

**State of Board of Health
Agenda
March 23, 2012 – 9:00 a.m.
Perimeter Center
9960 Mayland Drive
Richmond, Virginia 23233**

Welcome and Introductions	Bruce Edwards, Chair
Review of Agenda	Joseph Hilbert, Director of Governmental and Regulatory Affairs
Approval of December 2011 Minutes	Mr. Edwards
Commissioner’s Report	Karen Remley, MD, MBA, FAAP State Health Commissioner
Legislative Update	Mr. Hilbert
Budget Update	Michael McMahon, Deputy Director Office of Financial Management
Break	
Obesity Prevention Overview	Dr. Diane Helentjaris, Director Office of Family Health Services Mr. Hilbert
Public Comment	
Pending Regulatory Actions Update	Mr. Hilbert

Lunch

Luncheon Speaker – Debbie Secor, VDH Chief Information Officer
Michael Matthews, CEO, Community Health Alliance
“Commonwealth Health Information Exchange”

Regulatory Action Items

Regulations Governing Virginia Newborn Screening Services 12VAC5-71 (Fast Track Amendments)	Dr. Helentjaris
Rabies Regulations 12VAC5-105 (Proposed Regulations)	Dr. Laurie Forlano, Acting Director Office of Epidemiology

Proposed Amendments to Bylaws

Mr. Hilbert

Appointment of Nominating Committee

Mr. Edwards

Member Reports

Other Business

Adjourn

MEMORANDUM

DATE: March 5, 2012

TO: Virginia State Board of Health

FROM: Diane Helentjaris, MD, MPH
Director, Office of Family Health Services

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

Enclosed you will find proposed amendments for 12VAC5-71, Regulations Governing Virginia Newborn Screening Services. The proposed amendments update references to program names, the federal recommendation source, and technical names for newborn screening conditions.

The proposed amendments are a result of a periodic review conducted pursuant to Executive Order 14 (2010). The review commenced on February 8, 2011. The public comment period was between February 28, 2011, and March 22, 2011. No public comments were received. A periodic review ad-hoc regulatory workgroup met on March 23, 2011 and recommended amending the regulations to update the list of disorders for which newborn screening is performed to reflect standard nomenclature and abbreviations and to update references.

VDH believes that the proposed amendments, while substantive, are not likely to be controversial with stakeholders. Therefore, VDH believes that these amendments are appropriate to be proposed under the fast track regulatory promulgation process.

The Board of Health is requested to approve the proposed amendments. Following approval, the proposed amendments will be submitted to the Office of the Attorney General under the fast track process. Following executive branch review and approval, the proposed regulation will be published on the Virginia Regulatory Town Hall and in the Virginia Register of Regulations for a 30-day public comment period.

Thank you for your consideration. I look forward to discussing the proposed regulatory changes with you at the March 23, 2012 Board meeting.



Fast Track Proposed Regulation Agency Background Document

Agency name	State Board of Health (Virginia Department of Health)
Virginia Administrative Code (VAC) citation	12VAC5-71
Regulation title	Regulations Governing Virginia Newborn Screening Services
Action title	Update following periodic review
Date this document prepared	February 2, 2012

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 regulation is proposed to be amended as the result of a periodic review conducted in March 2011. The proposed changes will update names and references to programs, state regulations, and federal recommendation entities.

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 proposed changes to 12VAC5-71, Regulations Governing Newborn Screening Services on March 23, 2012.

Legal basis

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

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

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

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

Purpose

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

The regulation needs to be amended as the result of a periodic review conducted pursuant to Executive Order (EO) 14 (2010).

The regulation is essential to protect the health of citizens as conditions identified through newborn screening can lead to death or permanent disability if left unidentified or untreated.

The regulation provides oversight for the Virginia Newborn Screening Program. The benefits of newborn screening are to identify rare genetic and heritable disorders at birth in order to reduce infant mortality and permanent disabilities which can result from unidentified and untreated disease. The proposed regulation updates names and references to programs, state regulations, and federal recommendation entities.

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.

The fast track process is being utilized as the changes to regulation are to update names and references to programs, state regulations, and federal recommendation entities. These changes are not expected to be controversial.

Substance

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

Definitions in Section 10 for "certified nurse midwife", "child", "hospital", "parent", "pool of funds", and "preterm infants" have been updated to be consistent with other regulations or to provide more clarity to the definition. References to "Virginia Newborn Screening Services" or "newborn screening services" have been changed to reflect the current program name, "Virginia Newborn Screening Program" throughout the regulation. In Section 30, the reference to the federal newborn screening recommended screening panel has been updated and standardized nomenclature for newborn screening condition names and abbreviations has been incorporated into the list of conditions. In Section 70, the term "from the hospital" has been added to the term "at the time of discharge" for clarity. Sections 80 and 120 have been restructured to be formatted in the correct style. In Section 90, the term "Information relative to" has been stricken to clarify information to be recorded in the record. The reference to the federal regulation for laboratories has been clarified in Section 100. In Section 160, the word protocol has been substituted for "procedure" and the term "resident adults" has been added to clarify that persons ages 19 and 20 are covered.

Issues

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

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

The primary advantage to the public is that infants in Virginia will continue to be screened for conditions as recommended by the federal government. There are no disadvantages related to the proposed changes.

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.

The federal government issues recommendations through the United States Department of Health and Human Services Secretary's Advisory Committee on Heritable Disorders in Newborns and Children.

These are only recommendations however; there are no federal requirements for state newborn screening programs.

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.

All localities will be equally affected by the proposed regulation.

Regulatory flexibility analysis

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

The proposed changes to the regulation will not impact small businesses. Alternative regulatory methods would not adequately protect the health of infants. Under the current regulation and proposed amendments, small businesses may not be exempted as a category because screening for all infants must be managed equitably by their providers, regardless of business size, to assure optimal outcomes.

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.

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	There is no projected cost to the state to implement the proposed changes.
Projected cost of the <i>new regulations or changes to existing regulations</i> on localities.	There is no projected cost to localities to implement the proposed changes.
Description of the individuals, businesses or other entities likely to be affected by the <i>new regulations or changes to existing regulations</i>.	There are no projected changes that would affect newborns and their families, hospitals, primary care physicians, or others who are involved with the newborn screening program.
Agency’s best estimate of the number of such entities that will be affected. Please include an	No small businesses will be impacted by the proposed changes.

<p>estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	
<p>All projected costs of the <i>new regulations or changes to existing regulations</i> for affected individuals, businesses, or other entities. Please be specific and include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.</p>	<p>No projected costs will be incurred by affected individuals, businesses, or other entities.</p>
<p>Beneficial impact the regulation is designed to produce.</p>	<p>The proposed regulation will continue to benefit infants born in Virginia through newborn screening and early identification of rare but serious heritable diseases.</p>

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

There are no alternatives which would comply with the current § 32.1-67 of the Code of Virginia. This section would need to be amended through the legislative process to make promulgation of these regulations optional. This is not a viable or desired alternative.

Periodic review/small business impact review result

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

If this fast-track regulation is the result of a periodic review/small business impact review, please (1) summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and (2) indicate whether the regulation meets the criteria set out in Executive Order 14 (2010), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable. In addition, please include, pursuant to § 2.2-4007.1 E and F, a discussion of the agency’s consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

Commenter	Comment	Agency response
Cholesterol Objawy	Generic comment of support	Comment noted
Bob Watkins	Generic comment of support	Comment noted
Leslie	Comment on proposed abortion regulations	DPB notified regarding comment placement
Belle Noneya	Comment on proposed abortion regulations	DPB notified regarding comment placement
Mark	Comment on proposed abortion regulations	DPB notified regarding comment placement
Eric Sampo	Generic comment of support	Comment noted
Heather Strang, Pediatric Audiology Services	Comments on Proposed Newborn Hearing Guidelines	Comment is on guidance document related to newborn hearing screening which is handled under separate section (12VAC5-80). This comment is not applicable to this regulatory action.

