.1-290, which were repealed by the 2007 General Assembly, with references to the Revised Uniform Anatomical Gift Act (§ 32.1-291.1 et seq.).

Changes have been made in Section 10 (Definitions) to make definitions consistent with the Revised Uniform Anatomical Gift Act (§ 32.1-291.1 et seq.); to delete definitions no longer required or used in the text; and to amend or add definitions to include donor registration processes available the DonateLifeVirginia.org website and clarify other functions and entities. Section 30 (Administration) will be amended to cite data requirements to be maintained and annually reported to the Board of Health. Section 40 (Access) will be moved and become a new Section 75. This Section will be amended to

include that designees may assist individuals to complete a signed application and that persons may indicate their willingness to donate through a donor registration process or mail-in form available on the DonateLifeVirginia.org website. The proposed amendment to Section 60 (Data to be recorded) will eliminate the recording of the telephone number in the Registry. References to the registry forms (VTC 1 and VTC 0) have been deleted.

No public comments were submitted during the 60-day comment period, and there are no changes between the proposed amendments and the final amendments.

**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 Implementing the Virginia Organ and Tissue Donor Registry, 12VAC5-475 on September 18, 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 32.1-292.2 of the Code of Virginia provides the authority for the State Board of Health, in consultation with the Virginia Transplant Council, to promulgate regulations necessary to create, compile, maintain, modify as necessary, and administer the Virginia Donor Registry. The imperative form of the verb “shall” is used in § 32.1-292.2, making the Board’s authority to regulate 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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The amendments will assist in ensuring the public health, safety and welfare of the citizens of the Commonwealth. Several aspects of the regulations regarding the Virginia Donor Registry need updating and clarifying. The current regulations were the first to be promulgated under statutory authority granted by the 2000 session of the Virginia General Assembly and have been in effect since March 27, 2002 without amendment. The passing of more than ten years since the initial promulgation and review of the current regulations have led the Board to conclude that it is appropriate to amend the regulations to provide clarity; improve efficiency and effectiveness; and bring the regulations in line with current practice.

## 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) Changing the references from the "Virginia Organ and Tissue Donor Registry" to the "Virginia Donor Registry."
- 2) Replacing references to §§ 32.1-289 et seq. and 32.1-290, which were repealed by the 2007 General Assembly, with references to the Revised Uniform Anatomical gift Act (§32.1-291.1 et seq.).
- 3) Updating definitions in Section 10 for "anatomical gift"; "decedent"; "document of gift"; "donor"; "eye bank"; "guardian"; "organ procurement organization"; "part"; and "tissue bank" to be consistent with the Revised Uniform Anatomical Gift Act (§32.1-291.1 et seq.).
- 4) Amending the definition of "Document of gift" to reference the donor registration form available on the DonateLifeVirginia.org website and amending the definition of "Registry" to clarify that the Virginia Transplant Council has responsibility for creating, compiling, maintaining, and modifying the Virginia Donor Registry.
- 5) Adding a definition for "designee" which has been used throughout the regulation to refer to a person who is designated to use the Virginia Donor Registry for certain limited purposes.
- 6) Adding "DonateLifeVirginia.org" to the definition section to identify the official website that provides information on organ and tissue donation and provides a registration form to indicate a willingness to donate.
- 7) Clarifying data requirements that the Virginia Transplant Council shall maintain and annually report to the Board of Health in Section 30 (Administration).
- 8) Designating that persons may indicate their willingness to donate by completing the Donor Registration form available on the DonateLifeVirginia.org website and eliminating the necessity for the Virginia Transplant Council to contact persons who identify their willingness to be a donor through the Department of Motor Vehicles to complete a registration form (VTC 1).
- 9) Deletion of Sections 20 (Purpose) and movement of 40 (Access) to 75 (Access). The last paragraph of this section has been deleted.

## 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. The identification of the DonateLifeVirginia.org website as an available resource on organ and tissue donation and the ability to complete an online registration to indicate a willingness to donate are advantages for the public.
- 2) There are no disadvantages to the agency or the Commonwealth. An advantage to both the Board of Health and the Virginia Transplant Council is that the amended regulations will provide greater clarification of the information that the Council must annually report to the Board.
- 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.*

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.*

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             |

Enter any other statement here

**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 through 90   | N/A  | Current regulations refer to “Virginia Organ and Tissue Donor Registry”.                                   | Change references to the “Virginia Donor Registry.”  |
| Section 10 through 90   | N/A  | Current regulations reference §§ 32.1-289 et seq. and 32.1-290.  | Replace references to §§ 32.1-289 et seq. and 32.1-290, which were repealed by the 2007 General Assembly, with updated references to the Revised Uniform Anatomical Gift Act (§32.1-291.1 et seq.) |
| Section 10: Definitions | N/A  | Current regulations do not identify the <a href="http://DonateLifeVirginia.org">DonateLifeVirginia.org</a> | Amends definition of “Document of gift” to reference the donor registration form now available on the <a href="http://DonateLifeVirginia.org">DonateLifeVirginia.org</a>                           |