Note: Town Hall web site states that four comments will be hidden due to violation of Town Hall policy.

The regulation is essential to protect the health of citizens as conditions identified through newborn screening can lead to death or permanent disability if left unidentified or untreated. The regulation is required by Section 32.1-67 of the Code of Virginia. No complaints or comments specific to newborn screening services have been received regarding the regulation. The regulation is of moderate complexity. The federal government does not mandate state newborn screening programs. No federal regulations exist which are applicable. Scientific advances and technology will continue to increase the capability of newborn screening programs. The regulation will continue to be periodically reviewed as required and the list of screened conditions will be reviewed every two years as stated in the regulation.

Family impact

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

Although the testing is mandated by the Code of Virginia, provisions remain in the statute for parents to refuse newborn screening if the test conflicts with their religious practices or tenets. Because parents retain the right to refuse testing, the regulation does not erode the authority or rights of parents.

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, rationale, and consequences
10		Definition of "Certified nurse midwife"	Update citation to applicable state regulations
10		Definition of "Child"	Update definition to be consistent with other regulations
10		Definition of "Hospital"	Update definition to be consistent with other regulations
10		Definition of "Parent"	Update definition to be consistent with other regulations
10		Definition of "Pool of Funds"	Grammatical change
10		Definition of "Preterm infant"	Grammatical changes
10, 30, 100, 120, 130, 140, 150, 170, 180, 190		References to "Virginia Newborn Screening Services" or "newborn screening services"	References changed where appropriate to "Virginia Newborn Screening Program" or "the newborn screening program" to reflect correct reference and current program name
20		Administration of chapter	Repealed as this section is no longer necessary in regulation
30		Reference to "recommendations for screening by the American College of Medical Genetics in its 2005 report Newborn Screening: Toward a Uniform Screening Panel and System"	Updated reference to "United States Department of Health and Human Services Secretary's Recommended Uniform Screening Panel" to reflect change in how federal recommendations are issued
30		Listing of conditions by name and abbreviation	Updates multiple condition names and abbreviations using national standardized nomenclature. List is re-alphabetized.
70		Use of term "at the time of discharge"	Phrase "from the hospital" added throughout section for consistency and clarity
80		Restructured subsection D to include subsections E and F	To correct style and structure of text
90		Strike "Information relative to" in number 4 and substitute "The"	Clarification of information to be recorded
100		Addition of words "federal and "regulations" with use of term "Clinical Laboratory Improvement Amendments"	Clarification of reference

120		Restructure subsection D to include subdivisions 1 and 2	To correct style and structure of text
160		Removal of word "procedure" in subsection A and substitution of word "protocol"	Grammatical change
160		In subsections C and D, addition of term "resident adults"	Clarifies that subsections apply to those persons ages 19 and 20.

Project 2916 - NOIRA

DEPARTMENT OF HEALTH

Amend 12VAC5-71 (Newborn Screening) as Result of Periodic Review

12VAC5-71-10. Definitions.

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

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

"Board" means the State Board of Health.

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

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

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

"Certified nurse midwife" means a person licensed to practice as a nurse practitioner in the Commonwealth pursuant to § 54.1-2957 of the Code of Virginia and in accordance with Part II

(18VAC90-30-60 et seq.) of 18VAC90-30 and ~~18VAC90-30-120~~ 18VAC90-30-121, and subject to 18VAC90-30-160.

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

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

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

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

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

"Department" means the state Department of Health.

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

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

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

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

"Hospital" means ~~a medical care facility licensed as a hospital by the Virginia Department of Health~~ any facility as defined in § 32.1-123 of the Code of Virginia.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12VAC5-71-20. ~~Administration of chapter.~~ (Repealed.)

~~This chapter is administered by the commissioner.~~

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

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

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

A. The Virginia Newborn Screening System, which includes Virginia Newborn Screening ~~Services~~ Program and the Virginia Early Hearing Detection and Intervention Program, shall ensure that the core panel of heritable disorders and genetic diseases for which newborn screening is conducted is consistent with but not necessarily identical to the ~~recommendations for screening by the American College of Medical Genetics in its 2005 report "Newborn Screening: Toward a Uniform Screening Panel and System."~~ United States 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 acidemia aciduria (ASA);
2. ~~Beta-ketothiolase~~ Beta-Ketothiolase deficiency (~~±KT~~) (BKT);
3. Biotinidase deficiency (BIOT);
4. Carnitine uptake defect (CUD);
5. Classical galactosemia (galactose-1-phosphate uridylyltransferase deficiency) (GALT);
5. ~~6.~~ Citrullinemia type I (~~CIT~~) (CIT-I);
6. ~~7.~~ Congenital adrenal hyperplasia (CAH);
7. ~~Congenital hypothyroidism (CH);~~
8. Cystic fibrosis (CF);
9. ~~Galactosemia (GALT);~~
10. ~~9.~~ Glutaric acidemia type I (GA I);
11. ~~10.~~ Hemoglobin Sickle/Beta-thalassemia (Hb S/±Th) Hb S beta-thalassemia (Hb F,S,A);
12. ~~11.~~ Hemoglobin Sickle/C disease (Hb S/C) 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 ~~hydroxyacyl-CoA~~ 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 (~~mutase deficiency~~) (Methylmalonyl-CoA mutase deficiency) (MUT);
19. Methylmalonic acidemia (Adenosylcobalamin synthesis deficiency) (~~Cbl A,B~~) (CBL A, CBL B);
20. Multiple carboxylase deficiency (MCD);
21. Phenylketonuria (PKU);
22. Primary congenital hypothyroidism (CH);
- ~~22.~~ 23. Propionic acidemia (PROP);
- ~~23. Hb SS disease~~ ~~Sickle cell anemia (Hb SS disease) (Hb SS);~~
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 (~~3MCC~~) (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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. The physician or certified nurse midwife in charge of the infant's care at the hospital of birth shall:

- a. Cause the collection a newborn dried-blood-spot specimen before the newborn is transferred to another hospital;
- b. Cause the submission of the specimen; and
- c. Notify the receiving physician or healthcare provider that a newborn dried-blood-spot specimen was collected before 24 hours of age.

2. The receiving physician or healthcare provider shall:

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

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

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

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

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

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

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

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

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

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

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

4. If the newborn is hospitalized, the infant's healthcare provider shall cause the newborn dried-blood-spot screening specimen collection and submission in accordance with 12VAC5-71-70.

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

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

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

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

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

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

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

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

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

1. Collection of newborn dried-blood-spot screening specimens shall occur after 24 hours of birth, and collection and submission of the specimens shall meet the standards required by the testing laboratory;
2. Notification of the newborn's physician of record or designee shall occur within one business day in the event that the infant is discharged before the newborn dried-blood-spot screening specimen has been collected;
3. Communication of the newborn dried-blood-spot screening test results to the newborn's physician of record or designee shall occur so that test results may become part of the infant's medical record on file with the physician;
4. ~~Information relative to~~ The newborn screening dried-blood-spot results and treatment shall be recorded in the patient's medical record, and retention of the information shall comply with applicable medical record retention requirements; and
5. Training of staff on newborn dried-blood-spot screening specimen collection and submission and parental notification shall be implemented in a way that ensures an adequately trained and knowledgeable workforce is maintained for implementing specimen collection and submission and parental notification according to standards required by the testing laboratory and guidance from the department.

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

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

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

C. The testing laboratory shall perform required initial and secondary tests using validated analytical test methods and establish normal ranges and notification protocols as defined in the contract with the department. The testing laboratory may seek the advice of the Newborn Screening Subcommittee of the Virginia Genetics Advisory Committee.