|                            |                    |   |  |
|----------------------------|--------------------|---|--|
|                            |                    | website and do not include 'DonateLifeVirginia.org' in the definition section.  | website; amends definition of "Registry" to clarify that the Virginia Transplant Council has responsibility for creating, compiling, maintaining, and modifying the Virginia Donor Registry; and adds "DonateLifeVirginia.org" to the definition section to identify the official website that provides information on organ and tissue donation and provides a registration form to indicate a willingness to donate. |
| Section 10: Definitions    | N/A                |   | Addition of definition of "designee" as this term is used throughout the text of the regulation as person designated to use the registry and perform certain functions.  |
| Section 10: Definitions    | N/A                | Definitions for "agent"; "Commissioner"; "disseminate"; "informed consent"; and "UNOS"  | Removes these definitions as they are no longer used in the final regulatory text.   |
| Section 10: Definitions    | N/A                | Definitions for "anatomical gift or organ donation"; "decedent"; "document of gift"; "donor"; "eye bank"; "guardian"; "organ procurement organization"; "part"; and "tissue bank"   | These definitions are amended to be consistent with the Revised Uniform Anatomical Gift Act (§32.1-291.1 et seq.).   |
| Section 10: Definitions    | N/A                | Definitions for "procurement" and "VTC"   | These definitions are updated for clarity.   |
| Section 20: Purpose        | N/A                | Defines purpose of regulation.  | Section deleted as not needed.   |
| Section 30: Administration | N/A                | Subsection A states the board has responsibility for promulgating the regulations. Subsection B contains language stating that the State Health Commissioner is the executive office for the State Board of Health.                     | Removes subsections A and B as this language is not needed.  |
| Section 30: Administration | N/A                | Subsection D contains catchline "Confidentiality".  | This becomes subsection B. The catchline "Confidentiality" is removed and specific reference to §32.1-292.2 B is added.  |
| Section 30: Administration | N/A                |   | New subsection C clarifies eight data requirements that the Virginia Transplant Council shall collect and maintain and annually report to the Board of Health (e.g. number of recovered organ donors).   |
| Section 40: Access         | Section 75: Access | This section currently identifies who shall have access to the registry; the time frame for access; the terms for which access shall be granted; and specific registry monitoring data elements required to be reported to the Virginia | This section is moved to new Section 75 under Part III. The third paragraph which lists specific monitoring data (e.g. the number of times the registry is accessed or results in an unsuccessful search) is deleted.  |

|   |     |   |   |
|---|-----|---|---|
|   |     | Transplant Council.   |   |
| Section 50:<br>Registry<br>Membership       | N/A | Current regulations require the Virginia Transplant Council to contact persons who identify their willingness to be a donor through the Department of Motor Vehicles to complete a registration form (VTC 1). | Designates that persons may indicate their willingness to donate by completing the Donor Registration form now available on the DonateLifeVirginia.org website and eliminates the use of the VTC1 form.   |
| Section 60:<br>Data to be<br>recorded       | N/A | Current regulations require the donor's telephone number be recorded in the registry and information recorded by completing the VTC 1 form  | Deletes the requirement that the donor's telephone number be recorded in the Registry and eliminates the use of the Registry Form (VTC1).   |
| Section 70:<br>removal from<br>the registry | N/A | Current regulations require an individual to complete VTC 0 form to remove name from registry.  | Eliminates the required VTC 0 form and adds that a person may have his name removed in accordance with the Revised Uniform Anatomical Gift Act.   |
| Section 80:<br>Use                          | N/A | Current regulations address the use of the Registry data  | Removes excess use of term "decedent" and repetitive language forbidding searches on persons other than the decedent. Substitutes proper terminology for document of gift. Removes term "accredited" from organ procurement organization as this is not required.   |
| Section 90:<br>Dissemination                | N/A | Current regulations address dissemination of Registry data.   | Substitutes proper terminology for document of gift and anatomical gift. Removes term "accredited" from organ procurement organization as this is not required. Updates references to Code of Virginia. Removes last paragraph for disclosure from Virginia Transplant Council to Department of Motor Vehicles. |

**Project 1335 - Proposed**

**DEPARTMENT OF HEALTH  
Amend Organ/Tissue Donor Regulations for Clarity, Efficiency and Effectiveness**

CHAPTER 475  
REGULATIONS IMPLEMENTING THE VIRGINIA ORGAN AND TISSUE DONOR REGISTRY  
Part I  
Definitions and General Information

**12VAC5-475-10. Definitions.**

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

~~"Agent" means an adult appointed by the declarant under an advance directive, executed or made in accordance with the provisions of § 54.1-2983 of the Code of Virginia, to make health care decisions for him, including decisions relating to visitation, provided the advance directive makes express provisions for visitation and subject to physician orders and policies of the institution to which the declarant is admitted. The declarant may also appoint an adult to make, after the declarant's death, an anatomical gift of all or any part of his body pursuant to Article 2 (§ 32.1-289 et seq.) of Chapter 8 of Title 32.1 of the Code of Virginia.~~

~~"Anatomical gift" or "organ donation" means a donation of organs, tissues, or eyes or all or any part of a human body to take effect upon or after death~~ all or part of a human body to take effect after the donor's death for the purpose of transplantation, therapy, research, or education.

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

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

~~"Decedent" means a deceased individual and includes a stillborn infant or fetus whose body or part is or may be the source of an anatomical gift. The term includes a stillborn infant and, subject to restrictions imposed by law other than the restrictions imposed by the Revised Uniform Anatomical Gift Act (§ 32.1-291.1 et seq. of the Code of Virginia), a fetus.~~

~~"Department" means the State Virginia Department of Health.~~

~~"Designee" means a person designated by an organ procurement organization, eye bank, or tissue bank to identify and determine the suitability of a potential donor.~~

~~"Document of gift" means a donor card, a statement attached to or imprinted on a motor vehicle driver's or chauffeur's license or the record of the individual's motor vehicle driver's or chauffeur's license, a will, an advance directive, or other writing used to make an organ donation or an anatomical gift or other record used to make an anatomical gift. The term includes a statement or symbol made pursuant to § 46.2-342 G of the Code of Virginia on a driver's license, an identification card, or a donor registry. "Document of gift" also includes a record of the donor's gift stored in a registry.~~

~~"DonateLifeVirginia.org" means the official Virginia website that provides information on organ and tissue donation and provides a registration form for registrants to make an anatomical gift in accordance with the Revised Uniform Anatomical Gift Act (§ 32.1-291.1 et seq. of the Code of Virginia).~~

~~"Donor" means an individual who makes a donation of organs, tissues, or eyes or an anatomical gift of all of his body whose body or part is the subject of an anatomical gift.~~

~~"Disseminate" means to release, transfer, or otherwise communicate information orally, in writing, or by electronic means.~~

~~"Eye bank" means an agency a person that is licensed, accredited, or regulated under federal or state law to engage in the recovery, screening, testing, processing, storage, or distribution of human eyes or portions of human eyes and that is a member of the Virginia Transplant Council, accredited by the Eye Bank Association of America or the American Association of Tissue Banks and operating in the Commonwealth of Virginia.~~

~~"Guardian" means a person appointed by the a court who is responsible for the personal affairs of an incapacitated person, including responsibility for making decisions regarding the person's support, care, health, safety, habilitation, education, and therapeutic treatment, and, if not inconsistent with an order of commitment, residence. Where the context plainly indicates, the term includes a "limited guardian" or a "temporary guardian." The term includes a local or regional program designated by the Department for the Aging as a public guardian pursuant to Article 2 (§ 2.2-711 et seq.) of Chapter 7 of Title 2.2 of the Code of Virginia to make decisions regarding the support, care, education, health, or welfare of an individual. The term does not include a guardian ad litem, except when the guardian ad litem is authorized by a court to consent to donation.~~

~~"Informed consent" means the knowing and voluntary agreement, obtained without undue influence or any use of force, fraud, deceit, duress, or other form of constraint or coercion, of a person who is capable of exercising free power of choice.~~

~~"Organ procurement organization" means an agency certified by the United States Health Care Financing Administration a person designated by the Secretary of the U.S. Department of Health and Human Services as an organ procurement organization that is also a member of the Virginia Transplant Council.~~

~~"Part" means an organ, tissue, eye, bone, artery, blood, fluid or other portion of a human body an eye, or tissue of a human being. The term does not include the whole body.~~

~~"Personal information" means all information that describes, locates or indexes anything about an individual, as defined in § 2.2-3801 of the Code of Virginia.~~

~~"Procurement" means the recovery of any donated part by a licensed physician licensed, accredited, or approved under the laws of any state or a technician who is qualified in accordance with § 32.1-291.14 of the Code of Virginia.~~

~~"Registry" means the Organ and Tissue Virginia Donor Registry for the Commonwealth, which shall be administered by the Department of Health created, compiled, operated, maintained, and modified as necessary by the Virginia Transplant Council in accordance with § 32.1-292.2 of the Code of Virginia. The registry shall maintain and update, as needed, the pertinent information on all Virginians who have indicated a willingness to donate.~~

~~"Tissue bank" means an agency a person that is licensed, accredited, or regulated under federal or state law to engage in the recovery, screening, testing, processing, storage, or distribution of tissue, and that is a member of the Virginia Transplant Council, accredited by the American Association of Tissue Banks, and operating in the Commonwealth of Virginia.~~

~~"UNOS" means the United Network for Organ Sharing.~~

~~"VTC" means the Virginia Transplant Council, a program within the Virginia Department of Health that exists to promote and coordinate educational and information activities as related to the organ, tissue, and eye donation process and transplantation in the Commonwealth of Virginia.~~

#### **12VAC5-475-20. Purpose. (Repealed.)**

~~These regulations are designed to accomplish the tasks listed in § 32.1-292.2 C-1 and 2 of the Code of Virginia by establishing procedures for the administration of the registry.~~

### **12VAC5-475-30. Administration.**

~~A. The board has the responsibility for promulgating regulations, in consultation with the VTC, pertaining to the administration of the organ and tissue donor registry.~~

~~B. The commissioner is the executive officer for the State Board of Health with the authority of the board when it is not in session, subject to the rules and regulations of and review by the board.~~

~~C. A. The VTC, as delegated authorized by the board pursuant to § 32.1-292.2 D 2 of the Code of Virginia, is responsible for analyzing shall analyze registry data under research protocols directed toward determination and identification of means to promote and increase organ, eye, and tissue donation within the Commonwealth.~~

~~D. Confidentiality. B. All persons responsible for the administration of the organ and tissue donor registry Virginia Donor Registry shall ensure that the registry and all information therein shall be confidential in accordance with §§ 32.1-127.1:03 and 32.1-292.2 B of the Code of Virginia and other applicable state and federal law.~~

~~C. The VTC shall maintain and report annually the following information to the board: (i) the number of unique individuals registered in the registry; (ii) the number of recovered organ donors; (iii) the number or recovered organ donors who were identified through the registry; (iv) the number of recovered tissue donors; (v) the number of recovered tissue donors who were identified through the registry; (vi) the number of recovered eye/cornea donors; and (vii) the number of recovered eye/cornea donors identified through the registry. This report shall be made on or before September 30 of each year and contain information pertaining to the previous fiscal year.~~

### **12VAC5-475-40. Access. (Repealed.)**

~~The registry and all information therein shall be accessible 24 hours a day and only to the department and the specific designees of accredited organ procurement organizations, eye banks and tissue banks operating in or serving Virginia and which are members of the VTC, for the purpose of identifying a potential donor according to the provisions of §§ 32.1-127.1 and 32.1-292.2, and subsection F of § 46.2-342.~~

~~The name of such designees shall be provided to the VTC. All other persons or entities shall be prohibited from having access to the registry. If at any time the designee is unable to carry out his responsibilities with respect to the registry, a replacement shall be selected and the VTC shall be notified of such replacement.~~

~~All accredited organ procurement organizations, eye banks, and tissue banks with authorized access to the registry shall be required to report annually to the VTC the following outcome data: (i) the number of times the registry is accessed; (ii) the number of times access to the registry results in an unsuccessful search (i.e., the individual is not a member of the registry); (iii) the number of times an organ, tissue or eye procurement proceeds solely from accessing the registry; (iv) the number of times the next of kin's consent is obtained in addition to a successful search of the registry; (v) the number of times donation of organs, tissue, or eyes occurred as a result of alternative donation designation documentation; and (vi) the number of times the next of kin's consent is obtained without accessing the registry.~~

## Part II Registry Information

### **12VAC5-475-50. Registry membership.**

~~Those persons 18 years and older who have indicated a willingness to donate in accordance with § 32.1-290 of the Code of Virginia and have completed the required registration form (VTC-1) shall be recorded in the registry. Persons under the age of 18 may enter the registry upon completion of the registration form and only with the written consent of~~

~~his parent or legal guardian. No person may enter another person in the registry. The registry shall record anatomical gifts made in accordance with the Revised Uniform Anatomical Gift Act (§ 32.1-291.1 et seq. of the Code of Virginia). Designees may assist individuals to complete a signed donor registration form.~~