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

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

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

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

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

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

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

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

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

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

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

1. Ensure that infants born in the Commonwealth receive newborn dried-blood-spot screening, confirmatory testing, and follow-up services for selected heritable disorders or genetic diseases;
2. Locate and track infants with screened-abnormal results or unsatisfactory results, a short-term process of ensuring that the identified healthcare provider is informed of results, in a timely matter, by at least six months of age, to determine if the infant has a selected heritable disorder or genetic disease;

3. Ensure that the department receives all diagnostic test results, both normal and screened-abnormal results, from healthcare providers;
4. Ensure that appropriate diagnostic data are collected, stored, and organized in a secure data management information system that allows for efficient extraction of appropriate data from the testing laboratory to newborn screening services in accordance with federal and state laws and regulations;
5. Assess and evaluate the newborn screening ~~services~~ program follow-up activities by collecting and reporting data required annually for Title V national performance measures that address how well the system functions;
6. Educate healthcare providers, parents, and the general public by electronic or written materials and educational sessions, as deemed necessary by the department;
7. Facilitate the entry of infants with screened-abnormal results into medical and dietary management services as needed upon receiving notification from the contracted lab of such results;
8. Ensure that residents of the Commonwealth who are diagnosed with selected heritable disorders or genetic diseases identified through the newborn screening ~~services~~ program are referred to the Care Connection for Children network for care coordination services; and
9. Provide information to residents of the Commonwealth who are diagnosed with selected heritable disorders or genetic diseases identified through the newborn screening ~~services~~ program regarding available assistance for obtaining metabolic formula, low protein modified foods, and metabolic supplements that are medically necessary to manage their diagnosed heritable disorder or genetic disease listed in 12VAC5 71-30-D.

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

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

D. The Title V national performance measures, as required by the federal Government Performance and Results Act (GPRA; Public Law 103-62), shall be used to establish the newborn screening ~~services~~ program goals. The following goals shall change as needed to be consistent with applicable Title V national performance measures:

1. All infants who are born in the Commonwealth and who are residents of Virginia will receive appropriate newborn dried-blood-spot screening, confirmatory testing, and follow-up services.

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

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

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

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

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

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

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

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

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

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

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

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

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

1. Care coordination services for residents of the Commonwealth who are diagnosed with selected heritable disorders or genetic diseases and are referred to the network by the Virginia Newborn Screening Services 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 services program.

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

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

B. Expenditures shall be limited to available funding.

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

and federal medical assistance programs and must demonstrate that they do not have insurance coverage for metabolic formula.

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

E. Resident adults ages 21 or older who have a diagnosis of a heritable disorder or genetic disease listed in 12VAC5-71-30 D and who have a gross family income at or below 300% of the federal poverty level in accordance with the State Board of Health Regulations Governing Eligibility Standards and Charges for Medical Care Services to Individuals (12VAC5-200) may qualify to receive metabolic formula at no cost. Applicants who qualify must demonstrate that they are not eligible for available state and federal medical assistance programs and must demonstrate that they do not have current insurance coverage for metabolic formula.

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

G. Residents who have a diagnosis of a heritable disorder or genetic disease listed in 12VAC5-71-30 D and who have a gross family income at or below of 300% of the federal poverty level in accordance with the State Board of Health Regulations Governing Eligibility Standards and Charges for Medical Care Services to Individuals (12VAC5-200) may be eligible to receive reimbursement from the department up to \$1,500 per year for purchase of low protein

modified foods and metabolic supplements. Applicants who qualify must demonstrate that they are not eligible for available state and federal medical assistance programs and must demonstrate that they do not have current insurance coverage for low protein modified foods or metabolic supplements for which they are seeking reimbursement.

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

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

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

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

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

12VAC5-71-190. Confidentiality of information.

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

March 10, 2012

Memorandum

To: State Board of Health

From: Laurie Forlano, D.O., M.P.H.
Acting Director, Office of Epidemiology

Subject: Proposed Amendment to the *Regulations for Rabies*

Enclosed are proposed regulations for your review and discussion at the March 23, 2012, meeting of the Board of Health. The proposed regulations are necessary to implement the revisions made to certain rabies-related sections of the *Code of Virginia* (§§ 3.2-6521, 3.2-6522, 3.2-6525, 18.2-313.1, and 54.1-3812) during the 2010 General Assembly session. In addition, a rabies related section (§ 3.2-6562.1) was added to the Code of Virginia during that session. The Board of Health, in accordance with the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia), has been directed to adopt regulations to implement the provisions of the act which became effective on July 1, 2010.

These proposed regulations have been reviewed and approved by Robin Kurz of the Office of the Attorney General. If the Board approves these regulations, the proposed regulation will be posted to the Virginia Town Hall for Executive Branch review prior to publication in the *Virginia Register*. The proposed amendment will be open for a 60-day comment period after publication. I look forward to discussing this regulatory action with you at the upcoming meeting.



Proposed Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12VAC5-105
Regulation title	Rabies regulations
Action title	Rabies response, prevention and control regulations.
Date this document prepared	3-5-2012

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.

HB322 and HB621 of the 2010 General Assembly amended five rabies related sections of the Code of Virginia (§§ 3.2-6521, 3.2-6522, 3.2-6525, 18.2-313.1, and 54.1-3812) and enacted one new section (§3.2-6562.1)(Chapters 182 and 834 of the 2010 Acts of Assembly. In addition, the General Assembly directed the Board of Health to promulgate regulations to implement the provisions of the act. The specific language associated with this directive is “That the Board of Health, in accordance with the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia), shall adopt regulations to implement the provisions of this act. Such regulations shall include a model plan that may be used by localities to comply with the requirements of § 3.2-6562.1 of this act. The model plan shall provide alternatives that reflect variations in local circumstances across the Commonwealth.” The Virginia Department of Health in collaboration with many stakeholder groups, has developed proposed regulatory language to support the implementation of these changes to the *Code of Virginia*. This proposed language addresses the procedure for rabies vaccination exemptions, the development of a rabies response plan by local health departments, recordkeeping associated with rabies clinics and defines common terms that are used in the rabies related sections of the *Code of Virginia*.

Acronyms and Definitions

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

The acronyms that appear in the proposed regulations are as follows: (i) LHD as an abbreviation of local health department and (ii) PEP as an abbreviation for rabies post-exposure prophylactic.

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.

Chapters 182 and 834 of the 2010 Acts of Assembly, as well as §32.1-12 of the Code of Virginia, authorize the Board to promulgate these regulations. The regulations are necessary to implement the revisions made to certain rabies related sections of the *Code of Virginia* (§§ 3.2-6521, 3.2-6522, 3.2-6525, 18.2-313.1, and 54.1-3812) during the 2010 General Assembly session. In addition, a rabies related section (§ 3.2-6562.1) was added to the *Code of Virginia* during that session. The Board of Health, in accordance with the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia), has been directed to adopt regulations to implement the provisions of the act which became effective on July 1, 2010.

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.

These regulations are necessary for the protection of public health. Rabies is nearly 100 percent fatal and is highly endemic in the Commonwealth. It is very important that human and animal exposures are addressed promptly and correctly. Greater detail than is appropriate for the *Code* has been articulated in these regulations to support the implementation of rabies related sections of the *Code* modified and introduced during the 2010 General Assembly session. In addition, the Board of Health has been specifically instructed to develop regulations addressing rabies exemptions and a model rabies response plan. Goals of the proposed language include: (i) to define commonly used terms in the rabies related sections of the *Code of Virginia* to increase the likelihood these terms would be interpreted and applied in a consistent way, (ii) to improve the recordkeeping associated with rabies clinics to increase the likelihood that an animal's vaccinations status can be verified in response to a rabies exposure, (iii) to outline the procedure a veterinarian must use to apply for a rabies vaccination exemption and the role of local authorities in that process, (iv) to offer a model rabies response plan that localities may use to comply with § 3.2-6562.1 of the *Code of Virginia*. The proposed language of these regulations has been developed in cooperation with stakeholders from potentially affected groups such as local health departments, animal control agencies, veterinary associations, humane groups, wildlife agencies, agriculture agencies, the Board of Veterinary Medicine and local government associations. These stakeholders have been engaged to discuss issues such as the entity that grants rabies exemptions and restrictions placed on animals that are exempt as well as the authority local health directors now have to direct animal control officers in the pursuit of their duties in certain circumstances. It is hoped that this

participatory approach has resulted in proposed language that is clearly written, understandable and functional for all those involved in rabies prevention, control and response efforts.

Substance

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

The provisions in these new regulations address commonly used terms in the rabies related sections of the *Code of Virginia*, the health department's recordkeeping responsibilities associated with rabies clinics, a mechanism whereby dogs and cats may be granted a rabies vaccination exemption and fulfill the requirement, as put forward by the 2010 General Assembly, for the Board of Health to develop a model plan that may be used by localities to comply with the requirements of § 3.2-6562.1.

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 main issues associated with the proposed regulatory action include defining common terms used in the *Code of Virginia*, rabies vaccination exemptions, recordkeeping associated with rabies clinics and the development of a model rabies response plan. The primary advantages of these regulations for individual private citizens, veterinarians in private practice and the Commonwealth include: (i) increasing the likelihood that the terms used in the rabies related sections of the *Code of Virginia* will be applied and interpreted in a consistent way in all health districts, (ii) increasing the likelihood that the rabies vaccination status of an animal that was vaccinated as part of a rabies clinic can be verified, (iii) providing a mechanism for granting rabies vaccination exemptions which will allow for a dog or cat owner whose animal is likely to have a life threatening reaction in response to vaccination to be in compliance with local licensing laws, but also contains provisions that will assist local authorities with protecting public health and (iv) improving coordination and communication among local government authorities in response to a rabies exposure event to ensure that residents living in a locality and their animals receive timely and accurate guidance about rabies by creating a model rabies response plan which can be used by local health departments. A potential disadvantage of these regulations includes the time and effort veterinarians in private practice may need to complete the application for vaccination exemption.

Requirements more restrictive than federal

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

There are no applicable federal requirements associated with these regulations.

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.

It is not anticipated that any one locality will bear a disproportionate material impact that would not be experienced by other 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.

The Virginia Department of Health used a participatory approach in the development of these regulations. Stakeholders from potentially affected groups such as local health departments, animal control agencies, veterinary associations, humane groups, wildlife agencies, agriculture agencies, the Board of Veterinary Medicine and local government associations were engaged in discussing and offering comments associated with issues such as rabies vaccine exemptions, definitions of common terms in the rabies related laws and developing a model plan for rabies exposure response at the local level. No public hearing is planned as part of the development of these regulations.

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 Julia Murphy, D.V.M., Virginia Department of Health, 109 Governor St., Richmond, VA 23219, (804) 864-8113 (phone), (804) 864-8139 (fax), Julia.murphy@vdh.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last date of the public comment period.

Economic impact

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

<p>Projected cost to the state to implement and enforce the proposed regulation, including (a) fund source, and (b) a delineation of one-time versus on-going expenditures.</p>	<p>The projected cost is minimal. It is not anticipated that the implementation of these regulations will require additional funding. The additional governmental responsibilities associated with these regulations will be undertaken as part of administrative duties and funded through existing resources.</p>
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<p>Projected cost of the <i>new regulations or changes to existing regulations</i> on localities.</p>	<p>The projected cost is minimal. It is not anticipated that the implementation of these regulations will require additional funding.</p>
<p>Description of the individuals, businesses or other entities likely to be affected by the <i>new regulations or changes to existing regulations</i>.</p>	<p>Veterinary hospitals and private practice veterinarians, particularly those that focus on providing primary care to small animals (i.e., dogs and cats.)</p>
<p>Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than \$6 million.</p>	<p>There are over 700 full service veterinary hospitals licensed in Virginia, many of which provide primary care small animal medicine and surgery services. The vast majority, if not all, of these entities are small businesses.</p>
<p>All projected costs of the <i>new regulations or changes to existing regulations</i> for affected individuals, businesses, or other entities. Please be specific and include all costs. Be sure to include the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses. Specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.</p>	<p>It is estimated that 1-2 hours of time may be required for a veterinarian to gather the necessary information to complete a rabies vaccination exemption application. There is likely to be a cost associated with this additional time. Veterinarians may decide to absorb this cost or ask for compensation from the client for all or part of these efforts. It is not anticipated that any real estate development will be necessary in response to these regulations.</p>
<p>Beneficial impact the regulation is designed to produce.</p>	<p>Veterinarians will have the opportunity to apply for a rabies vaccination exemption for dogs or cats who they anticipate will have a life threatening reaction to the vaccine, while still allowing their clients to be in compliance with local licensing laws.</p>

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in §2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

No alternatives have been considered as The Board of Health, in accordance with the Administrative Process Act (§ 2.2-4000 et seq. of the Code), has been directed to adopt regulations to implement the provisions of this act which will become effective on July 1, 2010.

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.

No alternatives have been considered as The Board of Health, in accordance with the Administrative Process Act (§ 2.2-4000 et seq. of the Code), has been directed to adopt regulations to implement the provisions of this act which will become effective on July 1, 2010.

The main impact these regulations may have on small businesses would be the impact to veterinarians in private practice and the time and effort veterinarians may need to complete the application for a rabies vaccination exemption. Representatives of veterinarians working in clinical practice participated in the development of the proposed language associated with vaccination exemptions.

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
pregnancy week by week	we have to prevent rabies	none

The only comment received in response to the NOIRA publication is listed above.

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 direct impact expected on families.

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.

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

Section number	Proposed requirements	Other regulations and law that apply	Intent and likely impact of proposed requirements
2VAC5-105-10. Definitions	Section defines common terms in the <i>Code of Virginia</i>	Terms used in or applicable to rabies related sections of the <i>Code of Virginia</i> which are not found in the definitions section of the <i>Code of Virginia's</i> comprehensive animal laws (§ 3.2-6500).	All of these or similar terms are used in the <i>Code of Virginia</i> and defining them will increase the likelihood they would be interpreted and applied in a consistent way. The language used in the proposed regulations supports current agency interpretations of these terms.
12VAC5-105-20. Rabies clinics	Instructs the local health department to maintain information about rabies clinics approved by the local governing body for 48 months.	§ 3.2-6521, in part, addresses rabies clinics and the recordkeeping responsibilities of other stakeholders involved in those events.	Regulation will increase the likelihood that the vaccination status and/or history of an animal that was vaccinated as part of a clinic can be verified.
12VAC5-105-30. Rabies vaccine exemptions	Provides a mechanism whereby dogs and cats may be exempted from the requirement to be vaccinated for rabies.	§ 3.2-6521 instructs owners of dogs and cats 4 months of age and older shall have them current vaccinated and also instructs the Board of Health to provide an exemption to this requirement provided that the exemption would not risk public health and safety.	Regulation will allow for a dog or cat owner whose animal is likely to have a life threatening reaction in response to vaccination to be in compliance with local licensing laws, but also contains for provisions that will assist local authorities with protecting public health. Veterinarians may be impacted in regard to the time and effort needed to apply for an exemption.
12VAC5-105-40. Model plan for localities	Provides a model plan that localities can use to improve coordination and communication in responding to rabies related events.	§ 3.2-6521.1 of the <i>Code of Virginia</i> instructs localities adopt a plan to control and respond to the risk of rabies exposure to persons and companion animals.	This plan may be used by local health departments to improve coordination and communication among local government authorities in response to a rabies exposure event to ensure that residents living in a locality and their animals receive timely and accurate guidance about rabies.

DEPARTMENT OF HEALTH

Rabies Regulations

CHAPTER 105

RABIES REGULATIONS

12VAC5-105-10. Definitions.