~~Those persons who have indicated a willingness to donate designated an anatomical gift on their driver's license or personal identification card as authorized by the Department of Motor Vehicles will be automatically entered into the registry. Through inter-agency interagency agreement, the Department of Motor Vehicles will assist the department by electronically providing this information to the registry on a daily regular basis as agreed upon by the Department of Motor Vehicles and the VTC. The VTC shall contact any such self-identified persons by United States mail regarding notification of membership to the registry and request the completion of the registration form (VTC-1). Persons who make an anatomical gift by completing the donor registration form available on the DonateLifeVirginia.org website will also be automatically entered into the registry.~~

**12VAC5-475-60. Data to be recorded.**

The following information shall be recorded in the registry: the donor's full name, address (including county or independent city of residence with zip code), ~~telephone number~~, date of birth, age, sex, race, and driver's license number or unique identification number. If the donor is under the age of 18, the name, ~~telephone number~~, address, and unique identification number of the donor's parent or legal guardian shall be recorded.

~~Information shall be recorded by completing the Virginia Organ and Tissue Donor Registry Form (VTC-1).~~

**12VAC5-475-70. Removal from the registry.**

A. A person who has joined the registry may ~~have his name removed~~ amend his anatomical gift or revoke the anatomical gift by filing an appropriate form (VTC-0) with the VTC or in accordance with subsections E and F of § 32.1-290 the Revised Uniform Anatomical Gift Act (§ 32.1-291.1 et seq. of the Code of Virginia) or subsection G I of § 46.2-342 of the Code of Virginia.

B. Persons who revoke an anatomical gift shall be automatically removed from the registry by the VTC.

C. Persons can revoke an anatomical gift by completing any of the following actions:

1. Notifying the VTC in writing using an appropriate form provided by the VTC, which shall result in being removed from the registry upon receipt of notification by the VTC;
2. Completing the form available on the DonateLifeVirginia.org website, which shall result in immediate removal from the registry by the VTC; or
3. Not renewing an anatomical gift when renewing or replacing a driver's license or personal identification card at the Department of Motor Vehicles, which will result in being removed from the registry within 24 hours of receipt of notification to the VTC from the Department of Motor Vehicles.

D. The name of a person entered in the registry who has died shall be removed from the registry within 90 days of notification of death by the Virginia Office Division of Vital Records and Health Statistics.

Part III

Access, Use, and Dissemination of Registry Information

**12VAC5-475-75. Access.**

A. Except as otherwise provided by law, no person shall have access to the registry except as provided in this section.

B. Designees shall have access to the registry for the purpose of creating, amending, or revoking the registrant's anatomical gift.

C. The registry and all information therein shall be accessible 24 hours a day and only to specific designees of organ procurement organizations, eye banks, and tissue banks for the purpose of identifying a potential donor according to the provisions of §§ 32.1-127 and 32.1-292.2 of the Code of Virginia. The name of such designees shall be provided to the VTC. If at any time the designee is unable to carry out his responsibilities with respect to the registry, a replacement shall be selected and the VTC shall be notified of such replacement.

D. Persons who require access to the registry for operational and maintenance purposes shall have access to the registry upon receipt from VTC of appropriate access privileges.

E. The department shall be provided access to the registry for the purpose of exercising responsibility for oversight of VTC activities. The department shall not have access to personal information of registrants unless such access is required for the department's oversight responsibilities.

### Part III

#### Use and Dissemination of Registry Information

##### **12VAC5-475-80. Use.**

The designees of ~~accredited~~ organ procurement organizations, eye banks, and tissue banks and all other persons with authorized access to the registry shall have an organizational or individual pass code, or both, assigned by the VTC to gain entry to the registry via the VTC website.

Once entry to the registry has been established, the designees shall enter the decedent's full name, ~~the decedent's date of birth, the decedent's driver's license number, the decedent's~~ unique identification number, or any combination thereof, to verify whether the decedent made a donor designation in the registry. Once the decedent's donor designation has been verified, the designees shall include the ~~intent to donate~~ document of gift as part of the donor record maintained by the ~~accredited~~ organ procurement organization, eye bank, and tissue bank.

If the decedent is not in the registry, the designees shall exit the registry. ~~Designees shall not perform a search of the registry on any other person other than the decedent.~~

##### **12VAC5-475-90. Dissemination.**

The ~~accredited~~ organ procurement organizations, eye banks, and tissue banks with authorized access to the registry may disclose the contents of the decedent's documented donation designation document of gift to the decedent's next of kin, the nearest available relative, a member of the decedent's household, an individual with an affinity relationship, ~~and the primary treating physician~~ decedent's physicians, and any other person or entity specified in §§ 32.1-291.9 and 32.1-291.11 of the Code of Virginia, in order to demonstrate that the decedent's wish to donate decedent made an anatomical gift in accordance with ~~§§ 32.1-290 the Revised Uniform Anatomical Gift Act (§ 32.1-291.1 et seq. of the Code of Virginia), § 46.2-342 of the Code of Virginia, 54.1-2984, and 54.1-2986 or an advance directive executed pursuant to the Health Care Decisions Act (§ 54.1-2981 et seq. of the Code of Virginia).~~

~~The VTC may disclose to the DMV the donor designation on those persons who are recorded in the registry in order that the driver's record accurately reflect those persons' wishes to donate pursuant to subsections E and F of § 46.2-342 of the Code of Virginia.~~

##### FORMS (12VAC5-475)

~~Virginia Organ and Tissue Donor Registry Removal Form, VTC-0 (eff. 7/00).~~

~~Virginia Organ and Tissue Donor Registry Form, VTC-1 (eff. 7/00).~~

[Registry Removal Form, Donate Life Virginia \(undated\)](#)

## MEMORANDUM

DATE: June 9, 2014

TO: Virginia State Board of Health

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

SUBJECT: Proposed Amendments to 12VAC5-71, Regulations Governing 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 implemented as emergency regulations while a NOIRA for permanent replacement regulations is pending.