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

"Currently vaccinated" means the animal was (i) vaccinated by a licensed veterinarian or a licensed veterinary technician under the direct supervision of a licensed veterinarian on the premises and (ii) the animal was vaccinated and revaccinated in accordance with the current National Association of State Public Health Veterinarian's Compendium of Animal Rabies Prevention and Control or as described on the United States Department of Agriculture approved vaccine label. For the purposes of rabies exposure response and § 3.2-6522 of the Code of Virginia, animals will not be considered currently vaccinated until it has been at least 28 days since the initial vaccination and then immediately after every subsequent vaccination.

"Department" means the Virginia Department of Health.

"Rabid animal" means an animal that has had the diagnosis of rabies confirmed by the Virginia Division of Consolidated Laboratory Services, Fairfax Health Department Laboratory, Centers for Disease Control and Prevention Rabies Laboratory, or a laboratory in any state that is recognized by that state to perform rabies testing for public health purposes. Any suspected

rabid animal that has exposed a companion or agricultural animal or a person and is not available for laboratory testing should be presumed to be rabid.

"Rabies exposure/exposed to rabies" means any circumstance where saliva or central nervous system tissue from a rabid or suspected rabid animal entered or could have entered a fresh, open wound or come in contact with a mucous membrane of a person or susceptible species of companion or agricultural animal. For the purposes of companion and agricultural animal exposure, the actual witnessing of a bite or attack by a rabid or suspected rabid animal is not necessary to define an exposure; however, a rabid or suspected rabid animal needs to have been witnessed in close proximity to the exposed animal and where, in the judgment of the local health director or his designee, it is reasonable to assume that the rabid or suspected rabid animal could have exposed the susceptible companion or agricultural animal. The Department should notify the Virginia Department of Agriculture and Consumer Services when agricultural animals meet exposure criteria and coordinate exposure response with that agency. This definition notwithstanding, decisions regarding the disposition of animals housed or maintained with an agricultural animal that is diagnosed with rabies shall be at the discretion of the local health director.

"Rabies vaccination certificate/certificate of vaccination" means a document provided by a licensed veterinarian or a licensed veterinary establishment indicating a specific animal has been vaccinated or revaccinated in accordance with the National Association of State Public Health Veterinarian's Compendium of Animal Rabies Prevention and Control or as described on the United States Department of Agriculture approved vaccine label and includes at least, but is not limited to, the following: signature of the veterinarian, the animal owner's name and address, the locality where the animal resides, the species of the animal, the sex, whether or not the animal is spayed or neutered, the age, the color, the primary breed, the certificate expiration date, and the vaccination number, also known as the serial lot number. In lieu of

individual certificates, a herd certificate can be issued for livestock other than horses that includes at least the signature of the veterinarian, the owner's name and address, the species of animal, the sex, the approximate age, the primary breed, date of vaccination, the rabies vaccine product name, the vaccination number, identifying information for each animal such as ear tag number, tattoo or other permanent identification, and the name and contact information of the veterinarian who administered the vaccine. In lieu of individual certificates, a certificate of veterinary inspection for use in shipping equine may be generated for horses that includes at least the signature of the veterinarian, the owner's name and address, the sex, the approximate age, the date of vaccination, the rabies vaccine product name, the vaccination number, identifying information for each horse, such as name, color, markings, tattoo or brand, and the name and contact information of the veterinarian who administered the vaccine.

"Suspected rabid animal" means any animal that has not been tested for rabies and that the Department considers to be a species at high risk for acquiring or transmitting rabies whether or not the animal is exhibiting clinical signs compatible with rabies and any animal the Department considers at low risk for acquiring or transmitting rabies that is exhibiting clinical signs compatible with rabies. At the discretion of the local health director, any animal to which an observation period will be applied that may have bitten a person shall be considered a suspected rabid animal until the end of the observation period. The status of an animal to which an observation period will be applied and that is or becomes ill during an observation period or develops active signs of rabies at any time will be at the discretion of the local health director. The status of animals for which an observation period will not be applied and/or that the Department has not identified as either high or low risk for acquiring or transmitting rabies shall be at the discretion of the local health director.

Statutory Authority

§ 32.1-12 of the Code of Virginia.

12VAC5-105-20. Rabies clinics.

The local health department (LHD) will maintain and provide upon request the following information about rabies clinics that it and the local governing body have approved within the previous 48 months:

1. Date.
2. Clinic site.
3. Name of sponsoring organization.
4. Name, address, and phone number of attending veterinarian.

Statutory Authority

§ 32.1-12 of the Code of Virginia.

12VAC5-105-30. Rabies vaccine exemptions.

A. The local health director, in consultation with the state public health veterinarian, may grant an exemption to the requirement for rabies vaccination as articulated in § 3.2-6521 of the Code of Virginia if a vaccination would likely endanger the animal's life due to a previously diagnosed disease or other previously documented medical considerations as documented by a licensed veterinarian.

B. Such exemption may be granted for an individual animal only after the veterinarian has consulted with the local health director and completed and submitted to the LHD an

application for exemption from rabies vaccination on a form approved by the Department and submitted other documents or medical records as may be requested by the LHD. After approval of such exemption, the LHD shall issue a rabies vaccination exemption certificate, copies of which shall be provided to the veterinarian, the owner of the dog or cat exempted from rabies vaccination, and the animal control office of the municipality in which the dog or cat resides. Certification that a dog or cat is exempt from rabies vaccination may be presented in lieu of a rabies vaccination certificate for the purposes of veterinary inspection by designated local authorities and for the purposes of licensing by the locality where the animal resides. Certification that a dog or cat is exempt from rabies vaccination shall be valid for one year, after which time the animal shall be vaccinated against rabies or the application for exemption shall be renewed.

C. The governing body of any locality may require that an exempted animal be confined on the owner's property and/or kept on a leash or otherwise restrained if it is thought necessary to protect public health and safety. The governing body of any locality may require that a form of unique identification is associated with an exempted animal. An exempted animal shall be considered unvaccinated by the Department in the event of the animal's exposure to a confirmed or suspected rabid animal. Any requirement to vaccinate an exempted animal for rabies in the event of that animal's exposure to a confirmed or suspected rabid animal shall be at the discretion of the local health director.

Statutory Authority

§ [32.1-12](#) of the Code of Virginia.

12VAC5-105-40. Model plan for localities.

A. Localities are required to have a rabies exposure response plan by § 3.2-6562.1 of the Code of Virginia. Pursuant to the second enactment of Chapter 834 of the 2010 Acts of Assembly, the Department has developed a model plan that localities may use in part or in total to fulfill this requirement. In addition, localities may want to consider including information that will assist the plan's users with assessing rabies exposure and making post-exposure prophylactic (PEP) treatment recommendations, communicating with local authorities involved in rabies exposure response, documenting information associated with rabies exposure and any other duties associated with response.

B. Model Plan.

Title: Human and Companion Animal Rabies Exposure Protocol.

Section I. Purpose. The purpose of this plan is to:

A. Ensure the prompt capture, confinement, isolation, or euthanasia of any animal that has exposed, or poses a risk of exposing, a person or companion animal to rabies by standardizing procedures associated with investigating such incidents.

B. Identify the authority and responsibility of the LHD, law-enforcement officers, animal control officers, and any other persons with a duty to control or respond to a risk of rabies exposure.

C. Establish consistent communication and reporting of possible rabies exposure incidents to ensure residents living in the locality and their animals receive appropriate guidance and protection against rabies infection from those within the scope of the LHD epidemiology staff, LHD environmental health staff, LHD nursing staff, and locality animal control staff or any personnel acting in the

capacity of a locality animal control officer and locality law enforcement. Officials who have entered into a memorandum of understanding with the LHD agree to employ standard written guidelines in response to possible human and animal rabies exposures.

D. Establish a plan to control the risk of rabies exposure and ensure prompt response to rabies related incidents in order to minimize companion animal and human morbidity and mortality in the locality.

Section II. Locality Employees to Whom Policy Applies. This policy applies to positions assigned to the LHD environmental health staff, LHD nursing staff, LHD epidemiology staff and any LHD or locality animal control staff employee who receives an initial report of an animal bite/possible rabies exposure. Further, this policy outlines the roles of locality animal control staff and any personnel who may be acting in the capacity of a locality animal control officer and any locality law enforcement officials who have entered into an memorandum of understanding with the LHD for this purpose and shall herein be referred to as "locality animal control services."

Section III. Legal Authority. Authority for the local health director to develop a local authority and responsibility plan that shall provide for those within the locality with a duty to control or respond to a risk of rabies exposure and to be directed by the local health director for such purposes is articulated in § [3.2-6562.1](#) of the Code of Virginia. (included below).

§ [3.2-6562.1](#). Rabies exposure; local authority and responsibility plan.

The local health director, in conjunction with the governing body of the locality, shall adopt a plan to control and respond to the risk of rabies exposure to persons and companion animals. Such plan shall set forth a procedure that promptly ensures the

capture, confinement, isolation, or euthanasia of any animal that has exposed, or poses a risk of exposing, a person or companion animal to rabies. The plan shall identify the authority and responsibility of the LHD, law-enforcement officers, animal control officers, and any other persons with a duty to control or respond to a risk of rabies exposure. The plan shall provide for law-enforcement officers, animal control officers, and other persons to report to and be directed by the local health director for such purposes.

Section IV. Maintenance: This plan is a working document. In an effort to maintain a current rabies response plan, which addresses emergent issues and changing knowledge, the plan will be reviewed and supplemented as needed as a result of lessons learned during investigations or to comply with updated guidance and legislative requirements.

Section V. Disclaimer: This plan is meant to be used as a guide. No single set of guidelines applies to all situations involving rabies or can provide all of the information needed. The contents of the plan are meant to offer a framework for response as well as support and complement appropriate, practical public health knowledge and experience.

Section VI. Responsibility of Locality Animal Control Services. As directed by the local health director, it shall be the duty of locality animal control services to capture, confine, isolate, or euthanize any animal that has exposed, or poses a risk of exposing, a person or companion animal to rabies. If such personnel is unable to capture, confine, isolate, or euthanize a companion animal that (i) is reasonably suspected to be rabid and (ii) has exposed, or poses an immediate risk of exposing, a person or companion animal to rabies, such personnel shall ensure the humane destruction of such animal.

A. Companion Animal Response. Locality animal control services shall within 24 hours of receiving information about a companion animal exposure:

1. Investigate reports of susceptible companion animals exposed to rabies.
2. Determine if the companion animal has or may have been exposed to a rabid animal, and if the companion animal is currently vaccinated.
3. Evaluate the exposure of the companion animal and prescribe the appropriate action according to state and local regulations.
4. Ensure that exposed, currently vaccinated companion animals receive a booster vaccination.
5. Notify the LHD about any unvaccinated, exposed companion animals or exposed companion animals with an expired vaccination status in order to relay details of the exposure, vaccination history if applicable and discussion with the owner concerning the potential options.
6. Notify the LHD about any exposed companion animals that are not dogs, cats or ferrets.
7. Immediately notify the LHD about any illness associated with any animal in confinement or isolation.
8. Facilitate the submission of the head of any animal that may have exposed a companion animal to rabies as directed by the LHD.
9. Carry out euthanasia or humane destruction of companion animals and suspected rabid animals that may have exposed companion animals as directed by the state agency with jurisdiction over that species.

10. Submit reports associated with any companion animal exposures to the LHD.

B. Human Exposure Response. In regard to situations involving human exposure, locality animal control services shall:

1. Upon receiving information about a human exposure immediately report the exposure to the LHD by the fastest means possible.

2. Not disclose the identity of any victim of an animal bite or rabies exposure except to a health care provider or official of the LHD.

3. If possible, secure any animal that may have exposed a person pending advice from the LHD as to how to proceed with either observation or testing.

4. Carry out euthanasia or humane destruction of companion animals and suspected rabid animals that may have exposed a person as directed by the state agency with jurisdiction over that species.

5. Facilitate the submission of the head of any animal that may have exposed a person to rabies as directed by the LHD.

Section VII. Responsibility of the LHD. As directed by the local health director, it shall be the duty of LHD environmental health staff, LHD nursing staff and LHD epidemiology staff to respond to human and companion animal rabies exposures as detailed below. Any LHD employee who receives a report associated with a companion animal or human rabies exposure shall notify a member of the LHD's environmental health staff, LHD nursing staff or LHD epidemiology staff within 24 hours of receiving the report.

A. LHD Environmental Health Staff. Environmental health staff members are primarily responsible for the following activities in regard to companion animal and human rabies exposure response:

1. Interfacing with locality animal control services and ensuring that any animals involved in a possible rabies exposure incident are appropriately managed to control the spread of rabies viral infection.

2. Initiating contact with a human exposure victim and coordinating contact with a companion animal owner with locality animal control services when necessary by phone or site visit within 2 hours of receiving an exposure report.

3. Conducting a site visit to investigate a human exposure and coordinating a site visit with a companion animal owner with locality animal control services when necessary within 24 hours of the report.

4. Notifying the LHD nursing staff and the local health director within 24 hours of receiving a report of a human exposure victim.

5. Coordinating with locality animal control services to locate, and contain or retrieve animals, and collect clinical animal specimens as necessary.

6. Coordinating the submission of rabies samples to a laboratory that has been designated by the Commonwealth for rabies testing.

7. Maintaining a record of human and companion animal exposures as well as test results associated with rabies sample submissions.

8. Immediately notifying LHD nursing staff and the local health director of any positive results associated with human exposures.

9. Notifying any human exposure victims of positive results within 2 hours of receiving the result and referring the victim to the LHD nursing staff in regard to PEP treatment options.

10. Coordinating with locality animal control services the notification of owners of positive results associated with exposed companion animals within 24 hours of receiving the result.

11. Coordinating with locality animal control services the response to exposed companion animals and owner follow up to evaluate the situation for any human exposures.

12. Notifying the local health director, LHD nursing staff and LHD epidemiology Staff within 24 hours of any negative results associated with rabies sample submissions.

d3. Notifying the LHD Epidemiology Staff with 24 hours of any positive results associated with rabies sample submissions.

14. Notifying local health director, LHD nursing staff and locality animal control services within 24 hours of any companion animal that has been placed in isolation or confinement that is manifesting clinical signs that could be compatible with rabies.

15. Notifying locality animal control services within 24 hours of a companion animal for which rabies vaccination is required that is not vaccinated or has an expired status.

16. Developing and maintaining a human and companion animal rabies exposure communication plan that is shared with locality animal control services.

17. In coordination with the local health director, LHD nursing staff and LHD epidemiology staff, developing and maintaining a training program that can be used to review locality rabies control and response procedures with locality animal control services on an as needed basis and/or as new staff are hired.

B. LHD Nursing Staff. LHD nursing staff members are primarily responsible for the following activities in regard to companion animal and human rabies exposure response:

1. Ensuring that any humans involved in a possible rabies exposure incident are appropriately counseled/treated to control the risk of rabies viral infection.

2. Notifying the environmental health staff of a human or companion animal exposure within 2 hours of receiving a report if the report did not originate with environmental health staff.

3. Coordinating human exposure follow up with environmental health staff and assisting with human exposure assessment interviews within 24 hours of receiving a report of an exposure.

4. Coordinating the notifying of human exposure victims with environmental health staff immediately after receiving a positive test result.

5. Coordinating the notification of human exposure victims with environmental health staff within 24 hours of receiving a negative test result.

6. Discussing PEP treatment options within the locality with human exposure victim(s).

7. Discussing medical conditions and history with human exposure victims that may affect PEP treatment.

8. Maintaining a record of medical information associated with all human exposure victims interviewed and counseled including the exposure victim's decision concerning PEP treatment and if treatment was completed.