The regulatory changes were implemented in accordance with House Bill 387, which was signed by the Governor on February 20, 2014, and Senate Bill 183, which was signed by the Governor on March 5, 2014. Both bills require VDH to convene a workgroup to provide information and recommendations for the development of regulations to require all hospitals with newborn nurseries to perform a screening test for critical congenital heart disease on all babies born in the hospital.

Most hospitals in Virginia are already voluntarily performing this screening. The regulations would require a small number of additional hospitals to implement the screening. The regulations will also permit VDH to collect information via the Virginia Congenital Anomalies Reporting and Education System so that infants identified with a critical congenital heart disease could be referred to the Care Connections for Children program in order to obtain care coordination services.

VDH convened a workgroup which reviewed draft regulations and met on May 9, 2014 to discuss the regulations and language changes. An updated draft of the regulations was sent to workgroup members after the meeting, and they were then asked to submit a second set of proposed language changes. All relevant changes were incorporated into the draft regulations.

Should the Board approve these amendments, the regulations will be forwarded for Executive Branch Review. Following this review and approval, the regulations will be published in the Virginia Register of Regulations and will take effect as emergency regulations. At that time, the public comment period for the Notice of Intended Regulatory Action for the permanent replacement regulations will begin.



Virginia  
Regulatory  
Town Hall

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

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

|  |  |
|--|--|
| <b>Agency name</b>                                 | Virginia Department of Health (VDH)  |
| <b>Virginia Administrative Code (VAC) citation</b> | 12VAC5-71  |
| <b>Regulation title</b>                            | Regulations Governing Virginia Newborn Screening Services  |
| <b>Action title</b>                                | Amend regulations to add critical congenital heart disease (CCHD) to the Virginia Newborn Screening System |
| <b>Date this document prepared</b>                 | June 9, 2014   |

This form is used when an agency wishes to promulgate an emergency regulation (to be effective for up to one year), as well as publish a Notice of Intended Regulatory Action (NOIRA) to begin the process of promulgating a permanent replacement regulation.

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*.

### Preamble

*The APA (Code of Virginia § 2.2-4011) states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of subdivision A. 4. of § 2.2-4006.*

Legislation enacted during the 2014 legislative session requires VDH to implement regulations relating to screening for critical congenital heart disease: HB387, which was signed by the Governor on February 20, 2014, and SB183, which was signed by the Governor on March 5, 2014. Both bills require VDH to promulgate regulations for CCHD screening within 280 days of enactment.

The legislation requires that the regulations include provisions to implement CCHD screening for all babies born in hospitals with newborn nurseries. Both bills also required VDH to convene a workgroup to provide information and recommendations for the development of the regulations.

Most hospitals in Virginia are already voluntarily performing this screening. The regulations would require a small number of additional hospitals to implement the screening. The regulations will also permit VDH to collect information via the VaCARES reporting system so that infants identified with a critical congenital heart disease could be referred to the Care Connections for Children program to obtain care coordination services.

### Legal basis

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

HB387, which was signed by the Governor on February 20, 2014, and SB183, which was signed by the Governor on March 5, 2014, both require VDH to promulgate regulations requiring CCHD screening within 280 days of enactment.

Section 2.2-4011 of the Code of Virginia states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act or federal law or federal regulation requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of subdivision A. 4. of § 2.2-4006.

### 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.*

In April, 2012, Governor McDonnell issued an Executive Order to develop a plan to implement screening for CCHD. Subsequently, VDH received a three-year Health Resources and Services Administration grant to develop a pilot screening project. The Governor's Work Group on CCHD convened soon after, followed by the development of a pilot project that was launched in the fall of 2012, implementing CCHD screening at six birthing hospitals across the state.

The pilot project was very successful, and additional Virginia hospitals voluntarily began CCHD screening. The purpose of this regulation is to ensure that all Virginia hospitals with newborn nurseries implement CCHD screening, and to ensure that newborns diagnosed with CCHD are reported to VDH so that they may be linked to care coordination services through the Care Connections for Children program.

### 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.*

Congenital heart defects are the most common birth defects in the United States, affecting about one in every 110 babies. A few babies born with congenital heart defects have more serious forms of heart disease, or CCHD. CCHDs are heart defects that result in abnormal blood flow and oxygen deprivation.

These defects require intervention within the first year of life and delayed diagnosis can result in death. Screening newborns for CCHD using pulse oximetry has been recommended through the U.S. Department of Health and Human Services Recommended Uniform Screening Panel. The screening is simple, quick, and painless. A sensor wrapped around the baby’s right hand or either foot measures the amount of oxygen in the baby’s blood.

Most Virginia hospitals already provide CCHD screening voluntarily. These regulations would require a small number of additional hospitals to implement the screening. The regulations will also permit VDH to collect information via the Virginia Congenital Anomalies Reporting and Education System (VaCARES) reporting system so that infants identified with a critical congenital heart disease could be referred to the Care Connections for Children program in order to obtain care coordination services.

**Substance**

*Please detail any changes that will be proposed. Please outline new substantive provisions, all substantive changes to existing sections, or both where appropriate.*

Changes to existing regulations:

| <b>Current section number</b> | <b>Proposed new section number, if applicable</b> | <b>Current requirement</b>   | <b>Proposed change, intent, and likely impact of proposed requirements</b>  |
|-------------------------------|---|--|---|
| 5-71-30                       | N/A   | The Virginia Newborn Screening System includes the Virginia Newborn Screening Program and the Virginia Early Hearing Detection and Intervention Program. | CCHD is added as a third element of the Virginia Newborn Screening System.  |
| 5-71-200                      | N/A   | Care coordination services will be provided for Virginia residents who are diagnosed with selected heritable disorders or genetic diseases.              | CCHD is added as a third diagnosis that would make an individual eligible for care coordination services.   |
| 5-191-260                     | N/A   | The Virginia Newborn Screening System includes the Virginia Newborn Screening Program and the Virginia Early Hearing Detection and Intervention Program. | CCHD is added as a third element of the Virginia Newborn Screening System. The mission, scope of services, governing regulations, criteria, and goal of the screening are documented. |