9. Notifying the LHD Epidemiologist Staff when a human exposure victim initiates PEP treatment and provide any information about the situation necessary for statistical purposes.

10. Coordinating follow up with exposure victims if PEP treatment recommendations are not followed.

11. Coordinating the notification of human exposure victims with environmental health staff in regard to confinement release results within 24 hours after the confinement period.

C. LHD Epidemiology Staff. LHD Epidemiology Staff members (ES) are primarily responsible for the following activities in regard to companion animal and human rabies exposure response:

1. Collecting and maintaining the following data in coordination/consultation with the environmental health staff and NS for animal exposures/bites, animal bites to humans and other human exposures:

2. Demographics of person exposed;

3. Information about the animal and its owner;

4. Details of exposure;
5. PEP recommendations and actions;
6. Animal euthanasia secondary to suspect rabies; and
7. Animal quarantine or confinement.

D. Local Health Director. The local health director is primarily responsible for the following activities in regard to companion animal and human rabies exposure response:

1. Developing memoranda of understanding with locality animal control services for the purpose of organizing an integrated response to human and companion animal exposures within the locality and acknowledging the need for locality animal control services to be directed by the local health director in certain rabies related situations.
2. Overseeing companion and human exposure response within the locality.
3. Providing medical advice and consultation in regard to human exposure victims to environmental health staff, NS and human exposure victims within the locality.
4. Providing medical advice and consultation about rabies and rabies PEP treatment with healthcare providers within the locality.
5. Developing a guidance document for locality animal control services that contains examples of rabies response and control situations requiring locality animal control services staff to be specifically directed by the local health director.

Statutory Authority

§ 32.1-12 of the Code of Virginia.

Historical Notes

DOCUMENTS INCORPORATED BY REFERENCE (12VAC5-105)

REQUEST FOR RABIES VACCINATION EXEMPTION FOR LICENSING AND INSPECTION PURPOSES

REQUEST FOR RABIES VACCINATION EXEMPTION FOR LICENSING AND INSPECTION PURPOSES

Virginia Department of Health

1/2012

Please submit this completed form as directed by your local health department. A directory of local health departments can be found at <http://www.vdh.virginia.gov/>.

According to the *Code of Virginia* §3.2-6521, the Board of Health shall, by regulation, provide an exemption to rabies vaccination requirements if an animal suffers from an underlying medical condition that is likely to result in a life-threatening condition in response to vaccination and such exemption would not risk public health and safety. For the purposes of rabies exposure response, such exemption shall mean that the animal is considered **not** currently vaccinated for rabies. For the purposes of dog and cat licensing and inspection by designated authorities, such exemption shall be considered in place of a current certificate of vaccination. Each exemption request is reviewed on an individual basis, and the submitting veterinarian may be asked to provide additional information as needed. Please submit the following information, including all associated medical information to support your request, for review. Please print clearly and fill in all information.

Veterinarian Information		
Name:		
Virginia License #:		
Address:		
City:	State:	Zip:
Practice name:		
Address:		
City:	State:	Zip:
Phone	FAX:	
Patient Information		
Patient name:	Age:	Date of birth:
Species: <input type="checkbox"/> Feline <input type="checkbox"/> Canine		
Breed:		
Sex: <input type="checkbox"/> Male <input type="checkbox"/> Female		
Reproductive Status: <input type="checkbox"/> Spayed <input type="checkbox"/> Neutered <input type="checkbox"/> Intact		

Owner Information		
Owner Name:	Phone:	
Address:		
City:	State:	Zip:
Medical History of Animal		
Reason for requesting exemption:		
Pre-existing conditions:		
Date(s) of diagnosis:		
Clinical signs:		
Rabies Vaccination History		
List all previous rabies vaccinations given. Specify date(s) of vaccination, type(s) of vaccine given and the manufacturer(s) of the vaccine:		
<hr/>		

Owner Education
Has the owner been informed that this is an exemption only for licensing and inspection purposes by designated authorities and that, if this animal is exposed to rabies, the locality will require euthanasia or 6 months strict isolation? <input type="checkbox"/> Yes <input type="checkbox"/> No
Has the owner been informed about the possibility that the locality may require some restrictions in regard to this animal's movement? <input type="checkbox"/> Yes <input type="checkbox"/> No
Has the owner been informed that businesses such as privately owned veterinary hospitals, grooming facilities, boarding facilities and dog parks may not accept an exemption certificate in lieu of a current rabies certificate and, therefore, an exempted animal's access to these facilities may be limited? <input type="checkbox"/> Yes <input type="checkbox"/> No

Signature of Veterinarian

Date

State Board of Health By-Laws Proposed Revisions

The review of the by-laws was initiated by the Chair. VDH staff, in consultation with the Attorney General's Office, have drafted proposed revisions to the by-laws for the Board's consideration.

The proposed revisions consist of:

- 1) Corrections to certain referenced Code of Virginia sections
- 2) Allowing the Board to vote by show of hands
- 3) Clarifying that election of Board officers shall be determined by a simple majority of those present and voting
- 4) Changing the timeframe for amending the by-laws, by requiring that amendments be submitted in writing at the previous regular meeting.

New proposed language is underscored. Existing language proposed for deletion is ~~struck through~~.

During the review of the bylaws, two additional issues were identified.

First, § 32.1-8 establishes the size of the quorum for the Board as six members. Given that there are now 15 members on the Board, eight members is probably a more appropriate quorum. However, this would require a change to the Code.

Second, the by-laws require that at least one Board meeting be held in the City of Richmond each year. This is pursuant to § 32.1-6 of the Code, which requires that the Board meet annually in the City of Richmond. For the past several years, the Board has been meeting at the Perimeter Center in Henrico (i.e., in the Richmond Metropolitan Area), but has not met in the City of Richmond.

VDH plans to develop a legislative proposal for consideration by the Secretary of Health and Human Resources, prior to the 2013 Session, that would make appropriate amendments to §§ 32.1-6 and 32.1-8 of the Code of Virginia.

Finally, VDH staff recommends that the Board modify its current practice, such that newly elected officers assume their duties at the close of the meeting at which they are elected, rather than on the subsequent July 1. This will bring the Board's policy and practice into compliance with the current by-laws. To enable this to occur, VDH will update the Board roster at the conclusion of the meeting during which elections are held.

STATE BOARD OF HEALTH BYLAWS

ARTICLE I. APPLICABILITY

Section 1. General.

The provisions of these Bylaws are applicable to all proceedings of the State Board of Health ("Board") to the extent that the same are not otherwise governed by the requirements set forth in the Code of Virginia or by Executive Order. Whenever the provisions and authorizations of these Bylaws are in conflict with the provisions and authorizations mandated by the Code of Virginia or by Executive Order, the latter shall control.

Section 2. Authority and Limitations.

The Board is constituted under Va. Code §§ 32.1-5 and 2.2-2100 ~~9-6-25:2~~ as a "Policy Board." As a "Policy" board pursuant to Va. Code § 2.2-2100 ~~9-6-25~~, the Board is specifically charged with the duties and responsibilities set forth in the Basic Law governing the actions of the Board, as generally established in Title 32.1, as well as in such other Titles of the Code of Virginia as authorizations and duties may arise, to promulgate public policies or regulations and, consistent with the basic law, specifically to set rates, distribute federal funds, and adjudicate regulatory or statutory law including, but not linked to, the Virginia Administrative Process Act, the Public Procurement Act, the Personnel Act, the State and Local Government Conflicts of Interest Act, the Freedom of Information Act, the Privacy Protection Act, the basic law, and such other enactments or amendments as the General Assembly may, from time to time, provide.

ARTICLE II. MEETINGS

Section 1. Regular Meetings.