New Sections:

| <b>Section number</b> | <b>Proposed requirements</b>                                | <b>Other regulations and law that apply</b> | <b>Intent and likely impact of proposed requirements</b> |
|-----------------------|---|---|--|
| 5-71-200              | This is a new definition section for the CCHD requirements. | N/A   | Intent is to make the regulation as clear as possible.   |

|          |  |     |   |
|----------|--|-----|---|
| 5-71-210 | This is a new section requiring hospitals to develop protocols for screening, timely evaluation, and timely referral of newborns with abnormal screening results.  | N/A | Intent is to allow hospitals to develop their own protocols in three required areas.  |
| 5-71-220 | This is a new section requiring a licensed practitioner to perform the screening, and setting forth when the screening is to occur. If screening is not indicated, documentation requirements are set forth for the medical record. Hospitals shall develop screening protocols for specialty and sub-specialty nurseries.   | N/A | <p>Intent is to ensure that qualified personnel perform the screening within the relevant time frame, and to set forth exceptions when screening is not required.</p> <p>Intent is to permit hospitals with specialty and subspecialty nurseries to develop protocols for screening within those specialized units.</p> |
| 5-71-230 | This is a new section requiring all screening results to be entered into the medical record and the electronic birth certificate system. The section also requires health care providers to report abnormal screening results immediately and to evaluate the newborn in a timely manner. Newborns shall not be discharged unless a cause for the abnormal screening result has been determined or CCHD has been ruled out. Parents or guardians and the infant's primary care provider after discharge from the hospital shall be notified of any abnormal results and any diagnoses. | N/A | Intent is to ensure that screening results are properly documented, responded to, and communicated to parents or guardians and the infant's primary care provider after discharge from the hospital.  |
| 5-71-240 | This is a new section requiring hospitals to report individuals diagnosed with CCHD to VDH so that the newborn's parent or guardian may be referred to care coordination services through the Care Connection for Children.  | N/A | Intent is to refer parents and guardians of infants with CCHD to care coordination services.  |
| 5-71-250 | This is a new section specifying what documents shall be provided when requested by the VaCARES  | N/A | Intent is to allow VDH to research final outcomes of abnormal CCHD screening results and evaluate screening   |

|          |  |     |   |
|----------|--|-----|---|
|          | system at VDH, and specifying the confidentiality rules for these documents.   |     | activities in the state.  |
| 5-71-260 | This is a new section that permits parents to refuse CCHD screening based upon religious practices or tenets, and to specify that the hospital must report the refusal to VDH. | N/A | Intent is to allow parents to refuse CCHD screening in accordance with their religious tenets, as specified in the authorizing legislation. |

**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 describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.*

There are no alternatives to this regulatory action because VDH is required to promulgate regulations to meet the statutory mandate. VDH convened a group of 20 stakeholders to provide information and recommendations for the regulations, and to help achieve the statutory mandate in the most efficient, cost-effective manner.

**Public participation**

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

*Please also indicate, pursuant to your Public Participation Guidelines, whether a Regulatory Advisory Panel or a Negotiated Rulemaking Panel has been used in the development of the emergency regulation and whether it will also be used in the development of the permanent regulation.*

The agency is seeking comments on the regulation that will permanently replace this emergency regulation, including but not limited to 1) ideas to be considered in the development of the permanent replacement regulation, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) the 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 Emily McClellan, 109 Governor Street, Richmond, Virginia 23219, phone 804-786-7249, fax number 804-864-7380, or email [Emily.McClellan@vdh.virginia.gov](mailto:Emily.McClellan@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.

Pursuant to 12VAC5-11, a regulatory advisory panel was used to assist in the development of the emergency regulation and will also be used to assist in the development of the permanent regulation. Anyone interested in serving on this panel should contact Emily McClellan, 109 Governor Street, Richmond, Virginia 23219, phone 804-786-7249, fax number 804-864-7380, or email [Emily.McClellan@vdh.virginia.gov](mailto:Emily.McClellan@vdh.virginia.gov).

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

### Family impact

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

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

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

The proposed amendment will not strengthen or erode marital commitment.

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

## CHAPTER 71

### REGULATIONS GOVERNING VIRGINIA NEWBORN SCREENING SERVICES

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

A. The Virginia Newborn Screening System, which includes the Virginia Newborn Screening Program, ~~and~~ the Virginia Early Hearing Detection and Intervention Program, and Virginia Critical Congenital Heart Disease Screening, 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 U.S. Department of Health and Human Services Secretary's Recommended Uniform Screening Panel.

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 aciduria (ASA);
2. Beta-Ketothiolase deficiency (BKT);
3. Biotinidase deficiency (BIOT);
4. Carnitine uptake defect (CUD);
5. Classical galactosemia (galactose-1-phosphate uridyltransferase deficiency) (GALT);

6. Citrullinemia type I (CIT-I);
7. Congenital adrenal hyperplasia (CAH);
8. Cystic fibrosis (CF);
9. Glutaric acidemia type I (GA I);
10. Hb S beta-thalassemia (Hb F,S,A);
11. Hb SC-disease (Hb F,S,C);
12. Hb SS-disease (sickle cell anemia) (Hb F, S);
13. Homocystinuria (HCY);
14. Isovaleric acidemia (IVA);
15. Long chain L-3-Hydroxy acyl-CoA dehydrogenase deficiency (LCHAD);
16. Maple syrup urine disease (MSUD);
17. Medium-chain acyl-CoA dehydrogenase deficiency (MCAD);
18. Methylmalonic acidemia (Methylmalonyl-CoA mutase deficiency) (MUT);
19. Methylmalonic acidemia (Adenosylcobalamin synthesis deficiency) (CBL A, CBL B);
20. Multiple carboxylase deficiency (MCD);
21. Phenylketonuria (PKU);
22. Primary congenital hypothyroidism (CH);
23. Propionic acidemia (PROP);
24. Tyrosinemia type I (TYR I);
25. Trifunctional protein deficiency (TFP);
26. Very long-chain acyl-CoA dehydrogenase deficiency (VLCAD);
27. 3-hydroxy 3-methyl glutaric aciduria (HMG); and
28. 3-Methylcrotonyl-CoA carboxylase deficiency (3-MCC).

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.

F. Newborns born in Virginia shall be screened for critical congenital heart disease in accordance with the provisions set forth in §32.1-65.1 and 67 of the Code of Virginia and as governed by 12VAC5-71-200 et seq.

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, or critical congenital heart disease and are referred to the network by the Virginia Newborn Screening Program.

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 program.

12 VAC 5-71-200. Definitions.

As used in the following sections relating to critical congenital heart disease screening, the following words and terms shall have the following meanings unless the context clearly indicates otherwise:

“Abnormal screening results” are all results that indicate the newborn has not passed the screening test.

“Critical congenital heart disease” or “CCHD” means a congenital heart disease that places a newborn at significant risk of disability or death if not diagnosed and treated soon after birth. The disease may include, but is not limited to: hypoplastic left heart syndrome; pulmonary

atresia (with intact septum); tetralogy of fallot; total anomalous pulmonary venous return; transposition of the great arteries; tricuspid atresia; and truncus arteriosus.

“CCHD screening” means the application of screening technology to detect CCHD.

“Echocardiogram” means a test that uses an ultrasound to provide an image of the heart.

“Licensed practitioner” means a licensed health care provider who is permitted, within the scope of his practice pursuant to Virginia Code sections 54.1-2900 et seq., or 54.1-3000 et seq., to provide care to a newborn.

“Newborn” means a person in the first 28 days of life who was born in Virginia or on federal property within Virginia.

“Newborn nursery” means a general level, intermediate level, or specialty level newborn service as defined in 12 VAC 5-410-443(B)(1)-(3).

“Screening technology” means pulse oximetry testing in the right hand and either foot. Screening technology shall also include alternate medically accepted tests that measure the percentage of blood oxygen saturation, follow medical guideline consensus and recommendations issued by the American Academy of Pediatrics, and are approved by the Board of Health.

“Specialty nursery” means the same as defined in 12 VAC 5-410-443(B)(3) and as further defined as Level III Neonatal Care by the Guidelines for Perinatal Care (7<sup>th</sup> edition) written by the American Academy of Pediatrics and the American College of Obstetrics and Gynecology.

“Sub-specialty nursery” means the same as defined in 12 VAC 5-410-443(B)(4). 12VAC5-71-210. Critical Congenital Heart Disease Screening – Protocols.

- A. Hospitals shall develop protocols for critical congenital heart disease screening in accordance with these regulations and national recommendations from the American Academy of Pediatrics.
- B. Hospitals shall develop protocols to determine the time between an abnormal screen and the physical evaluation by licensed practitioners of newborns with abnormal screening results.
- C. Hospitals shall develop protocols to determine the time between an abnormal screen and the referral of newborns with abnormal screening results, if needed, after evaluation.

12VAC5-71-220. CCHD Screening.

- A. A licensed practitioner shall perform the screening.
- B. Except as specified in subparagraph (C) of this section and 12VAC5-71-260, CCHD screening shall be performed on every newborn in the birth hospital between 24 and 48 hours of life, or, if the newborn is discharged from the hospital before reaching 24 hours of life, the CCHD screening shall be performed as late as practical before discharge.
- C. If CCHD screening is not indicated, the reason shall be documented in the newborn's medical record. The reasons include but are not limited to:
  - 1. The newborn's current clinical evaluation has included an echocardiogram that ruled out CCHD; or
  - 2. The newborn has confirmed CCHD; or
  - 3. The newborn was premature and is still under the care of a Specialty or Sub-specialty nursery.

- D. Hospitals shall develop protocols for screening newborns in Specialty and Sub-specialty nurseries in accordance with national recommendations from the American Academy of Pediatrics.

12VAC5-71-230. Results.

A. Recording Results.

1. All CCHD screening results shall be recorded in the newborn's medical record.
2. All CCHD screening results shall be entered into the electronic birth certificate system with the following information:
  - a. CCHD screening completed; and
  - b. CCHD pass or fail.

B. Abnormal Screening Results.

1. Abnormal screening results shall be reported by the authorized health care provider who conducted the screening to the attending physician or his designee immediately.
2. A newborn shall be evaluated by an attending physician or his designee according to the timeframes within the hospital protocol developed in accordance with 12VAC5-71-210(B) to complete the protocol recommended by the American Academy of Pediatrics.
3. A newborn shall not be discharged from care until:
  - a. A cause for the abnormal screening result has been determined; or
  - b. An echocardiogram has been performed, read, and determined not to indicate CCHD.
4. Any diagnosis arising from abnormal screening results shall be entered into the electronic birth certificate system.

5. The attending physician or his designee shall provide notification of abnormal results and any diagnoses to the newborn's parent or guardian and to the primary care provider in charge of the newborn's care after the newborn leaves the hospital.

12VAC5-71-240 Referral for Care Coordination.

- A. For any person diagnosed under these regulations, the chief administrative officer of every hospital, as defined in §32.1-123 of the Code of Virginia, shall make or cause to be made a report to the Commissioner in accordance with §32.1-69.1 of the Code of Virginia.
- B. Upon receiving the notification described in subparagraph (A), the Newborn Screening Program at the Virginia Department of Health shall refer the newborn's parent or guardian to the Care Connection for Children network for care coordination services.

12VAC5-71-250. Records.

- A. The screening of newborns pursuant to this chapter is a population-based public health surveillance program as defined by the Health Insurance Portability and Accountability Act of 1996.
- B. Upon request, a hospital shall make available to the Virginia Congenital Anomalies Reporting and Education System (VaCARES):
  1. Medical records;
  2. Records of laboratory tests; and
  3. Any other information that VaCARES considers necessary to:
    - a. Determine final outcomes of abnormal CCHD screening results; or

- b. Evaluate CCHD screening activities in the state, including performance of follow-up evaluations and diagnostic tests; initiation of treatment when necessary; and surveillance of the accuracy and efficacy of the screening.