Regular meetings of the Board shall be held at least on a quarterly basis at such time and place as the Board may determine, provided, however, that at least one meeting shall be held in the City of Richmond. No business requiring a vote or final decision of the Board may be conducted in the absence of a quorum, as defined under Va. Code § 32.1-8.

Section 2. Annual Meetings.

The regular meetings held in the second quarter of the calendar year shall be designated as an annual meeting. Elections shall be held at the Annual Meeting.

Section 3. Committee Meetings.

The Executive Committee, the establishment and constitution of which are hereinafter set forth, and such other Committees as the Board or Chair may designate, pursuant to Article IV, Section 2 of these Bylaws, may convene from time to time as such times may be established by the appropriate committee; provided, however, that all such meetings are open to the public and must comply with the notice requirements set forth in Va. Code § ~~2.2-3707~~ ~~2-1-343~~ of the Virginia Freedom of Information Act, Va. Code § 2.2-3700 ~~et seq. 2-1-340 to 2-1-346.1.~~

Section 4. Special Meetings.

The Chair or any three members of the Board may call a special meeting for specific purpose or purposes. No business shall be transacted at such special meeting except that expressly sent out in the notice of the special meeting.

Section 5. Notice of Meeting.

In all cases, public notice of meetings shall be provided at a time and in a manner consistent with the requirements of the then current Freedom of Information Act, Va. Code § 2-2-3700 ~~et seq. § 2-1-343.~~

Section 6. Quorum.

A quorum for all purposes shall be that established by Va. Code § 32.1-8, as the same may be amended from time to time.

Section 7. Conduct of Meetings.

The Chair shall preside over all meetings of the Board, except that, in the absence or disability of the Chair, the Vice Chair shall preside. The State Health Commissioner ("Commissioner"), the executive officer of the Board pursuant to Va. Code § 32.1-18, shall serve as Secretary or, with the approval of the Board, shall name his designee to serve as Secretary, as specified by Va. Code § 32.1-9. The Secretary or Secretary-designees shall provide staff support, record all

minutes of the meetings, and record in a minute book all resolutions adopted and all transactions occurring at the meeting. The then current edition of Robert's Rules of Order shall govern the conduct of all meetings of the Board when not in conflict with statutory requirements set forth in the Code of Virginia, Executive Orders, or established policies of the Department of Health. Pursuant to Va. Code § ~~2.2-3710~~ ~~2.1-343~~, no written or secret ballots shall be taken in an open meeting, but all voting shall be accomplished by voice vote, show of hands, or roll-call vote.

ARTICLE III. OFFICERS

Section 1. Number and Title.

The officers of this Board shall be as follows:

1. Chair
2. Vice Chair
3. Secretary, who shall be the Commissioner or, with the approval of the Board, his designee, as prescribed by Va. Code § 32.1-9

Section 2. Duties.

The duties of the officers shall be those usually incident to the respective office and such other special duties as may, from time to time, be specified by the Board. Officers shall be elected annually and shall assume their duties at the close of the meeting at which they are elected.

Section 3. Vacancies.

Vacancies in the position of Chair or Vice Chair shall be filled for the remainder of the term by voice vote, show of hands, or roll-call vote of the Board at its next full meeting following the departure or resignation of the former incumbent.

ARTICLE IV. COMMITTEES

Section 1. Executive Committee.

The Executive Committee of the Board shall be composed of the Chair, the Vice Chair, and two non-officer members of the Board, who shall be elected by the Board. The Chair of the Board shall also serve as Chair of the Executive Committee. The Executive Committee shall undertake

all such responsibilities as are required or requested by the Board, and, to the extent the Board may officially delegate certain duties to the Executive Committee, all such delegated duties when the full Board is not in session. All actions taken on delegated duties shall be described in full report to the next successive full Board meeting for review, approval or disapproval, or ratification by the Board, as appropriate.

Section 2. Other Committees.

The Board or Chair, as its discretion, may appoint such other committees of its members as it may deem advisable and may designate the responsibilities of any such committees.

Section 3. Vacancies.

Vacancies arising on the Executive Committee or any other committee established by the Board may be filled for the unexpired term by the Board at its next full meeting.

ARTICLE V. ELECTIONS

Section 1. Nominations.

Nominations for Chair, Vice Chair, and two Executive Committee members may be made by a nominating committee appointed by the Chair or the Board for that purpose. Additional nominations may be received by voice from the floor.

Section 2. Voting.

Elections of officers and Executive Committee members must be conducted in open session of at least a quorum of the Board by voice vote, show of hands, or roll-call vote, as required by Va. Code § 2.2-3710 ~~2.1-343~~. Election to office or Executive Committee membership shall be determined by a simple majority of those present and ~~eligible to vote~~ voting.

ARTICLE VI. AMENDMENTS

The Bylaws of the Board may be amended at any regular meeting of the Board at which at least a quorum is present by an affirmative vote of two-thirds of the Board membership present and ~~eligible to vote~~ voting, provided that the amendment has been submitted in writing at the previous regular meeting.

Virginia State Board of Health Public Participation Policy

The Board of Health (~~the~~ Board) encourages public participation in the performance of its duties and responsibilities. To assure that public comment submitted to the Board is properly processed and to assure that all Board actions are made in compliance with the Administrative Process Act, the Board hereby adopts this Public Participation Policy.

A. Public Comments at Board of Health Meetings

These procedures establish the times for the public to provide appropriate comment to the Board for its consideration. In light of these established procedures, the Board accepts public comment on regulatory actions, as well as general comments, at Board meetings in accordance with the following:

1. REGULATORY ACTIONS (adoption, amendment or repeal of regulations): Public participation for regulatory actions is governed by the Administrative Process Act and the Department of Health's Public Participation Guidelines. ~~12-VAC-5-10-10-12VAC5-11~~ *et seq.* Public comment is accepted during the Notice of Intended Regulatory Action phase (which is a minimum of 30 days and may include a public hearing when required under the Department of Health's Public Participation Guidelines) and during the Notice of Public Comment Period on Proposed Regulatory Action (which is a minimum of 60 days and may include a public hearing if required by the NOIRA). Notice of these comment periods is announced in the Virginia Register. The comments received during the announced public comments periods are summarized for the Board and considered by the Board when making a decision on regulatory action.

2. PUBLIC COMMENT PERIOD

The Board schedules a public comment period at the beginning of each regular meeting to provide an opportunity for citizens to address the Board. Anyone wishing to speak to the Board during this time should, at the beginning of the Board meeting, indicate his or her desire on the sign-in sheet. Presentations during the Public Forum shall not exceed two minutes per person. The public comment period shall be no more than twenty minutes.

The Board reserves the right to alter the time limitations set forth above without notice and to ensure that comments presented at the meeting conform to this policy.

B. Public Comment submitted to Board Members outside of Board of Health meetings

Whenever a Board member receives written or verbal comment pertaining to the Department of Health's programs or personnel he or she should decline to make a substantive response and should proceed as follows.

1. Comment that appears to address specific pending regulatory action should be immediately referred to the [Commissioner/or agency other designee]. If the subject of a verbal or written comment received by a Board member pertains to specific proposed regulatory action that will be subject to Board approval, the member should immediately forward it to the Commissioner for inclusion in the agency record with other public comment in accordance with the Administrative Process Act. If the comment is a verbal communication, the Board member should immediately report the substance of the comment to the Commissioner who will place a summary of it in the agency record.
2. Comment that is not the subject of specific pending regulatory action: such as comments or complaints about the implementation of specific health programs, or actions of agency staff also should be referred to the [Commissioner/ or other agency designee] for appropriate review and handling. A Board member may, in the alternative, inform the author of the public comment that it should be directed to the appropriate agency staff.
3. When a Board member receives public comments outside Board meetings he or she should acknowledge receipt of the comment and, when appropriate, notify the sender that his comment has been forwarded to the Commissioner for appropriate review and handling.

Adopted October 23, 2003