C. Information that VDH receives under this section is confidential and may only be used or disclosed:

1. For research and collective statistical purposes, pursuant to §32.1-67.1 of the Code of Virginia;
2. For state or federally mandated statistical reports;
3. To ensure that the information received by the Virginia Department of Health is accurate and reliable; or
4. For reporting to the Virginia Congenital Anomalies Reporting and Education System pursuant to §32.1-69.1 of the Virginia Code and 12VAC5-191-280. The Newborn Screening Program shall refer the newborn's parent or guardian to the Care Connection for Children network for care coordination services.

D. The hospital administrator shall ensure that CCHD screening is included in the perinatal quality assurance program and provide the results of the quality improvement program to the Virginia Department of Health upon request.

12VAC5-71-260. Parental Refusal.

A. In the instance of parental refusal of the CCHD screening based on religious practices or tenets, the parental refusal shall be documented on a refusal form provided by the Virginia Department of Health and made a part of the newborn's medical record.

B. The administrator of the hospital shall ensure that the Newborn Screening Program at the Virginia Department of Health is notified in writing of the parent's refusal within five days of the newborn's birth.

12VAC5-191-260. Scope and content of the Virginia Newborn Screening System.

A. The Virginia Newborn Screening System consists of ~~two~~ three components: (i) Virginia Newborn Screening Services, ~~and~~ (ii) Virginia Early Hearing Detection and Intervention Program, and (iii) Virginia Critical Congenital Heart Disease Screening.

B. Virginia Newborn Screening Services.

1. Mission. The Virginia Newborn Screening Services prevents ~~mental retardation~~ intellectual disability, permanent disability, or death through early identification and treatment of infants who are affected by selected inherited disorders.

2. Scope of services. The Virginia Newborn Screening Services provides a coordinated and comprehensive system of services to assure that all infants receive a screening test after birth for selected inherited metabolic, endocrine, and hematological disorders as defined in Regulations Governing the Newborn Screening and Treatment Program, ~~12VAC5-70~~ 12VAC5-71.

These population-based, direct, and enabling services are provided through:

- a. Biochemical dried bloodspot screening tests.
- b. Follow up of abnormal results.
- c. Diagnosis.
- d. Education to health professionals and families.
- e. Expert consultation on abnormal results, diagnostic testing, and medical and dietary management for health professionals.

Medical and dietary management is provided for the diagnosed cases and includes assistance in accessing specialty medical services and referral to Care Connection for Children.

The screening and management for specified diseases are governed by Regulations Governing the Newborn Screening and Treatment Program, ~~12VAC5-70~~ 12VAC5-71.

3. Criteria to receive Virginia Newborn Screening Services. All infants born in the Commonwealth are eligible for the screening test for selected inherited disorders.

4. Goal. The Title V national performance measures, as required by the federal Government Performance and Results Act (GPRA-Pub. L. 103-62), are used to establish the program goals.

The following goal shall change as needed to be consistent with the Title V national performance measures:

All infants will receive appropriate newborn bloodspot screening, follow up testing, and referral to services.

#### C. Virginia Early Hearing Detection and Intervention Program.

1. Mission. The Virginia Early Hearing Detection and Intervention Program promotes early detection of and intervention for infants with congenital hearing loss to maximize linguistic and communicative competence and literacy development.

2. Scope of services. The Virginia Early Hearing Detection and Intervention Program provides services to assure that all infants receive a hearing screening after birth, that infants needing further testing are referred to appropriate facilities, that families have the information that they need to make decisions for their children, and that infants and young children diagnosed with a hearing loss receive appropriate and timely intervention services. These population-based and enabling services are provided through:

a. Technical assistance and education to new parents.

- b. Collaboration with physicians and primary care providers.
- c. Technical assistance and education to birthing facilities and those persons performing home births.
- d. Collaboration with audiologists.
- e. Education to health professionals and general public.

Once diagnosed, the infants are referred to early intervention services. The screening and management for hearing loss are governed by the regulation, Virginia Hearing Impairment Identification and Monitoring System, 12VAC5-80.

### 3. Criteria to receive services from the Virginia Early Hearing Detection and Intervention Program.

- a. All infants born in the Commonwealth are eligible for the hearing screening.
- b. All infants who are residents of the Commonwealth and their families are eligible for the Virginia Early Hearing Detection and Intervention Program.

4. Goals. The Title V national performance measures, as required by the federal Government Performance and Results Act (GPRA-Pub. L. 103-62), are used to establish the program goals. The following goals shall change as needed to be consistent with the Title V national performance measures:

All infants will receive screening for hearing loss no later than one month of age, achieve identification of congenital hearing loss by three months of age, and enroll in appropriate intervention by six months of age.

#### D. Virginia Critical Congenital Heart Disease Screening

1. Mission. Virginia Critical Congenital Heart Disease Screening promotes early detection of and intervention for newborns with critical congenital heart disease to maximize positive health outcomes and help prevent disability and death early in life.

2. Scope of services. Newborns receive a critical congenital heart disease screening 24 to 48 hours after birth in a hospital with a newborn nursery, as defined in §32.1-65.1 and 67 of the Code of Virginia and the Regulations Governing Critical Congenital Heart Disease Screening, 12VAC5-71-200 et seq. These population-based, direct, and enabling services are provided through:

a. Critical congenital heart disease screening tests using pulse oximetry or other screening technology as defined in 12VAC5-71-200;

b. Hospital reporting of test results pursuant to §32.1-69.1 of the Code of Virginia and 12VAC5-191-280; and

c. Follow-up, referral processes, and services, as appropriate, through Care Connection for Children.

3. The screening and management for newborn critical congenital heart disease are governed by the Regulations Governing Critical Congenital Heart Disease Screening, 12VAC5-71-200 et seq.

4. Criteria to receive Critical Congenital Heart Disease Screening. Except as specified in 12VAC5-71-220(C) and 12VAC5-71-260, all newborns born in the Commonwealth in a hospital with a newborn nursery shall receive the screening test for critical congenital heart disease 24 to 48 hours after birth using pulse oximetry or other screening technology.

5. Goal. Except as specified in 12VAC5-71-220(C) and 12VAC5-71-260, all newborns born in the Commonwealth in a hospital with a newborn nursery shall receive appropriate critical congenital heart disease screening 24 to 48 hours after birth.